December 21, 2017

Commissioner Scott Gottlieb, MD
c/o Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20825

Re: Tobacco Product Manufacturing Practice

Docket No. FDA-2013-N-0227

Dear Commissioner Gottlieb:

The Public Health Law Center is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) regarding the Good Manufacturing Practice (GMP) proposal submitted by a group of tobacco product manufacturers on June 7, 2017. The Public Health Law Center is the coordinating center of the Tobacco Control Legal Consortium, a national network of nonprofit legal centers providing legal technical assistance to public health professionals and advocates concerning legal issues related to tobacco and public health.¹ We submit these comments on behalf of these centers.

We have reviewed the June 7 letter from RAI Services Company to the FDA and note that it represents a wholesale adoption of the proposal submitted to the agency by R.J. Reynolds on January 10, 2012, with a short list of additional considerations related to e-cigarettes. Because there was no significant change in R.J. Reynolds' proposal, we attach to this letter our May 20, 2013 comment on the previous proposal. All of the information contained in that comment is equally relevant to the minimally supplemented June 7, 2017 proposal.

¹ The Tobacco Control Legal Consortium's activities are coordinated by the Public Health Law Center, at Mitchell Hamline School of Law in St. Paul, Minnesota. The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.
As a threshold matter, we would like to reiterate our view that the tobacco industry has demonstrated that they cannot be relied upon to participate in the creation of meaningful regulation or to comply in good faith with any regulations that do survive their attempts to block them. As we mentioned in our previous comment, when the tobacco industry puts forward a proposal, such as the one at issue here, the FDA should question the industry’s motivation. The tobacco industry’s agenda is not to help the FDA create meaningful regulation; it is to thwart strong regulations and preserve industry profits at the expense of public health. The original proposed practices and these e-cigarette-related addendums support that position.

In addition to our previous – and continuing – objections, we have two concerns specific to the most recent proposal. First, on page five of the 2017 proposal, the tobacco product manufacturers attempt to reassert that the purpose of GMP regulations is to “prevent[] the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products.” This is false.

The letter recognizes that “Congress, the U.S. Surgeon General, and public health authorities have identified certain inherent risks associated with the use of different categories of tobacco products.” While this premise is true, it does not logically follow that because tobacco products cause harm, the FDA’s role in regulating the products is merely to protect the public from additional harm. As is discussed at length in the attached comment, this proposal is merely an attempt to persuade the FDA to reject the public health standard in favor of an individual risk standard which affords the industry more leeway to introduce new, harmful products.

Rather than accept the industry’s entirely false premise, the FDA must promulgate GMP regulations in such a way as to protect public health from the disastrous health effects of tobacco products, not just from the incidental risk of exposure to materials not ordinarily found in tobacco products. In promulgating GMP regulations, the FDA must use the public health standard, a legal standard intended to reduce harm at the population level.

Second, while the FDA has taken some important steps to increase the transparency of various aspects of tobacco product regulation, for information and documentation submitted by the tobacco industry to the agency, in making decisions about disclosure, the FDA has often seemed to prioritize the industry’s interest in confidentiality over the public’s interest in transparency. The history of this proposal is only one example of this misplaced priority.

The tobacco product manufacturers submitted their initial proposal to the FDA on January 10, 2012. According to the cover letter to the proposal, the dialogue that led to the proposal began in 2011 and the letter also requests an in-person meeting
with agency staff. However, neither the prior nor subsequent correspondence between the FDA and any tobacco product manufacturers regarding the GMP proposal was placed into the docket for public inspection and comment. The agency did, in fact, have a meeting on May 20, 2012, regarding the GMP proposal and manufacturers corresponded with the FDA prior to that meeting. The agency and the industry also developed materials in advance of the meeting. All of these materials were in existence when the FDA published the GMP proposal for comment on March 19, 2013, and yet none of them were made available. The Consortium had to submit a request under the Freedom of Information Act in order to review these materials, which we attach to this letter.

It should be the FDA’s standard practice to publish all relevant materials on a given subject so that the public can submit fully informed comments. We respectfully request that when the FDA’s Center for Tobacco Products requests public comments on a tobacco industry proposal, the Center make it a standard practice publish all tobacco industry submitted materials and in-person meeting notes relevant to that particular docket. The industry’s history of deceptive practices underscores the importance of prioritizing transparency in the FDA’s interactions with the tobacco industry, especially in a situation where the FDA seeks public input on industry-submitted information.

We urge the FDA to promulgate GMP regulations designed to improve public health rather than working from an industry-drafted proposal. In addition, we request that the agency publish all information submitted by the tobacco industry when seeking comment on regulatory proposals submitted by tobacco product manufacturers.

Respectfully,

Joelle Lester
Director

Desmond Jenson
Staff Attorney

Attachments
May 20, 2013

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comment to FDA-2013-N-0227
Tobacco Product Manufacturing Practice; Establishment of a Public Docket

Dear Sir or Madam:

The Tobacco Control Legal Consortium is pleased to submit these comments to assist the U.S. Food and Drug Administration (“FDA”) in analyzing the tobacco product good manufacturing practices proposal submitted by the tobacco industry. Specifically, we will address the fact that any such offering by the tobacco industry ought to be considered in light of the industry’s history of avoiding meaningful regulation. We will discuss that this proposal in particular, is an attempt to advance the industry’s agenda of subverting the public health purpose of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We will also outline the FDA’s broad authority to promulgate meaningful regulation that can improve public health.

Founded in 2003, the Tobacco Control Legal Consortium (“the Consortium”) is the leading source of legal technical assistance on tobacco control policy in the United States. The Consortium promotes evidence-based and legally sound approaches to tobacco control policy, and provides legal technical assistance to federal, state, and local public health advocates, officials, and attorneys across the country. The Consortium’s team of attorneys, based at the Public Health Law Center in St. Paul, Minnesota, provides legislative drafting and policy assistance, prepares educational materials, and files legal briefs as amicus curiae in key cases before the highest courts of the nation.

I. Untrustworthy Racketeers

The tobacco industry has a long history of deceitful behavior that is well-chronicled. The industry’s behavior and tactics are documented by many sources, including a massive archive of internal industry documents housed at the University of California San Francisco, which this comment will frequently use as reference material. In addition, Judge Gladys Kessler’s landmark 2006 opinion in U.S. v. Philip Morris provides a comprehensive compilation of the tobacco industry’s deception. In this case, the government charged the tobacco industry defendants with violating the Racketeer Influenced and Corrupt Organizations Act (RICO). Many of Judge Kessler’s findings are directly relevant to the issue of whether the tobacco industry can be trusted to participate in good faith in the regulatory process, and therefore must inform the FDA’s
consideration of this tobacco industry proposal. That ruling should also serve as a guide, more generally, for the FDA’s decision-making in its regulation of tobacco products. Any decisions made or regulations promulgated by the FDA should be consistent with the findings and the ruling in that case.

Among the deceitful acts recounted in Judge Kessler’s opinion are the tobacco industry’s long history of secretly conducting and hiding scientific research on the health effects of tobacco use, the addictiveness of and the ability to manipulate nicotine, the lack of any health benefit from light and low tar cigarettes, and the hazard of secondhand smoke. Judge Kessler also details the industry’s efforts to ensure that none of its research would be seen by courts or the general public. The tobacco industry has also been found to deliberately market its products to youth for decades, and has been found to destroy and suppress damaging information. Industry efforts to suppress evidence of the catastrophic health effects of tobacco products has included publicly disparaging any research finding a link between tobacco use and disease and death, as well as attempting to discredit the researchers who publish such findings.

In the latter half of the twentieth century, when the mounting evidence of the health effects of tobacco use became undeniable and the public finally began to question the motives of the tobacco industry, the tobacco companies conspired to create front groups that appeared to be legitimate, independent third-parties and used them to continue to disseminate false information. The tobacco industry has demonstrated a continued effort to avoid willfully availing itself of meaningful regulation. The industry has expended tremendous efforts to ensure that its public statements could not be used against it, even when those statements were patently untrue. This strategy was summed up by one executive who said, “[o]ur basic position in the cigarette controversy is subject to the charge, and may be subject to a finding, that we are making false or misleading statements to promote the sale of cigarettes.”

If there is a single, clear message that one can take away from Judge Kessler’s momentous opinion, it is this: the tobacco industry racketeers simply cannot be trusted. They have demonstrated that they cannot be relied upon to participate in the creation of meaningful regulation or to comply in good faith with any regulations that do survive their attempts to block them. When the tobacco industry puts forward a proposal such as the one at issue here, the FDA should question the industry’s motivation. Its agenda is not to help the FDA create meaningful regulation; it is to thwart strong regulations and preserve industry profits at the expense of public health.

II. Attempts to Escape Regulation by Racketeers

If the tobacco industry has a single greatest skill (aside from manufacturing and marketing a highly addictive and deadly product), it is understanding the regulatory environment, fighting existing tobacco control regulations, and identifying every potential opportunity to prevent the adoption of new tobacco control regulations.

It is no secret that the tobacco industry has spent hundreds of millions of dollars over decades lobbying legislative branches at the state and federal levels. The industry’s manipulation of federal executive agencies is less visible, but just as critical to the industry’s agenda. The tobacco
industry has spent tremendous resources to track the actions and potential actions of executive agencies for the purpose of preventing and challenging unfavorable agency actions.

For example, beginning in 1986, the Department of Health and Human Services (HHS) required cigarette manufacturers to submit lists of cigarette ingredients. In response, the tobacco companies prepared elaborate defensive measures in the event this information was made public. The six largest American tobacco companies collaborated on a strategy to respond to a potential leak of the ingredient list or a prepared report that HHS could submit to Congress. The tobacco industry was keenly aware that pooling its resources and presenting a unified front would minimize any potential reputation damage created by its ingredient lists becoming public. The tobacco industry lawyers knew that even though ingredient lists were confidential in the hands of HHS, once a list became a part of a report to Congress, HHS could publish the list without violating the law. Anticipating the ingredient list becoming public, the industry and its lawyers developed complex strategies for every potential “leak” scenario, including a small leak of information, a formal report severely critical of industry practices, sustained critical media coverage or even congressional hearings. The industry continued to update its strategy throughout the 1980s and into the early 1990s until its focus shifted to potential regulatory actions by the FDA.

In 1994, Representative Henry Waxman chaired a congressional hearing at which the CEOs of each of the seven largest tobacco companies infamously testified that they believed that nicotine was not an addictive substance. Internal documents indicate that the industry knew that nicotine was addictive as early as the 1960s. This hearing and the subsequent public scrutiny of the industry mark the beginning of an even more concerted effort by the tobacco industry to monitor federal action and attempt to prevent future regulation. In July of 1994, the Tobacco Institute, a tobacco industry front group, prepared an extensive report assessing the potential of fourteen federal agencies and forty-two sub-agencies of the Department of Health and Human Services to regulate tobacco. The report also identified 229 recipients of federal grants to study tobacco, the funding each organization received, and the specifics of what was being studied. Finally, the report identified thirty-one national, non-governmental tobacco control organizations and described their activities. The industry was preparing for potential federal action by researching any agency or group that might stand in the way of its goal of avoiding regulation.

On August 11, 1995, the FDA published a notice that it intended to assert jurisdiction over cigarettes. Internal documents show that the tobacco companies were already well prepared to take action. In fact, Philip Morris (now a division of Altria) had an “FDA Media Plan” devoted to thwarting any potential regulations initiated by the FDA. This plan outlined strategies for several potential regulatory scenarios, including a notice of proposed rulemaking by the FDA, a leak of information from the FDA about a rule, or the issuance of a report that disparaged the industry. For each scenario, Philip Morris was prepared with press conference statements, press releases, radio and television advertising scripts, newspaper op-ed pieces, prepared speeches for industry-friendly congressional representatives, grassroots campaign information, and telephone contact lists for FDA employees. This plan evolved into an “FDA Crisis Communication Plan,” a minute-by-minute plan of the activities for a team of at least thirty-seven people who prepared for FDA action by running a “crisis simulation” on June 7, 1995. This group was prepared for every step that FDA Commissioner David Kessler made, even disseminating rebuttals to speeches on the very day that Commissioner Kessler made them.
All of these efforts were in addition to the formal channels that the tobacco industry used to challenge the FDA’s proposed rule. From August 11, 1995 until January 2, 1996 and for an additional 30 days starting on March 18, 1996, the FDA’s rule was open for public comment. During the public comment period, the industry mobilized tobacco retailers by providing them with form letters to send to the FDA, and by sending out an “Action Alert” describing the FDA’s plan and outlining how retailers could get involved. The tobacco industry also placed petitions inside tobacco retail stores so that customers could respond to the proposed rule. Philip Morris solicited comments from its own employees by placing letter-writing booths outside employee cafeterias. The tobacco industry also effectively motivated the advertising industry to respond negatively to the proposed rule by focusing on the rule’s limitations on tobacco advertising and how it might affect advertising agency revenues. This particular effort also included the provision of form letters. In total, the massive mobilization campaign yielded the largest response to a proposed rule in FDA history. The agency “received more than 700,000 individual pieces of mail, representing the views of nearly 1 million individuals.” This tremendous plan to overwhelm the FDA with comments represents how much effort the industry is willing to spend in order to utilize the formal legal processes to oppose regulation of its products. The notice-and-comment rulemaking process necessitates comments from the public but the tobacco industry’s domination of the process demonstrates its capability and determination to avoid FDA regulation.

The industry mobilization did not block the FDA’s efforts and the final rule was published on August 28, 1996. While the tobacco industry identified possible tactics to thwart the FDA’s efforts, such as lobbying Congress to limit FDA’s enforcement ability by freezing its funding levels and/or forcing it to devote all of its employees to other tasks, the industry ultimately resorted to the last tool in its toolbox: litigation. This was another strategy that the tobacco industry had been preparing for. Complaints had been drafted in advance and were prepared to be filed with the courts. Five tobacco companies and one advertising agency filed suit against the FDA and Commissioner Kessler on August 11, 1996, the same day the FDA published its final rule. After a protracted legal battle that was eventually decided by the U.S. Supreme Court, the FDA’s rule was struck down on March 21, 2000. With the FDA rendered powerless to regulate tobacco, the industry returned its focus to Congress, monitoring and lobbying against any bill that could empower the FDA to regulate tobacco in the future.

After numerous attempts, Congress passed the Family Smoking Prevention and Tobacco Control Act and President Obama signed the bill into law on June 22, 2009. This Act finally granted the FDA the express authority to regulate tobacco products. However, this did not mark the end of the tobacco companies’ attempts to evade regulation. Before the FDA had exercised any meaningful authority and even before most of the statutory provisions of the act had gone into effect, the tobacco industry challenged more than ten provisions within the Tobacco Control Act, including prohibitions on certain types of marketing activities directed toward youth and the Act’s provision mandating graphic warnings on cigarette packages. The industry later filed suit to challenge the FDA’s final rule implementing graphic warnings. The industry was unsuccessful in removing the FDA’s authority to create graphic warnings, but has thus far blocked implementation of the graphic warning rule. Additionally, the tobacco industry has tried, to forestall potential regulation of menthol cigarettes and dissolvable tobacco products by way of a lawsuit challenging the composition of the Tobacco Products Scientific Advisory...
Committee (TPSAC), which was formed pursuant to the Act to advise the FDA on safety and health issues, including those related to menthol cigarettes and dissolvable tobacco products. The industry has also attempted to use the Act’s narrow preemption provision to stamp out novel tobacco control policies at the local level, twice in New York City and once in Providence, RI. Finally, the tobacco industry has also attempted to argue that the passage of the Tobacco Control Act extinguishes the court’s jurisdiction in *U.S. v. Philip Morris* because it will be forced to comply with the Act’s comprehensive regulation, at the very same time that it was attempting to overturn the Act by arguing in another court that the Act was unconstitutional. All of these actions demonstrate the industry’s dedication to avoiding regulation.

In short, the industry has the resources and motivation to block health-protective tobacco regulations at every stage of the regulatory process: both pre-rule (through public comment, mobilization, and Congressional influence) and post-rule (largely through litigation but also Congressional influence). This is not just a matter of history; the industry’s recent responses to FDA actions made pursuant to the Tobacco Control Act show that the tobacco companies have not changed their ways. The proposal at issue in this comment is no exception. This history of underhanded tactics to avoid regulation provides context for the tobacco industry’s current proposal. This industry has not demonstrated a willingness to participate in the creation of meaningful regulation and in examining the industry’s current proposal, the FDA must account for the industry’s continued attempts to avoid regulation. This next section will provide an overview of the industry’s proposal and attempt to shed some light on its true intentions.

**III. The Racketeers’ Meaningless Proposal**

The tobacco industry’s tobacco product good manufacturing practices proposal represents the industry’s latest attempt to avoid meaningful regulation. Since the Tobacco Control Act was passed, the tobacco industry has not waited for the FDA to exercise all of its authority and instead has taken the initiative and petitioned the FDA, both formally and informally, to take actions that would be favorable to the industry rather than protective of public health. This industry proposal requests that the FDA codify a system of self-regulation. The FDA must be aware that allowing for self-regulation, for this industry in particular, will lead to disastrous consequences. It should be clear from the tobacco industry’s behavior that this is an industry that cannot simply be left to regulate itself. When there is no oversight, there is no length that it will not go to in order to sell a product that it knows to be addictive and deadly. The FDA should not use its broad authority to simply mandate that the industry take actions that it ought to already be taking such as ensuring basic safety and sanitation in tobacco manufacturing facilities. This proposal is nothing more than a request for the least amount of FDA oversight that still gives the appearance of regulation. Instead, the FDA should implement stringent regulations that can reduce the harm of tobacco and improve public health.

This comment will attempt to identify some of the problems with the tobacco industry’s proposal. Before detailing the specific failings with each subpart of the proposal, a few overarching problems must be addressed.

**A. Deliberate Inclusion of Meaningless Standards**
Predictably, the tobacco industry’s proposal would create no real binding requirements on the industry. Many of the proposed provisions would not require any safeguards, protection or testing procedures. Where requirements are established, no standards or criteria are set to measure the success or failure of the procedures. Instead, the regulations often refer to “adequate or appropriate standards” without making any attempt to define what is adequate or appropriate, presumably to afford deference to the manufacturer and make enforcement of the regulations very difficult.

These vague, undefined words appear so often in the proposal that even a quick glance can show the reader that the industry has no intention of providing meaningful guidance to regulators. Across the sixteen pages of proposed regulations the word “appropriate” appears eighteen times, “adequate” appears sixteen times, “suitable” appears six times and “proper” appears four times. In none of these cases are the words defined or provided in a context that makes it clear what they mean. The proposal also refers to “education and training” or similar language ten times without establishing what sort of education or training should be required for tobacco manufacturer employees.

The effect of this use of undefined terms is that the proposed regulations would have no real impact. For example, on page six of the regulations in Subpart B – Personnel, XXX.40(a), the proposal states: “each person engaged in manufacturing, testing, packaging, labeling, or holding, or in performing any quality control operations, shall have the education, background, training, and/or experience to adequately perform the person’s assigned functions.”

If this language were adopted, the FDA would find enforcement impossible. How a manufacturer complies with this requirement and how it can be enforced is unclear based on this language. It leaves many questions and no answers:

- What sort of education is required? Level of education is an easy standard to measure. Must an employee be a high school or college graduate or earn a particular degree?
- What background is required? Is a certain amount of experience necessary for a particular task?
- What sort of training is required? How many hours of training are required?
- Most importantly, how do we know whether an individual’s performance is adequate? What is the measure of adequacy?

Without a precise measure of adequacy, there is no way to enforce the standard. If this proposal became a regulation, how could the FDA seek enforcement against a manufacturer who employed personnel without the necessary “education, background and training” to adequately perform his or her assigned functions? The vagueness found throughout this proposal is just one reason the FDA should reject this proposal entirely.

**B. The Racketeers Attempt to Assert an Individual Risk Standard for Tobacco Regulation**

The second large, overarching problem with the proposal is the standard that is applied to what the industry calls “contamination.” This is the one and only defined standard found in this
The purpose of this proposal is to create a standard that is much more favorable to the tobacco industry and one that is not what Congress intended when it empowered the FDA to regulate tobacco.

The tobacco industry proposal’s definition of contaminate, found at Subpart A, XXX.3 Definitions, includes, “any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products.” This and other proposed provisions indicate that the tobacco industry is attempting to insert an “individual risk” standard into tobacco regulation. To understand why this is disingenuous, one must understand the standard, established by Congress, that the FDA is mandated to use when it exercises its authority to regulate tobacco. That standard, found throughout the Tobacco Control Act, including Section 906(e) – Good Manufacturing Practice Requirements, is known as the “Public Health Standard.”

1. The Public Health Standard

The Food, Drug and Cosmetic Act (FDCA) provides established standards for the regulation of food, drugs, devices and other products over which the FDA has regulatory authority. The regulation of food and drugs focuses on ensuring that consumers receive the benefits of products without being exposed to unnecessary and unregulated risks. For food, the FDA must ensure that food is safe, wholesome, sanitary, and properly labeled. For drugs, the FDA must ensure that drugs are safe and effective. Tobacco is different than these other products in that it is an inherently dangerous and deadly product. It is only effective at killing more than half of its users. Cigarette smoking kills over 440,000 Americans each year, and is the single largest cause of preventable death and disease in the U.S. Because tobacco is neither safe and effective nor safe, wholesome and sanitary, and because it has no health benefits, only risks, the food and drug standards are inappropriate for the regulation of tobacco products.

Thus, Congress had to develop a new standard for FDA regulation of tobacco products, the public health standard. Rather than using a standard that focuses on the safety of the individual, Congress established a standard that focuses on tobacco’s effect on the entire population. Under this standard, the FDA must consider three factors when regulating tobacco: 1) the risks and benefits to the population as a whole, including users and nonusers of tobacco products; 2) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and 3) the increased or decreased likelihood that those who do not use tobacco products will start using such products. This aggregate, public health standard can be a very powerful tool for the FDA, permitting the FDA to not just mitigate the ongoing damage caused by tobacco use, but also to prevent future harm by implementing stringent product and manufacturing standards and ensuring that new products improve rather than harm public health. The FDA is empowered to promulgate regulations that prevent youth from starting smoking, to help tobacco users quit tobacco, and to protect non-users from health hazards like secondhand smoke.

Focusing on the health of the population as a whole rather than on an individual allows the FDA to take an action such as prohibiting menthol flavoring in cigarettes. To an individual user, smoking a menthol flavored cigarette may pose the same risks with respect to cancer, COPD and
coronary heart disease as smoking an unflavored cigarette. However at the population level, it is clear that menthol is a starter cigarette that attracts more youth than unflavored cigarettes, and the unique properties of menthol make it more difficult for addicted smokers to quit. Menthol cigarettes have also had a disparate impact on the health of African-Americans and other minority populations. TPSAC published a report that found that a prohibition on menthol flavored cigarettes would improve the public health. Unsurprisingly, the tobacco industry’s rebuttal report focused on an individual risk standard rather than the public health standard. With this proposal, the industry attempts the same tactic: to create a regulatory scheme that is weak and not what Congress intended.

2. The Racketeers’ Attempt to Assert an Individual Risk Standard

The public health standard is so ubiquitous in the Tobacco Control Act and Congress was so deliberate as to how it ought to operate that it is glaringly obvious that the tobacco industry’s omission of this standard is deliberate. In fact, the public health standard appears in the Tobacco Control Act more than thirty-three times, and is mentioned every time Congress vests rulemaking authority with the FDA. There is only one place in the Tobacco Control Act that mandates the use of an individual risk standard: Section 908(c)(1) which governs mandatory tobacco product recalls.

The industry notes in its proposal that its concept of a contaminant is consistent with the mandatory recall language of Section 908(c)(1). For purposes of comparison, what follows is first, the tobacco industry proposal’s definition of contaminant and then the relevant language of Section 908(c)(1). The overlapping language is italicized.

“Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. . .”

“If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. . .”

Clearly, concept of contaminant is far from consistent with the mandatory recall language. The only apparent overlap is that both concepts address a substance that is not ordinarily contained in a tobacco product. Each provision creates a standard based on the risk of harm to the individual but the tobacco industry’s proposal misapplies the individual risk standard established by Congress.

The two most important distinctions between Section 908(c)(1) and the tobacco industry’s proposal are that 1) the Act requires only a reasonable probability of a defect not ordinarily found in a tobacco product, not actual evidence of “contamination” and 2) the Act only applies this individual risk standard when there is a chance of “serious, adverse health consequences or death.”
The first distinction speaks to the procedural requirements of the standard or when that standard is applied. The Tobacco Control Act is clear about when its standard applies: when there is a reasonable probability of a defect. The FDA defines a reasonable probability as more likely than not that an event will occur. The industry’s proposal provides a standard for contamination: when any added substance presents a risk of injury beyond the risk of similar products. However, it does not provide a mechanism for testing for contamination and thus provides no way to apply the standard. It makes several references related to preventing contamination and what should be done once a product is contaminated, but without a mechanism for determining which products are contaminated and which products are not contaminated, there is absolutely no way to determine when a product presents a risk greater than a similar product. Without this mechanism, the entire standard is rendered meaningless.

The second distinction is one of substance. The standard in Section 908(c)(1) only applies to a chance of “serious, adverse health consequences or death.” While this language may seem slightly ambiguous, there is additional guidance on exactly what this means. “Serious, adverse health consequences means any significant adverse experience, including those that may be either life-threatening or involve permanent or long-term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.” The tobacco industry’s proposed standard applies to a substance that “presents a risk of injury beyond the risks generally posed by the same category of tobacco products.” This standard is far too vague for the FDA to apply and leaves too many unanswered questions:

- What type of risk is anticipated? Death, disease or some other injury?
- How far must a risk be beyond the ordinary risk in order to qualify as a contaminant?
- What are the categories of tobacco products that should be used for comparison? Other products from the same manufacturer? Other products from all tobacco manufacturers?

The tobacco industry has attempted to use Section 908(c)(1)’s product recall standard to lend credibility to its own empty, meaningless standard. It is clear, however, that in doing so, it has only borrowed a few words from the Act and that it hasn’t actually incorporated the standard. Even if the tobacco industry had made a meaningful attempt to incorporate this individual risk standard, it would still be violating the spirit of the Act. As was mentioned previously, the proper standard to apply is the public health standard. The mere fact that the Tobacco Control Act includes an individual risk standard does not mean that it should be used in this context.

In fact, when one puts the language of Section 908(c)(1) in context with the rest of the FDCA it becomes perfectly clear why Congress inserted this individual risk standard for tobacco product recalls. Substantially similar language is used in the FDCA to determine when food, drugs and devices must also be recalled. For the purposes of so drastic a measure as a product recall, an individual risk standard is appropriate. A product recall is costly and difficult and should only be undertaken when absolutely necessary. For a recall, Congress intends the FDA to take drastic steps only when there is a serious threat of harm. Below are excerpts of the relevant language relating to the recalls of tobacco products, drugs and devices, and food, with similar language italicized.
Tobacco Products Recalls – 21 U.S.C. § 387h(c)(1)

“If the Secretary finds that there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the tobacco product) to immediately cease distribution of such tobacco product. . .”

Drug and Device Recalls – 21 U.S.C. § 360h(e)(1)(A) – (B)

“If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)--(A) to immediately cease distribution of such device, and
(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.”

Food Recalls – 21 U.S.C. § 350l(a)

“If the Secretary determines, based on information gathered through the reportable food registry under section 350f of this title or through any other means, that there is a reasonable probability that an article of food (other than infant formula) is adulterated under section 342 of this title or misbranded under section 343(w) of this title and the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals, the Secretary shall provide the responsible party (as defined in section 350f of this title) with an opportunity to cease distribution and recall such article.”

Congress’s intent is clear. In tobacco product regulation, the FDA must use this individual risk standard when considering a recall and only when it is considering a recall. By including this individual risk standard in the recall statute for tobacco products that is consistent with the recall language for other products, Congress has ensured that any FDA-enforced recalls should be based on the same sort of danger of harm to the public as for all the products it regulates. However, all other decision making by the FDA with regard to tobacco products must be evaluated under the public health standard.

Furthermore, this individual risk standard proffered by the tobacco industry and used only for product recalls is not found in the section that establishes the FDA authority over manufacturing regulations, Section 906(e). Instead, Section 906(e) instructs the FDA to use the public health standard found throughout the act. Thus, Congress’s intent is clear: when establishing manufacturing practice regulations, the FDA must use the public health standard, not an individual risk standard. With this proposal, the tobacco industry attempts to undermine the
Congressional intent of the Tobacco Control Act and the FDA’s authority to regulate its products.

C. Additional Problems in the Racketeers’ Proposal

1. Background and Related Information

The tobacco industry provides a preamble to its proposal and it is in the first section of this preamble that it lays the groundwork for its attempt to insert an individual risk standard into tobacco product regulation. The industry argues here that many medical device recalls are the result of manufacturers not conforming to good manufacturing practices. It states the problem in this fashion because, as was noted above, it is under the FDA’s recall authority that the individual risk standard is found.

In this section, the tobacco industry also establishes the three purposes of its proposal. The first stated purpose is to protect public health but it alleges that the proposal accomplishes this goal by preventing contamination, measured with an individual risk standard rather than the public health standard established by the Tobacco Control Act. This issue has been thoroughly discussed above and is the first of many examples throughout the proposal of a gross mischaracterization of the public health standard.

The second stated purpose of the proposal is preventing misbranded tobacco products. This inclusion is illogical when read in light of the rest of the document. Under the Tobacco Control Act, a product is misbranded if it does not comply with the FDA’s established labeling procedures. The industry’s proposed requirements governing labeling do not reference FDA labeling procedures or misbranding. In fact, the term, “misbrand” appears only in the preamble and not the text of the proposed regulations. It is included as an overarching goal in name only and not in substance.

The third stated purpose is to give manufacturers flexibility. Given the discussion of the public health standard above, clearly manufacturer flexibility should not be one of the FDA’s considerations when regulating manufacturing practices. Furthermore, the tobacco industry asserts that this regulatory flexibility is rooted in the fact that tobacco is an agricultural product that has inherent variations across plants and seasons. Because of this inherent variability, the tobacco industry asserts that it must be given flexibility to manufacture, label, pack and store tobacco products. While agricultural variability may affect manufacturing and possibly storing, it would not, in any way, affect labeling or packaging. This goal also mischaracterizes the issues at hand.

In promulgating a manufacturing regulation or any regulation, the FDA must have only one goal: protecting public health and this goal is inconsistent with the tobacco industry’s goal.

Following the tobacco industry’s establishment of the purpose of its proposal, it lays out its argument for an individual risk standard. This specious argument is as follows:

Underpinning the proposed cGMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health...
authorities have identified certain inherent risks associated with the use of different categories of such products. When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was "to continue to permit the sale of tobacco products to adults." FDCA § 907(d)(3)(A) (FDA is expressly "prohibited" from issuing a regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products.").

Thus the cGMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks and, given the purpose of the cGMPs, not require manufacturers to address those risks in this context.

Essentially, the tobacco industry’s argument is that tobacco products are risky and thus manufacturing standards cannot address that risk. The chain of reasoning of this argument is, at best, deceptive. It is true that leading public health authorities have identified the inherent risks of tobacco products and that Congress recognized those risks in developing the Tobacco Control Act. Even the tobacco industry has begrudgingly admitted that smoking is harmful. It is true that Congress did not prohibit any tobacco products and it is also true that Congress did not give the FDA authority to prohibit any tobacco products. However, there is no connection between the acknowledged risk of tobacco products and the lack of a tobacco product prohibition in the Tobacco Control Act. At no point is there a suggestion that the inherent risks of tobacco use cannot or should not be addressed by manufacturing standards or any other regulations. Were this true, there would be no reason for Congress to give the FDA regulatory authority over tobacco products.

This argument also fails because Congress specifically mandated that the FDA address the inherent risk of using tobacco products in the context of manufacturing practices. We know this because Congress mandates that the FDA use the public health standard when promulgating regulations relating to manufacturing practices. To say that manufacturing practices should not address the inherent risk of tobacco products is untrue; they can and they must.


This subpart discusses the applicability of the regulations and also includes the definitions for the regulations. The first paragraph of this subpart once again attempts to assert that the individual risk standard is the appropriate standard to consider in establishing good manufacturing practices. However, there are additional problems with this subpart.

The first of several glaring omissions occurs in XXX.1 Applicability, subsection (d). This subsection notes that a manufacturer may apply for a variance to any of the established good manufacturing practices and that variance submissions should follow the procedures set forth in 21 C.F.R. § 10.30, which are the procedures for filing a citizen petition. At first glance, it is clear that the industry has deliberately omitted any criteria that the FDA should rely on when deciding whether to grant such a variance. However upon further inspection, the omission is much larger. What have been omitted are the extensive procedures for granting a variance established by the Tobacco Control Act.
Within Section 906(e), subsection (1) outlines the FDA’s authority to establish good manufacturing practices regulations and subsection (2) establishes the procedures for granting a variance. This subsection, in part, states that a variance application must identify the basis upon which the variance is based, the methods and controls to be used in place of the required practice and any other information that the FDA requires. The Act also states that the FDA may refer the application to TPSAC, that any variance granted requires a showing that the procedures used will maintain compliance with the Act, and that the FDA can place additional conditions on any variance that it grants.

By leaving these procedures out of its proposal and replacing them with meaningless procedures, the tobacco industry has attempted to create a much weaker variance process that will make it difficult – if not impossible – for the FDA to enforce regulations to protect public health.

Subpart A also includes the definitions section of the tobacco industry’s proposal. It is in this section that the industry includes the definition of contaminant, which is thoroughly discussed above. Another important definition found in this section is “tobacco product.” Although the proposal language mostly tracks the language in the Tobacco Control Act, the tobacco industry added some language to the end of the definition that limits tobacco products to only those over which the FDA has asserted jurisdiction under Section 901(b). Nowhere in the Tobacco Control Act is the definition of tobacco product limited in this fashion. This limitation would prevent the FDA from regulating the manufacturing facilities of new and novel tobacco products that might fall outside the definition of tobacco product. Including this limitation is likely an attempt to limit FDA authority to regulate some manufacturing facilities.

3. Subpart B – Personnel: Lack of Dedicated Quality Control

As was indicated above, this subpart dealing with personnel, is rife with vagueness. Where there should be standards related to education and training, the tobacco industry’s proposal has indicated at XXX.40(a) that an employee’s background must only be sufficient to “adequately perform the person’s assigned functions.” This section would be difficult for the FDA to enforce and invites pointless, costly litigation.

This section, which purports to create requirements for quality control staff, does not mandate that the tobacco industry have staff dedicated to quality control. According to XXX.31, it is merely sufficient to have staff members who are assigned quality control tasks but do not have to dedicate their time to such tasks. Because of this lack of dedicated staff, it is very easy to foresee a situation where a manufacturing facility employs personnel who are quality control personnel in name only and do not actually perform quality control tasks or only perform them when there is an FDA inspection. It is particularly easy for the industry to accomplish this given the lack of education and training standards for such staff.

This subpart also contains the most instructive language on how a manufacturer should ensure that its employees can prevent contamination. Because this proposal is centered on preventing contamination which is measured by the individual risk standard proffered by the industry, one would expect this extremely important provision to be very extensive and detailed. XXX.35 reads as follows:
You shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

This provision contains no standards, no way to measure success or failure, and therefore is utterly unenforceable. The absolute deference to the tobacco product manufacturer contemplated by this proposal is unacceptable. The tobacco industry cannot and should not be allowed to regulate itself. In establishing manufacturing regulations, the FDA cannot simply ask the tobacco industry to do the bare minimum, as this proposal would have it do. The FDA must promulgate meaningful regulations that save lives and protect public health.


A regulation governing the physical plant and grounds must be thorough and outline regulations relating to the physical environment and the methods that should be used to prevent contamination. The industry’s proposed language does neither of those things. This section, much like the rest of the proposal, includes no real standards that can be applied to allow for effective regulation. Rather than rigorous standards relating to cleanliness, the proposal states at XXX.50(b) that the physical plant should be in a “clean and sanitary condition.” No definition for clean or sanitary is provided in the proposed regulations. The tobacco industry’s preamble, at Subpart C, suggests that clean and sanitary indicates that “a manufacturer’s physical plant shall be kept clean to the extent necessary to protect against contamination, taking into account the inherent risks of tobacco products and an analysis of the risks of contamination.” The preamble at Subpart C also states that the term “sanitary” is “not intended to require sanitization, sterilization, or any other specific form of cleaning beyond what the risk analysis determines is necessary.”

Predictably, this section makes another big push toward an improper individual risk standard. The tobacco industry applies this standard toward cleanliness. Because the standard is based on the risk of harm to an individual rather than a population, a manufacturer could significantly reduce the resources that it puts towards cleaning its facility as long as each individual cigarette is not rendered more harmful. Using an individual risk standard for cleanliness creates an impermissible amount of flexibility that ultimately imposes no standards at all.

This subpart also allows manufacturers complete freedom to use “insecticides, fumigants, fungicides or rodenticides.” The only qualifier on the use is that it must be done, “when monitoring indicates the need for the use.” Unsurprisingly, there are no monitoring requirements established nor are there any established thresholds for when the products should be used and so it seems that “when monitoring indicates the need,” means that the manufacturer can use its own discretion.

While this section indicates that these products should be used to protect against contamination, the language in no way anticipates that the pesticide products themselves might be contaminants even though these products could potentially be toxic and/or carcinogenic. The only attempt to
establish regulations on the use of pesticides is a passing reference to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The purpose of FIFRA is to regulate pesticide manufacturers by imposing regulations related to registration, labeling, recordkeeping and the import and export of various pesticides. FIFRA makes almost no references to the use of pesticides and none of the use regulations would apply in this context.\(^{75}\)

Finally, the FDA is given the specific authority, by the Tobacco Control Act, to create regulations that, “provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.”\(^{76}\) Any meaningful regulation of tobacco product manufacturing practices must use all of the FDA’s authority including testing of pesticide chemical residues.

5. Subpart I – Evaluation and Acceptance Activities: No Testing Necessary

This section purports to impose regulations relating to the receipt of tobacco products by manufacturers. Unfortunately, this section establishes no meaningful standards and does not actually mandate any kind of regulation. In fact, the tobacco industry notes in its preamble that, “because of the unique nature of tobacco products,. . . in-process or finished tobacco product testing is not required.” This section makes no attempt to impose any kind of regulation.

6. Subpart J – Nonconforming Tobacco Product: Contaminated Products Can Be Reworked But Don’t Need To Be Tested

This section establishes the procedures relating to what a manufacturer may do with a contaminated product. The industry’s proposed regulation would not require that a contaminated product be discarded as harmful, but instead would allow a manufacturer to “rework” the contaminated product.

Because of the potential risk of harm, the process of reworking a product should be thoroughly and stringently regulated. This is not the case in the industry’s proposal. A manufacturer would only need to establish a plan for ensuring that the reworked tobacco product meets specifications. A manufacturer would not be obligated to test the product to ensure that the contaminant was removed. As long as a plan is in place and followed, the manufacturer has fulfilled its obligations. It need not actually determine whether or not the reworking process was successful, which could result in contaminated products being introduced into the marketplace.

7. Subpart M – Complaints: Far From Enforcement

This section of the proposal provides language that is the closest that the tobacco industry’s proposal comes to creating a compliance and enforcement mechanism. Unfortunately, the only thing that this section actually does is suggest that the industry investigate complaints that it receives. The complaints would presumably come from tobacco product consumers, although there is no language that instructs the industry to make information on the process of submitting a complaint available nor are there any procedures for receiving complaints. Most egregiously, the proposal does not actually mandate an investigation, it only suggests that complaints be investigated, “[w]here appropriate.” Consistent with the rest of the proposal, there is no indication as to what must be measured to determine the appropriateness of an investigation. The
proposal also includes specific language that allows the tobacco industry to only conduct a single investigation for a group of similar complaints. One would expect that many similar complaints would indicate that a full and thorough investigation is necessary due to the risk of some large-scale, catastrophic contamination, but according to the tobacco industry’s proposal – no such investigation would be required.

8. Effective Date: Large Manufacturers vs. Small Manufacturers

One final problem with the racketeers’ proposal is found in the very last sentence of the industry’s proposal. While the tobacco industry suggests that the proposal cannot take effect for two years after the final rule is published, no such delay is required by the Tobacco Control Act. What the Act does mandate is that the FDA must give small tobacco product manufacturers four years before they are required to follow any established manufacturing practices. The large tobacco companies have used this last sentence of the proposal to weaken their smaller competitors, showing not just their contempt for public health but also for healthy competition.

D. Strategic Missing Elements

In addition to the problems found in the text of the industry’s proposal, there is also a significant problem with what has been left out of the proposal. Nowhere in this proposal is there any indication as to what might happen to a tobacco manufacturer who violates these regulations. It has been noted how weak and difficult to enforce these regulations are. However, assuming that a manufacturer did violate some established principal, there is no suggestion as to what procedures the FDA must follow in pursuing an enforcement action or what penalty might apply to a violating manufacturer. This omission is likely a deliberate one.

Further clouding the issue of enforcement is a strange quirk that is found throughout the proposal. Many but not all sections of the regulations refer to “you” and what “you” must do in regard to manufacturing standards. The use of second person language is very uncommon in statutes and regulations. Rather, precise regulations refer to the party that is being regulated – in this case, tobacco product manufacturers. Complex corporate relationships could potentially complicate enforcement of these regulations unless the regulations clearly indicate the party to be held responsible. This proposal fails utterly in this respect.

IV. The Full Extent of FDA Authority

Any action taken to regulate manufacturing practices must maximize the authority granted to the FDA by Congress. The Tobacco Control Act devotes all of Section 906(e) to discussion of the FDA’s broad authority to regulate tobacco product manufacturing. Congress has allowed the FDA to create different regulations for different types of products where such regulation is appropriate. The FDA can mandate the testing of pesticide chemical residue. The FDA can implement a stringent variance process that allows TPSAC to review all variance applications. The FDA can also implement strong enforcement mechanisms including large civil monetary penalties for violations. The FDA is also required to have an oral hearing before promulgating any manufacturing regulations, and the FDA must allow TPSAC to review any proposed regulation.
V. Conclusion

The tobacco industry’s history of avoiding and fighting meaningful regulation shows that it cannot be trusted to be a good-faith participant in the regulatory process. When the FDA exercises its authority to regulate tobacco product manufacturing, it cannot rely on this meaningless and deceptive proposal proffered by the tobacco industry.

The Tobacco Control Legal Consortium urges the FDA to consider the past actions of the tobacco industry when weighing the industry’s proposed tobacco product manufacturing regulations.

Respectfully,

Maggie Mahoney, J.D.
Deputy Director
Tobacco Control Legal Consortium

Desmond Jenson, J.D.
Staff Attorney
Tobacco Control Legal Consortium


3 This decision has led many in the tobacco control community to label the tobacco industry defendants, “racketeers.”

4 This proposal has been put forth by R.J. Reynolds Tobacco Company, a division of Reynolds American; along with Santa Fe Natural Tobacco Company, Inc. and American Snuff Company, LLC, also divisions of Reynolds American; Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company; Lorillard, Inc.; Commonwealth Brands, Inc., a division of Imperial Tobacco plc; Swedish Match North America, the SMARTT Coalition; Liggett Group LLC, Vector Tobacco Inc.; National Tobacco Company, L.P.; and Hail & Cotton, Inc. Not all of these companies and groups were defendants in United States v. Philip Morris and thus any references in this comment to the tobacco industry generally, unless otherwise noted, should be understood to reference the tobacco industry defendants in United States v. Philip Morris, and not necessarily all of the companies that have offered this proposal.

5 449 F.Supp. at 146-208.
7 449 F.Supp. at 430-561.
8 449 F.Supp. at 694-801.
9 449 F.Supp. at 801-839.
10 449 F.Supp. at 561-694.

Memorandum from Clausen Ely on Strategy for Responding to Inquiries Following the Release of a Report by the Department of Health and Human Services on Cigarette Ingredients to James L. Charles et al. (Apr. 12, 1989) available at http://legacy.library.ucsf.edu/tid/fqg62b00/pdf.

Memorandum from Clausen Ely on Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredients List, a Report by the Department of Health and Human Services, on Cigarette Ingredients or a Congressional Hearing on Ingredients Matters (Jan. 16, 1994) available at http://legacy.library.ucsf.edu/tid/bmi96e00/pdf.


http://legacy.library.ucsf.edu/tid/cef36e00/pdf.

http://legacy.library.ucsf.edu/tid/ref36e00/pdf.

http://legacy.library.ucsf.edu/tid/rav72e00/pdf.

http://legacy.library.ucsf.edu/tid/vbv72e00/pdf.

http://legacy.library.ucsf.edu/tid/me36e00/pdf.

http://legacy.library.ucsf.edu/tid/efs72e00/pdf.

http://legacy.library.ucsf.edu/tid/801-839.

http://legacy.library.ucsf.edu/tid/35-143.

http://legacy.library.ucsf.edu/tid/723-788.

http://legacy.library.ucsf.edu/tid/208.

http://legacy.library.ucsf.edu/tid/801-839.


Memorandum from Clausen Ely on Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredients List, A Report By the Department of Health and Human Services on Cigarette Ingredients or a Congressional Hearing on Ingredient Matters (Jan. 26, 1994).

Memorandum from Clausen Ely on Strategy for Responding to Inquiries in Connection with the Release of a Cigarette Ingredients List, A Report By the Department of Health and Human Services on Cigarette Ingredients or a Congressional Hearing on Ingredient Matters (Jan. 26, 1994).

http://legacy.library.ucsf.edu/tid/bmi96e00/pdf.

http://legacy.library.ucsf.edu/tid/801-839.

http://legacy.library.ucsf.edu/tid/vjw72d00/pdf (last visited Apr. 19, 2013).

http://legacy.library.ucsf.edu/tid/vbv72e00/pdf.

http://legacy.library.ucsf.edu/tid/me36e00/pdf.

http://legacy.library.ucsf.edu/tid/efs72e00/pdf.

http://legacy.library.ucsf.edu/tid/801-839.

http://legacy.library.ucsf.edu/tid/801-839.
40 Id.
42 Id. at 44418.
43 Id. at 44615.
47 FDA Tobacco Jurisdiction Legislation in the 107th Congress Senate Bills, LEGACY TOBACCO DOCUMENTS LIBRARY, http://legacy.library.ucsf.edu/tid/dth77a00/pdf.
49 Discount Tobacco City & Lottery, Inc. v. United States Food & Drug Admin., 674 F.3d 509 (6th Cir. 2011).
51 Id.
60 Id.
64 Id. at 16, 17.
65 Id. at 24-28.
68 21 U.S.C. § 387(21)(C); § 387c(a)(8)(B)(ii); § 387e(j)(3)(A)(ii); § 387f(d)(1); § 387f(d)(3)(B); § 387f(e)(1)(A); § 387g(a)(3)(A); § 387g(a)(3)(B)(ii); § 387g(a)(4)(A); § 387g(a)(4)(B); § 387g(c)(2)(A); § 387g(c)(3); § 387g(d)(1)(A); § 387g(d)(2); § 387g(e)(1); § 387f(f)(1); 387h(a)(1); 387t(a), (a)(3); § 387i(a)(6); 387j(3)(A)(ii); § 387j(c)(2)(A); § 387j(c)(4); § 387j(c)(5)(A); § 387j(d)(1)(A); § 387k(g)(2)(A)(i); § 387k(i)(2); § 387k(j)(3)(C); 387o(b)(1); §387o(b)(2); 387r(b)(1).
69 21 C.F.R. § 810.2(h).
70 21 C.F.R. 810.2(i).


7 U.S.C. § 136 et seq.


Id.

Id.


| Subject: | Updated: GMP Workgroup |
| Location: | 230V; Conference Number: 877-367-4916, Participant Code |
| Start: | Thu 4/26/2012 3:00 PM |
| End: | Thu 4/26/2012 4:00 PM |
| Recurrence: | Weekly |
| Recurrence Pattern: | every 2 weeks on Thursday from 3:00 PM to 4:00 PM |
| Meeting Status: | Accepted |
| Organizer: | Bautista, Andrea |
| Required Attendees: | Bautista, Andrea; Aikin, Ann; Boocker, Nancy; Buckler, Beth; Faranda, David; Fowler, Clarence (Grayson); Gerrity, Kevin T; Goldman, Tara D; Griffths, Christopher A; Kaneva, Diana; Nguyen, Ket; Perdue Jr, Paul; Price, Nakki; Raata, Dina; Richter, Patricia; Schmidt, Rachael; Taylor, Larry; Tobias, Lindsay; Wang, Emil P; Waltershausen, Joanna; Whipp, Valerie; Simoneau, Ann |

When: Thursday, April 26, 2012 3:00 PM-4:00 PM (GMT-05:00) Eastern Time (US & Canada)  
Where: 230V, Conference Number: non-responsive, Participant Code: non-responsive  
Note: The GMT offset above does not reflect daylight saving time adjustments.

---

**AGENDA**

1. Non-responsive
2. Non-responsive
3. May 5, 2012 Meeting with Industry  
   - Ground Rules
4. January 2012 GMP Proposal from Industry  
   - Discussion on content of industry proposal - does the proposal comprehensively and effectively provide adequate controls for the manufacture, testing, packaging, labeling, and distribution of tobacco products?  
   - Copy of industry proposal available at non-responsive

**MINUTES FROM 4/18/2012 WORKGROUP MEETING**

non-responsive
April 23, 2012

Re: **MAY 2, 2012 MEETING PARTICIPANTS AND PROPOSED AGENDA**

Dear Ms. Simoneau and Ms. Chernaik:

As requested, R.J. Reynolds Tobacco Company ("RJRT") hereby respectfully submits this letter to the United States Food and Drug Administration’s Center for Tobacco Products ("CTP") to provide CTP with the specific representatives from the various industry stakeholders1 who plan to participate in the May 2, 2012 meeting with CTP to discuss the Companies’ proposed Good Manufacturing Practice ("GMP") regulations and preamble. We also take this opportunity to provide CTP with the Companies’ proposed agenda.

The following Company representatives will attend the May 2, 2012 meeting:

- **James E. Swauger, Ph.D., DABT**
  - Vice-President – Regulatory Oversight
  - R.J. Reynolds Tobacco Company

- **Charles D. Garner, Ph.D., DABT, CIH**
  - Sr. Director – Regulatory Oversight
  - R.J. Reynolds Tobacco Company

- **Mitchell A. Neuhausser**
  - Managing Counsel – Regulatory
  - R.J. Reynolds Tobacco Company

---

1 The industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., and Hall & Cotton, Inc. (collectively referred to herein as the "Companies").
Mark S. Brown  
King & Spalding LLP  
Representing R. J. Reynolds Tobacco Company

Amanda J. Klingler  
King & Spalding LLP  
Representing R. J. Reynolds Tobacco Company

Gregory H. Ray  
Vice President, Quality Compliance  
Altria Client Services

Pamela D. Lieberman  
Director, Quality Compliance Management  
Altria Client Services

Ronald Gahagan  
Assistant General Counsel  
Altria Client Services

Stephen C. Payne  
Gilson, Dunn & Crutcher LLP  
Representing Altria Client Services

Sam Eich  
Director, Quality Management  
Lorillard Tobacco Company

Patricia Kovacevíc, JD  
Director Regulatory Affairs, Associate General Counsel  
Lorillard Tobacco Company

Frank Howell  
Vice President, Manufacturing  
Commonwealth Brands, Inc.

Ron. Wilkey  
Vice President & General Counsel  
Commonwealth Brands, Inc.

Billy T. Turner, Jr.  
Vice President Operations  
Liggett Group LLC
As discussed in our January 10, 2012 submission, the Companies propose the following agenda for the 90-minute meeting:

- Introductions and meeting objectives
- Discussion of the Companies’ approach to developing the proposed GMP regulations and preamble
- Overview of the proposed GMP regulations and preamble
- Discussion with CTP, including addressing CTP’s questions regarding the proposed GMP regulations and preamble

We will submit our planned presentation and any specific questions to CTP prior to the meeting. In addition, should CTP wish to provide the Companies with questions by April 25, 2012, we will be prepared to discuss them. If possible, please let us know who will be representing CTP at the meeting.
The Companies are committed to working with the Agency to establish appropriate GMP regulations for tobacco product manufacturers and look forward to discussing this matter with CTP. If you require any additional information or have any questions, please do not hesitate to contact me.

Respectfully Submitted

[Signature]

James E. Swaiger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
Proposed Good Manufacturing Practices for Tobacco Products:

Industry Stakeholder Presentation to CTP

May 2, 2012
Meeting Objectives

• Share with CTP:
  – The process the industry stakeholders used to develop the proposed GMP
  – Industry stakeholder perspective on the proposed GMP and preamble

• Help the industry stakeholders understand the CTP’s current thinking on the process and timing for the development of tobacco product GMPs

• Begin a dialogue with CTP on development of tobacco product GMPs
Developmental Process for Proposed GMP Regulation

- Diverse group of stakeholders including large and small manufacturers and suppliers
- Began initial discussions spring-2011 to develop a GMP approach appropriate for tobacco product manufacturing
- Considered the scope and range of both tobacco products and manufacturing processes
- Submitted proposed GMP regulation and preamble to the Agency, January 10, 2012
- In the ensuing period, other tobacco product manufacturers and suppliers have been supportive of this approach
- General consensus-current version appropriate for tobacco products
Supporting Industry Stakeholders

- R.J. Reynolds Tobacco Company
- Santa Fe Natural Tobacco Company, Inc.
- American Snuff Company, LLC
- Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company
- Lorillard, Inc.
- Commonwealth Brands, Inc
- Liggett Group LLC
- The SMARTT Coalition, which includes Nat Sherman, Commonwealth Brands, Inc. Japan Tobacco International, King Maker Marketing, Inc.
- Vector Tobacco Inc.
- National Tobacco Company, L.P.
- Hail & Cotton, Inc.
- Swedish Match North America
- CITMA
- Mundet
Statutory Requirements for GMP Regulation

- The FSPTCA* requires that the FDA prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing and storage of tobacco products conform to (i) cGMPs or (ii) hazard analysis and critical control point methodology ("HACCP").

* Federal Food, Drug and Cosmetic Act ("FDCA") Section 906(e), as amended by the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").
Proposed GMP Regulation and Preamble

• The proposed GMP Regulation is intended to meet the statutory requirements of the FSPTCA and draw from existing cGMP regulations where controls were deemed appropriate.

• The proposed GMP Regulation provides direction without a high degree of specificity, requiring a controlled manufacturing process but allowing each manufacturer discretion as to the types of controls and level of control (e.g. specifications).

• Such flexibility will also allow manufacturers to adopt additional controls in the future in the event tobacco production standards are promulgated by the FDA.
Proposed GMP Preamble

- Background and Related Information
  - Purpose
  - Inherent risks associated with the use of tobacco products
  - Inherent variability of tobacco products

- Proposed Rule
  - Rationale for key tobacco-related definitions
  - Explanation of key elements of the “proposed rule”
Proposed GMP Regulation

- Unlike the FDA cGMPs for drugs and medical devices, the proposed GMP regulations for tobacco products are not meant to assure the “safety and effectiveness” of a tobacco product (as those terms are traditionally used by FDA) – because of the inherent risks associated with the use of different categories of tobacco products – but rather to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the Act. Tobacco Control Act, §906(e)(1).
Purpose of Proposed GMP Regulation

- To protect the public health by providing assurance that tobacco products are not contaminated (prohibiting the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product);

- To provide assurance that the manufacturing of tobacco products does not result in such products being adulterated or misbranded; and

- To allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.
Proposed GMP Regulation: Inherent Risks of Tobacco Products

- Underpinning the proposed GMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products.

- When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was “to continue to permit the sale of tobacco products to adults.” Tobacco Control Act, §907(d)(3)(A).

- Thus the GMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks.

- Unlike drugs and medical devices, the tobacco product GMPs cannot require tobacco manufacturers to assure their products are safe and/or effective as those terms are traditionally used by FDA.
Proposed GMP Regulation:
Inherent Variability of Tobacco Products

- Tobacco is of an agricultural origin and therefore tobacco products are subject to natural variation.

- Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

- FDA acknowledged that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco . . . in order to maintain a consistent product” in a recent guidance document.*

---

* Center For Tobacco Products, Guidance For Industry And FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence For Tobacco Products 4 (2011).
Proposed GMP Regulation: Subparts

A. General Provisions
B. Personnel
C. Physical Plant and Grounds
D. Equipment and Utensils
E. Document Controls
F. Purchasing Controls
G. Identification and Traceability
H. Manufacture and Process Controls
I. Evaluation and Acceptance Activities
J. Nonconforming Tobacco Product
K. Labeling and Packaging Operations
L. Holding and Distribution
M. Complaints
N. Records and Recordkeeping
Subpart A: General Provisions
XXX.3 Definitions

- Batch or Lot
- Complaint
- Contact Surface
- Contaminant
- Finished tobacco product
- Import
- In-process tobacco product
- Label
- Master Manufacturing Record
- Material
- Package
- Pest
- Physical Plant
- Quality
- Reprocessing
- Rework
- Specification
- Tobacco Product
- Tobacco Product Manufacturer
Proposed GMP Regulation:

XXX.3 Definitions - Select Terms

- "Batch or lot means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications."

- "Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminant or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface."

- "Quality means that the tobacco product meets the manufacturer’s specifications and is not contaminated."

- "Specification means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform."

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation:
Illustrative Examples

• Subpart B - Personnel

  - Requires a manufacturer to “provide adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority.”

  For example, “quality assurance personnel shall assure all components, in-process materials, packaging materials, labels, and tobacco products meet specifications, as appropriate, and are not contaminated.”

  - Requires a manufacturer to “establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.”

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation:
Illustrative Examples

• Subpart C – Physical Plant and Grounds
  – Includes requirements necessary to protect against contamination for:
    • Grounds,
    • Physical plant facilities,
    • Cleaning compounds, pesticides and other toxic chemicals,
    • Pest control,
    • Water supply,
    • Plumbing, bathrooms and hand-washing facilities,
    • Trash disposal,
    • Sanitation Supervisors
  – Requires establishment of procedures for cleaning and pest control.

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

- Subpart D – Equipment and Utensils
  
  - Requires manufacturers to “use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.”
  
  - Establishes requirements for “instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination.”
  
  - Requires that manufacturers establish and maintain procedures and maintain records for such controls (e.g. calibration).

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

• Subpart H – Manufacture and Process Controls
  – Requires manufacturers to:
    • “develop, conduct, control and monitor manufacturing processes to ensure that tobacco products conform to specifications.”
    • “establish and maintain procedures for changes to a specification, process or procedure.”
    • “establish specifications for any point, step or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged and labeled as intended by the manufacturer.”
    • “conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions to prevent contamination” (e.g. application of HACCP concepts).
Proposed GMP Regulation: Illustrative Examples

- Subpart H – Manufacture and Process Controls -continued
  - Requires manufacturers to:
    - “prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes.”
    - “ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate” for the category of tobacco product.
    - “establish and maintain procedures to ensure a batch or lot manufacturing record is prepared for each batch or lot of a tobacco product”; including “records demonstrating that the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record.”

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulations: Illustrative Examples

- Subpart K – Labeling and Packaging Operations
  - Requires manufacturers to “establish and maintain a process to control labeling and packaging activities”:
    - Printing and application of labels to finished tobacco products
    - Ensuring labels received from suppliers conform to label specifications
    - Preventing mix-ups
    - Assuring numbers, codes or markings used to identify the tobacco product batch or lot are adequately applied

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation:  
Illustrative Examples

Subpart M – Complaints

- *Complaint* means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco product.

- Requires that “quality assurance or other qualified personne.”:
  - "review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products;
  - evaluate the need for an investigation; and
  - where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and another investigation is not necessary."

- Defines required complaint records.
Proposed GMP Regulation: Effective Date

• GMP regulations would take effect a minimum of two years from publication of the final rule in the Federal Register.

• The proposed effective date provides a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein.

• The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.

• Small tobacco manufacturers as defined by Section 900(16) of the FSPTCA are not required to comply with the GMP regulation for at least 4 years following the effective date of the regulation (See Section 906(e)(1)(B)(v))
Questions?
Center for Tobacco Products (CTP)
TPMP Development Working Group

Meeting Minutes

Thursday, 4/27/2012
9200 Corporate Blvd., Rockville, MD
Room 230V
3:00 pm - 4:00 pm

Meeting Minutes

- 5/2/2012 Industry Meeting
  - (b) (5)
  - Beverly Chernak and Ann Simoneau to lead meeting; Beverly, Ann, and Emil to ask questions on behalf of CTP
  - Submit proposed questions to Email
  - Come on time; leave on time
  - (b) (5)
  - There will be other opportunities for industry to give us SMP feedback (e.g., public meetings, IPSAC, oral hearing)
  - List of industry attendees and proposed agenda available at
  - non-responsive
  - Meeting minutes and list of all attendees will be shared with industry attendees

INTERNAL USE ONLY
Upcoming Meetings

- GMP Meeting with Industry: Wednesday, May 2, 2012
- non-responsive
January 10, 2012

Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Beverly Chernaik
Director, Office of Regulations
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Re: PROPOSED TOBACCO PRODUCT GOOD MANUFACTURING PRACTICES REGULATION AND REQUEST FOR MEETING

Dear Ms. Simoneau and Ms. Chernaik:

As indicated in its December 16, 2011 letter, R.J. Reynolds Tobacco Company ("RJRT") has worked with various tobacco industry stakeholders to develop proposed current Good Manufacturing Practice ("cGMP") regulations pursuant to Section 906(e) of the Family Smoking Prevention and Tobacco Control Act. Specifically, the industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., and Hail & Cotton, Inc. (collectively referred to herein as the "Companies").

RJRT, on behalf of the Companies, submits to the United States Food and Drug Administration's ("FDA") Center for Tobacco Products ("CTP") for its review and consideration (1) proposed cGMP regulations and (2) a preamble to the proposed regulation. While each of the Companies reserves its right to express its own opinions regarding the proposed regulations and preamble, the preamble provides the Companies' common perspective and interpretation of the provisions of the proposed cGMP regulations. (See Attachments 1-2.)

The Companies believe the proposed cGMP regulations and preamble will help to facilitate a productive dialogue consistent with CTP's expressed goal to engage with and understand the tobacco product manufacturing industry. In that regard, the Companies
respectfully request a 2-hour meeting to discuss the proposed cGMP regulations and preamble attended by you and any other appropriate CTP representatives and representatives from the Companies. We will identify the specific Companies' representatives that plan to participate at least one week prior to the meeting. The Companies propose the following general agenda:

- Introductions and meeting objectives
- The Companies' approach to developing the proposed cGMP regulations and preamble
- Overview of the proposed cGMP regulations and preamble
- Discussion with CTP, including addressing CTP's questions regarding the proposed cGMP regulations and preamble.

Any planned presentations will be submitted to CTP at least one week prior to the meeting. In addition, should CTP wish to provide the Companies with questions in advance of the meeting, we will be prepared to address them.

The Companies are committed to working with the Agency to establish appropriate cGMP regulations for tobacco product manufacturers and look forward to discussing this matter with CTP. RJRT will contact you in the upcoming weeks to schedule a meeting at your earliest convenience. If you require any additional information or have any questions, please do not hesitate to contact me.

Respectfully Submitted,

[Signature]

James E. Swauger, Ph.D., JABT
Vice President - Regulatory Oversight
R.J. Reynolds Tobacco Company

cc: Lawrence R. DeYon, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
Attachment 1
PART — CURRENT GOOD MANUFACTURING PRACTICE IN 
MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO 
PRODUCTS

Subpart A — General Provisions
XXX.1 Applicability
XXX.3 Definitions
XXX.5 Good Manufacturing Practice Regulation

Subpart B — Personnel
XXX.20 Resources
XXX.30 Responsibility and Authority
XXX.31 Quality Assurance Personnel
XXX.35 Contamination Prevention
XXX.40 Qualification, Education, and Training

Subpart C — Physical Plant and Grounds
XXX.50 Plant Grounds, Facilities, and Sanitary Operations
XXX.53 Physical Plant Construction and Design

Subpart D — Equipment and Utensils
XXX.60 Equipment and Utensils
XXX.65 Procedures, Records and Recordkeeping

Subpart E — Document Controls
XXX.70 Procedures

Subpart F — Purchasing Controls
XXX.80 General
XXX.85 Evaluation of Suppliers

Subpart G — Identification and Traceability
XXX.90 Identification
XXX.95 Traceability

Subpart H — Manufacture and Process Controls
XXX.100 General Controls and Change Controls
XXX.110 Specifications
XXX.114 Sanitation Requirements
XXX.116 Master Manufacturing Record
XXX.118 Batch or Lot Manufacturing Records
Subpart I — Evaluation and Acceptance Activities
XXX.120 Receiving Acceptance and In-Process Evaluation

Subpart J — Nonconforming Tobacco Product
XXX.130 Procedures for Nonconforming Tobacco Product

Subpart K — Labeling and Packaging Operations
XXX.140 Labeling and Packaging
XXX.145 Repackaging and Relabeling

Subpart L — Holding and Distribution
XXX.150 Handling and Storage
XXX.155 Distribution

Subpart M — Complaints
XXX.160 Review and Investigation of Complaints
XXX.165 Required Records

Subpart N — Records and Recordkeeping
XXX.170 General
XXX.174 Record Retention
XXX.178 Confidentiality
XX.1 Applicability

(a) Except as provided by paragraphs (b) and (c) of this section, you are subject to this Part if you manufacture, pack, label, repackage, relabel, store, or import cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, or any other tobacco products that the Secretary by regulations deems subject to this Part for sale or distribution in any State, territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. The requirements in this Part are intended to protect the public health by requiring the manufacture of tobacco products utilizing practices that protect against manufacturing defects not ordinarily contained in tobacco products that present a risk of injury beyond the risks generally posed by the same category of tobacco products. If you engage in only some operations subject to the requirements of this Part, and not in others, you need only comply with those requirements applicable to the operations in which you are engaged.

(b) The requirements pertaining to storing tobacco products shall not apply to you if you are storing those tobacco products at a retail establishment for the sole purpose of retail sale to individuals for personal consumption, including facilities where self-service displays of tobacco products are permitted.

(c) The requirements of this Part shall not apply to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, except to the extent such producer of tobacco leaf is engaged in an activity specified in paragraph (a) of this section or is controlled by a tobacco product manufacturer. A producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process shall not be subject to this Part. The requirements of this Part shall not apply to distributors as defined by Section 900(7) of the Tobacco Control Act if the distributor is not also a tobacco product manufacturer and is not controlled by a tobacco product manufacturer.

(d) Any person who wishes to petition for a permanent or temporary exemption or variance from any requirement of this Part is subject to the requirements of Section 906(c)(2) of the Tobacco Control Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in 10.39 of this chapter, the United States Food and Drug Administration's administrative procedures.

XXX.3 Definitions

The definitions and interpretations of terms in Section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) apply to such terms when used in this Part. For the purpose of this Part, the following definitions also apply:

Batch or lot means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications.

Complaint means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco...
Contact surface means any surface that contacts a tobacco product, material, or packaging during manufacture, processing, packaging or labeling.

Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminant or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface.

Finished tobacco product means any tobacco product that has completed the manufacturing and packaging process and is intended for commercial distribution.

Import means entry into the Customs territory of the United States for sale or distribution to consumers for consumption in the United States.

In-process tobacco product means any tobacco product that is fabricated, compounded, blended, ground, extracted, sifted, or processed in any other way by a tobacco product manufacturer for use in the manufacture of a finished tobacco product.

Label means a display of written, printed, or graphic matter upon the immediate package of any tobacco product.

Master manufacturing record means a compilation of records containing the procedure and specifications for manufacturing a finished tobacco product. A master manufacturing record may be prepared as a single document or file or may be prepared using an index system that specifies the location and identity of individual files, records, or documents that make up the master manufacturing record.

Material means any ingredient, additive or other substance other than tobacco incorporated into or added to a tobacco product during manufacturing.

Package means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including film), in which a tobacco product is offered for sale, sold, or otherwise distributed to tobacco product consumers. A shipping case is not included in the definition of package.

Pest means any objectionable insect or other animal including birds, roosters, flies, and beetles.

Physical plant means all or any part of a tobacco product manufacturer’s building or facility used for or in connection with manufacturing, packaging, labeling, or holding of a tobacco product.

Quality means that the tobacco product meets the manufacturer’s specifications and is not contaminated.

Reprocessing means using, in the manufacture of a tobacco product, uncontaminated tobacco product that has been previously removed from manufacturing and that is suitable for use in the
subsequent manufacture of a tobacco product. Reprocessing is a routine manufacturing process.

Rework means action taken on a non-conforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco product to be reworked require an evaluation and disposition prior to use.

Specification means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) that FDA has authority over pursuant to Section 901(u), 21 U.S.C. § 387a(b), of the Tobacco Control Act.

Tobacco product manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States.

XXX.5 Good Manufacturing Practice Regulation

The regulations in this Part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, label, or hold tobacco products.

Subpart B — Personnel

XXX.20 Resources

You shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment of activities, to meet the requirements of this Part.

XXX.30 Responsibility and Authority

You shall establish the appropriate responsibility, authority, and reporting relationships of personnel who manage, perform, and assess work affecting the quality of tobacco products.

XXX.31 Quality Assurance Personnel

There shall be select individuals, who through appropriate education, experience and training, are specifically designated to perform quality assurance responsibilities. These personnel may have responsibilities in addition to their quality assurance responsibilities. These individuals shall assure all components, in-process materials, packaging material, label, and tobacco product meet specifications, as appropriate, and are not contaminated. Quality assurance personnel shall assure tobacco products manufactured, processed, packed, or held under contract by another company meet specifications. Quality assurance personnel shall be responsible for the review and evaluation of complaints under Subpart M, Section XXX.160.
XXX.35 Contamination Prevention

You shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

XXX.40 Qualification, Education, and Training

(a) Each person engaged in manufacturing, testing, packaging, labeling, or holding, or in performing any quality control operations, shall have the education, background, training, and/or experience to adequately perform the person’s assigned functions.

(b) You shall assign personnel qualified by education, training, and/or experience to supervise the manufacturing, testing, packaging, labeling, or holding of tobacco products.

(c) You shall establish procedures for identifying training needs and ensure that appropriate personnel are trained to adequately perform their assigned functions. Training shall be documented to assure that personnel have a thorough understanding of their jobs, including the date of the training, the type or title of the training, and the person(s) trained.

Subpart C — Physical Plant and Grounds

XXX.50 Plant Grounds, Facilities, and Sanitary Operations

(a) Grounds. You shall keep the grounds of your physical plant in a condition that protects against contamination.

(i) Physical plant facilities. You shall maintain your physical plant in a clean and sanitary condition and repair to the extent necessary to protect against contamination.

(c) Cleaning compounds, pesticides, and other toxic chemicals. You shall use cleaning compounds and pesticides in a manner that does not result in contamination. Other toxic chemicals shall be used and stored in a manner that prevents them from coming into contact with tobacco products, materials, packaging, or contact surfaces.

(d) Pest control.

(1) You shall not allow animals in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination.

(2) You shall take effective measures to minimize pests from the physical plant and to protect against contamination.

(3) When monitoring indicates the need for the use of insecticides, fumigants, fungicides, or rodenticides, such products shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination.
(e) Water supply.

(1) You shall provide water that is safe and sanitary at suitable temperature and under pressure as needed for all uses where water does not become a component of the tobacco product.

(2) Water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product, e.g., when such water is used as an ingredient or otherwise contacts tobacco products or any contact surface, shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product.

(f) Plumbing. The plumbing used in your physical plant shall be of adequate size and design and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant into an adequate sewage system or through other adequate means;

(3) Avoid being a source of contamination or creating an unsanitary condition (e.g., not allow backflow or cross connection with wastewater or sewage); and

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(g) Bathrooms. You shall provide your employees with adequate, readily accessible bathrooms that are kept clean so as not to be a potential source of contamination.

(h) Hand-washing facilities. You shall provide adequate and accessible hand-washing facilities for manufacturing personnel.

(i) Trash disposal. You shall collect, store, and dispose of trash in a manner that protects against contamination. The handling, storage and disposal of trash shall not create malodors that contaminate tobacco products or result in an attraction, harborage or breeding place for pests.

(j) Sanitation supervisors. You shall assign one or more employees to supervise overall sanitation. Each of these supervisors shall be qualified by education, training, and/or experience related to the development or supervision of sanitation programs.

(k) Procedures. You shall establish procedures for cleaning the physical plant and for pest control.

XXX.53 Physical Plant Construction and Design

(a) Any physical plant you use in the manufacture of tobacco products shall:

(1) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitary operations necessary to protect against contamination; and
(2) Have adequate space for the placement of equipment and holding of tobacco products, packaging, and materials as is necessary to protect against contamination or mix-ups of components during manufacturing, packaging, labeling, or holding.

Subpart D — Equipment and Utensils

XXX.60 Equipment and Utensils

(a) You shall use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.

(b) Equipment and utensils shall be maintained and cleaned to prevent contamination.

(c) Instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination shall be:

(1) Accurate and precise for their intended use;

(2) Adequately maintained;

(3) Adequate in number for their designated uses; and

(4) Calibrated before first use and at a frequency specified by the manufacturer of the instrument or control or at intervals necessary to ensure their accuracy and precision.

(d) Equipment and utensils shall be removed, replaced or repaired when they no longer perform as designed or do not conform to the applicable reference standard.

(e) Automated, mechanical, and electronic equipment (including software for computer controlled processes), shall be:

(1) Appropriate for, and function in accordance with, its intended use;

(2) Controlled to consistently meet specifications, including controls to account for any changes to such equipment; and

(3) Routinely calibrated, inspected, or checked to ensure proper performance.

XXX.65 Procedures, Records and Recordkeeping

(a) You shall establish procedures for fulfilling the requirements of this subpart, including procedures for:

(1) Calibrating instruments and controls that you use in manufacturing or testing a tobacco product;

(2) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment;
PROPOSED TOBACCO PRODUCT GMP REGULATION

(3) Maintaining, repairing, and cleaning, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold tobacco products; and

(4) Identifying what actions are to be taken if calibration accuracy or precision is not met or post-maintenance/repair testing does not meet performance requirements.

(b) Where the performance or accuracy of equipment and instruments may be necessary to assure that tobacco products meet specifications, you shall document any calibration, maintenance, and/or repair, each time it is performed, for instruments and controls that you use in manufacturing or testing a tobacco product.

(c) You shall make and keep records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment.

(d) Where the performance of equipment may be necessary to assure that tobacco products meet specifications, you shall make and keep records of the controls that you use to ensure that equipment functions in accordance with its intended use.

Subpart E — Document Controls

XXX.70 Procedures

You shall establish and maintain procedures to control all documents that are required by this Part. The procedures shall provide for the following:

(a) Document approval and distribution. Quality assurance or other qualified personnel shall review for adequacy and approve prior to issuance all documents established to meet the requirements of this Part. The approval, including the date and identification of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this Part shall be available at all locations for which they are designated, used, or otherwise necessary, and all documents established under this Part that are obsolete shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) Document changes. Changes to documents shall be reviewed and approved. Approved changes shall be communicated to the appropriate personnel in a timely manner. You shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the identification of the approving individual(s), the approval date, and when the change becomes effective.

Subpart F — Purchasing Controls

XXX.80 General

(a) You shall establish and maintain procedures to confirm that all purchased or otherwise received tobacco products, materials, and packaging conform to your specified requirements.

(b) You shall establish and maintain data that clearly describe or reference the specifications for purchased or otherwise received tobacco products, materials, and packaging. Purchasing
documents shall include, where possible, an agreement that the suppliers agree to notify the manufacturer of changes in the tobacco product, material, or packaging so that manufacturers may determine whether the changes may affect the specifications of a finished tobacco product.

XXX.85 Evaluation of Suppliers

(a) You shall establish and maintain the requirements that must be met by suppliers of tobacco products, materials, and packaging.

(b) You shall evaluate and select suppliers on the basis of their ability to meet your specified requirements. The evaluation shall be documented.

(c) You shall define the type and extent of control to be exercised over the tobacco products, materials, and packaging suppliers based on the evaluation results.

(d) You shall establish and maintain a list of qualified suppliers.

Subpart G — Identification and Traceability

XXX.90 Identification

You shall establish and maintain procedures for identifying tobacco products, materials, and packaging during all stages of manufacture to prevent mix-ups. The procedures shall include where appropriate:

(a) Identifying electronically, by signage, or other method of identification all containers to identify their contents and, where necessary, the stage of processing of the batch or lot; and

(b) Identifying electronically, by signage, or other method of identification all processing lines and major equipment used during manufacturing, as necessary, to indicate their contents, including the name of the tobacco product and the specific batch number, control number, or lot number and, when necessary, the stage of processing of the batch or lot.

XXX.95 Traceability

You shall establish and maintain procedures providing for traceability between a finished tobacco product and its materials, packaging, and tobacco used to produce a given lot or batch of finished tobacco product. For tobacco, traceability extends to the tobacco as it was first introduced into the manufacturing process.

Subpart H — Manufacture and Process Controls

XXX.100 General Controls and Change Controls

(a) You shall develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to your specifications. Where deviations from specifications could occur as a result of the manufacturing process, you shall establish and maintain adequate process
control procedures to ensure conformance to specifications. Where process control procedures are necessary they shall include:

(1) Documented instructions or procedures that define and control the manner of manufacture;

(2) Monitoring and control of manufacturing processes to ensure conformance to specifications during manufacture; and

(3) A process for approving, in writing, new processes and process equipment or modifications thereto.

(b) You shall establish and maintain procedures for changes to a specification, process, or procedure. Prior to implementation, such changes shall be properly qualified, where appropriate.

XXX.110 Specifications

You shall establish specifications for any point, step, or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged, and labeled as intended by the manufacturer. Such specifications shall be contained or referenced in the master manufacturing record.

XXX.114 Sanitation Requirements

You shall conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions determined by your evaluation of potential biological, chemical, and physical hazard to prevent contamination.

XXX.116 Master Manufacturing Record

You shall prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate for tobacco products. The master manufacturing record shall include, or reference, the location of, the following information, where appropriate:

(a) Specifications;

(b) Manufacturing methods, manufacturing procedures, or any manufacturing environment requirements;

(c) Quality control procedures;

(d) Evaluation criteria and quality control measures associated with any reprocessing activities; and
PROPOSED TOBACCO PRODUCT GMP REGULATION

(e) Label and packaging specifications and methods and processes used to ensure conformance with such specifications.

XXX. 118 Batch or Lot Manufacturing Records

You shall establish and maintain procedures to ensure a batch or lot manufacture record is prepared for each batch or lot of a tobacco product that includes complete information relating to the manufacture and control of each batch or lot and accurately follows the appropriate master manufacturing record and each step taken in the manufacture of the batch or lot. The batch or lot manufacturing record shall include, or refer to the location of, the following information:

(a) The date(s) of manufacture;
(b) The quantity of tobacco product manufactured;
(c) The quantity of tobacco product distributed;
(d) The records demonstrating the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record;
(e) Any identification and control number(s) for the finished tobacco product and components, materials, and any labels and packaging included in the finished tobacco product; and
(f) A description of any reprocessing or rework activity associated with such batch or lot including records demonstrating the reprocessing conformed to the master manufacturing record.

Subpart I – Evaluation and Acceptance Activities

XXX.120 Receiving Acceptance and In-Process Evaluation

(a) You shall establish and maintain procedures for the acceptance of incoming tobacco products, materials, and packaging to assure specified requirements are met.

(b) You shall establish and maintain evaluation procedures, where appropriate, to ensure that specified requirements for in-process tobacco product are met.

(c) You shall maintain records of in-process tobacco product failing evaluation activities and their disposition required by this Part. These records shall include:

(1) Identification of such in-process tobacco product failing evaluation;
(2) The dates such in-process tobacco product failed the evaluations;
(3) The results of such evaluations;
(4) The identity of the individual(s) conducting the evaluation; and
(5) Where appropriate, the equipment used.
Subpart J — Nonconforming Tobacco Product

XXX.130 Procedures for Nonconforming Tobacco Product

(a) You shall establish and maintain a process to control tobacco products that do not meet specifications or are contaminated. The process shall address the identification, documentation, evaluation, segregation, and appropriate disposition of such nonconforming tobacco products.

(b) Identification of nonconforming tobacco products shall include documentation of the identity and quantity of the nonconforming tobacco product, the date the tobacco product was identified as nonconforming, the nonconformance, and the identity of the person who determined the tobacco product to be nonconforming.

(c) Evaluation of the nonconformance shall include an assessment of the risk posed by the nonconformance and a determination of the need for an investigation into the cause of the nonconformance. Where an investigation is conducted, it shall include a review of relevant manufacturing records, data and any other relevant information necessary to determine the cause of the nonconformance and to eliminate other possible causes.

(d) Segregation of the nonconforming tobacco product shall include clearly identifying and holding nonconforming tobacco product in a manner that prevents mix-ups.

(e) Disposition of nonconforming tobacco products that is nonconforming due to being out of specification may include an assessment of whether the nonconformance presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Personnel responsible for making such disposition determinations shall be identified.

(f) You may rework nonconforming tobacco product to bring it into conformance with specifications only if you can establish and verify a plan for ensuring the tobacco product meets specifications and is not contaminated.

(g) You shall establish and maintain a corrective action and preventive action program to address nonconforming tobacco products, when the risk posed by the nature of the nonconformance or the frequency of the nonconformance warrants such action. Such a program shall include the following:

1. An investigation of the root cause of the nonconformance;

2. Identification of the action(s) needed to correct and prevent recurrence of the nonconformance;

3. Implementing such action(s); and

4. Assessment and confirmation of the effectiveness of such action(s).

(h) You shall keep and maintain records of all activities required under this section.
PROPOSED TOBACCO PRODUCT GMP REGULATION

Subpart K — Labeling and Packaging Operations

XXX.140 Labeling and Packaging

You shall establish and maintain a process to control labeling and packaging activities.

(a) Labels shall be printed and applied to finished tobacco products so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and sale.

(b) You shall establish a process to ensure that labels received from suppliers conform to the label specifications.

(c) You shall manage label storage, label application and packaging operations to prevent mix-ups.

(d) You shall ensure that any numbers, codes and/or markings used to identify the tobacco product batch or lot are adequately applied to labels or packaging on finished tobacco products.

(e) Tobacco product packaging and shipping cases or containers shall be designed and constructed to protect against the contamination of finished tobacco products during customary conditions of processing, storage, handling, distribution and sale.

XXX.145 Repackaging and Relabeling

You shall establish and maintain a process to manage repackaging and relabeling operations that meet the requirements set forth in Section XXX.140.

Subpart L — Holding and Distribution

XXX.150 Handling and Storage

You shall establish and maintain procedures to ensure tobacco products are held under appropriate conditions to protect against the possibility of mix-up or contamination.

XXX.155 Distribution

You shall establish and maintain a process to ensure finished tobacco products are distributed under appropriate conditions to protect against contamination. You shall establish and maintain records that include:

(a) The identification of the initial consignee;

(b) The identification and quantity of the finished tobacco product shipped;

(c) The date of shipment; and

(d) Any code used to identify the finished tobacco product and/or batch or lot...
Subpart M—Complaints

XXX.160 Review and Investigation of Complaints

Quality assurance or other qualified personnel shall:

(a) Review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products;

(b) Evaluate the need for an investigation; and

(c) Where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

XXX.165 Required Records

(a) You shall make and keep the following complaint records:

(1) Procedures for fulfilling the requirements of this subpart.

(2) A record of every complaint. The record of the complaint shall include, where available, the following:

(i) The name and description of the finished tobacco product;

(ii) The batch, lot, or control number of the finished tobacco product;

(iii) The date the complaint was received and the name, address, or telephone number of the complainant;

(iv) The nature of the complaint including, if known, how the finished tobacco product was used;

(v) The reply to the complainant, if any; and

(vi) The identification of the person receiving the complaint.

(3) Where complaints are investigated, the record of the investigation shall include:

(i) A record of the investigational activities performed; and

(ii) The findings of the investigation and follow up action(s) taken as a result of the investigation.
XXX.170 General

(a) You shall establish procedures to fulfill the requirements of this Part.
(b) You shall make and keep records required under this Part in accordance with this subpart.
(c) All records required by this Part shall be maintained at the establishment where the operations were conducted or other location that is reasonably accessible to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available during the retention period to FDA employee(s) for inspection and copying when requested. Such records shall be legible and shall be stored to minimize deterioration and to protect against loss. Those records stored in automated data processing systems shall be backed up.
(d) Records shall be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. You use reduction techniques, such as microfilming, you shall make suitable reader and photocopying equipment readily available to FDA.

XXX.174 Record Retention

You shall keep records for at least 2 years beyond the date of manufacture of the last batch of finished tobacco products associated with those records.

XXX.178 Confidentiality

Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in Part 20 of this chapter.

Effective Date:

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register.
Attachment 2
PART___—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO PRODUCTS

AGENCY: Food and Drug Administration, HHS

SUMMARY: The Food and Drug Administration ("FDA") is proposing to establish current good manufacturing practice ("cGMP") regulations for tobacco products. The proposed rule establishes cGMP requirements for the manufacture, labeling, packing, and storage of tobacco products to ensure that the tobacco products are not adulterated or misbranded. The proposed rule is one of many actions related to tobacco products that FDA is taking pursuant to the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (the "Tobacco Control Act" or "Act"). The Tobacco Control Act added authorities to the Federal Food, Drug, and Cosmetic Act ("FDCA") to enhance public health protection.

I. Background and Related Information

A. Purpose

The Tobacco Control Act became law on June 22, 2009. This Act gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. To that end, FDA is empowered to prescribe regulations to protect the public health and assure that tobacco products are in compliance with the provisions of the Act by requiring good manufacturing practices or hazard analysis and critical control point methodology. Accordingly, certain members of the tobacco industry ("Identified Companies") are proposing the attached cGMP regulations for consideration by the FDA.

The tobacco industry produces a diverse array of tobacco products, many of which involve different manufacturing processes. Even the manufacturing processes within the same category of tobacco product may vary in numerous ways. Thus the Identified Companies are proposing cGMPs that provide sufficient direction for the establishment of adequate manufacturing controls without providing detailed instruction for what specific criteria should be used to implement the controls. This framework will enable the Agency to protect the public health with respect to this unique product category while giving individual manufacturers the opportunity to meet the goal of the cGMPs in an effective manner that allows for flexibility and innovation. More specifically, the cGMPs require each manufacturer to identify and establish certain procedures and practices but allow the specific practices and procedures to be tailored to the category of tobacco product, and the attributes of the specific tobacco products, produced by the manufacturer. The extent and nature of documentation and practices necessary to meet the

requirements of the proposed cGMPs will vary according to the complexity of the manufacturing operations and the risks associated with the failure to implement a given practice.

The proposed cGMPs take into account that tobacco products are unique when compared to other products regulated by the FDA because of the inherent variability of tobacco (as an agricultural crop) and the inherent risk to users of the products. For example, the cGMP regulations for drugs and medical devices were established in part to ensure that the drug or device meets the safety requirements of the FDCA. See 43 Fed. Reg. 45014 (Sept. 29, 1978) (a drug is deemed adulterated unless it "conforms to [cGMP] so that the drug meets the safety requirements of the Act and has the identity and strength and meets the quality and purity characteristics that it is represented to have."); 43 Fed Reg. 31508 (July 21, 1978) (medical devices must "conform to [cGMP] requirements, as prescribed in the regulation, to assure that devices are safe and effective and otherwise in compliance with the act").

FDA found that many device recalls "resulted from manufacturers' failure to follow good manufacturing practices" and, therefore, found it "vitally important that devices be manufactured in accordance with quality assurance principles that help prevent the production of defective products that can endanger consumers." Id. The cGMP regulations for dietary supplements were established to ensure that consumers do not suffer harm and obtain the purported health benefit from the consumption of dietary supplements. 68 Fed Reg. 12159 (Mar. 13, 2003) (a dietary supplement is adulterated if it "contains contaminants because [the supplement] does not contain the dietary ingredient it is represented to contain or because the amount of the dietary ingredient thought to provide a health benefit is not actually present in the supplement"). Unlike the cGMPs for drugs, medical devices, and dietary supplements, cGMP regulations for tobacco products are not meant to assure the safety and effectiveness of a tobacco product—because of their inherent risk to users of the products—but rather to "assure that the public health is protected and that the tobacco product is manufactured in compliance with the Act. Tobacco Control Act, §906(e)(1).

Therefore, the purpose of the proposed cGMP regulation is threefold: (1) to protect the public health by providing assurance that tobacco products are not contaminated (preventing the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product); (2) to prevent misbranded tobacco products; and (3) to allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.

B. Inherent Risks Associated With the Use of Tobacco Products

Underpinning the proposed cGMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products. When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was "to continue to permit the sale of tobacco products to
adults." FDCA § 907(d)(3)(A) (FDA is expressly "prohibited" from issuing a regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products.").

Thus the cGMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks and, given the purpose of the cGMPs, not require manufacturers to address those risks in this context. Unlike for drugs, medical devices, dietary supplements, and food, the tobacco product cGMPs cannot require tobacco manufacturers to assure their products are safe and/or effective.

In light of these considerations, the Identified Companies' proposed cGMP regulation provides direction to tobacco product manufacturers to control their manufacturing processes in a manner that would prevent the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products. Further, the proposed regulation directs tobacco product manufacturers to control their manufacturing processes so that the tobacco product is not misbranded. The Identified Companies believe that these elements are central to meeting the Congressional intent as expressed in Section 906(e) of the Tobacco Control Act.

C. Inherent Variability of Tobacco Products

Tobacco — the main ingredient in tobacco products — is of an agricultural origin, and therefore tobacco products are subject to natural variation. Each type of tobacco, e.g., flue-cured, dark air-cured, fire cured, burley, and oriental, has its own particular taste and aroma. Moreover, there are variations in these attributes within each type according to the tobacco’s grade (i.e., quality), stalk position, geographic origin, and year of harvest. Tobacco product manufacturers combine different types of tobacco to produce a distinctive “blend” that is primarily responsible for giving each tobacco product its distinctive sensory characteristics (similar to the blending processes that occur in other agricultural based consumer products, such as coffee, wine, and beer). Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

This inherent variability of tobacco results in unavoidable variations in the tobacco blends. To compensate for these natural variations and maintain the consistency of the tobacco product, a tobacco product manufacturer must routinely adjust the tobacco blends — for example, by blending across several crop years of one type of tobacco. FDA acknowledged that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco ... in order to maintain a consistent product” in a recent guidance document. CENTER FOR TOBACCO PRODUCTS, GUIDANCE FOR INDUSTRY AND FDA STAFF: SECTION 905(j) REPORTS: DEMONSTRATING SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS 4 (2011). FDA has also acknowledged that such adjustments to the tobacco blend are not “intended to alter the chemical or perception properties” of a tobacco product, but rather maintain a consistent product.
Therefore, the direction to manufacturers provided by the proposed cGMP regulation recognizes the inherent variability unique to tobacco products. This is achieved by providing tobacco product manufacturers the flexibility necessary to manufacture, label, pack, and store in a manner allowing for such variability but not permitting (a) the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products or (b) misbranding.

II. Proposed Rule

Subpart A – General Provisions

XXX.1 Applicability

The language in subsection (a) of this section essentially tracks the Tobacco Control Act authority over tobacco product manufacturers. In other words, if a facility meets the Tobacco Control Act definition of a tobacco product manufacturer, then it will be covered by the proposed cGMP regulation to the extent it manufactures tobacco products within FDA’s jurisdiction under Section 901(b). While the storage of tobacco products by a tobacco product manufacturer is within the scope of the regulation, a distributor as defined in Section 900(7) of the FDCA is exempt from these regulations. Subsection (b) provides further clarity with respect to the non-applicability of the requirements to storage activities at retail. The other subsections essentially restate other provisions of the Tobacco Control Act. Also, small tobacco product manufacturers, as defined by Section 900(16) of the Tobacco Control Act, are not required to comply with the cGMP regulation for at least 4 years following the effective date of the regulation. See Section 906(e)(1)(B)(v).

XXX.3 Definitions

This section provides definitions for certain relevant terms used in the proposed cGMP regulation that are not defined in Section 201 of the FDCA or the Tobacco Control Act. While the defined terms in the regulation speak for themselves, we have elaborated on the intent of certain of the defined terms below.

The definition for “batch or lot” provides the tobacco manufacturer with the flexibility to define “any specific quantity or manufacturing period” as a “batch or lot” as long as tobacco product being manufactured during such a “batch or lot” is intended to meet the same specifications. Such flexibility is necessary for tobacco product manufacturers because some tobacco products are not made in discrete “batches” but are manufactured by continuous production.

The definition of “contaminant” recognizes the unique risk profile of tobacco products. They are agricultural products that, for that reason, naturally include substances other than tobacco. This definition also acknowledges the inherent risks associated with tobacco products, as described in Section 1.B. Thus, a substance becomes a “contaminant” only when it has been added to a tobacco product, is not intended to be in the tobacco product, and presents a risk beyond that generally posed by the same category of tobacco products. This concept is consistent with the
language in the mandatory recall provisions of Section 908(c)(1). It is not necessary to eliminate from tobacco products added substances that ordinarily are contained in tobacco products because of their agricultural nature or that do not increase the health risk of the tobacco products. The “master manufacturing record” is where the procedures and specifications for manufacturing a finished tobacco product are found. It is the key repository of manufacturing requirements and controls and may comprise several documents or files or an index identifying them and their location.

The “quality” of a tobacco product refers to whether the product meets the manufacturer’s specifications and is not contaminated. Because of the inherent risks posed by tobacco products, those are the two elements of what is ordinarily considered product quality that need to be addressed by this Part in order to protect the public health.

"Rework" means action taken on a nonconforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

A “specification” is any requirement that a manufacturer defines as a specification in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform. The manufacturer defines what the product and processing specifications should be. What the manufacturer may describe as parameters, limits, criteria, or like terms are not specifications unless the manufacturer defines them as such in the master manufacturing record. This provision also recognizes that tobacco product manufacturers may use in-process rather than finished product specifications if the manufacturer otherwise is in compliance with this Part.

Subpart B – Personnel

Sections XXX.20, XXX.30, and XXX.31 require a manufacturer to have adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority. At the same time these provisions recognize that no formal quality unit is required. In the case of tobacco products, such personnel may have duties other than quality assurance as well, as long as the quality assurance duties are well-defined and adequately carried out, as specified in the regulation.

Section XXX.35 requires a manufacturer to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

Subpart C – Physical Plant and Grounds

The terms “clean and sanitary”, as used in Section XXX.50(b), mean a manufacturer’s physical plant shall be kept clean to the extent necessary to protect against contamination, taking into account the inherent risks of tobacco products and an analysis of the risks of contamination, as
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

that term is defined in Section XXX.3. The term “sanitary” is not intended to require sanitation, sterilization, or any other specific form of cleaning beyond what the risk analysis determines is necessary. This requirement is consistent with the application of the concepts associated with hazard analysis and critical control point (HACCP) methodology to sanitation in Section XXX.114.

Section XXX.50(d)(3) requires that insecticides, fumigants, fungicides, or rodenticides, used for pest control activities shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination. Foreign manufacturers not subject to the Federal Insecticide, Fungicide and Rodenticide Act shall comply with their own national or local requirements governing the use of such pesticides and shall not contaminate the tobacco product.

Section XXX.50(e)(2) requires that water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product, shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product. Foreign manufacturers shall comply with their own national or local requirements governing water quality and shall not contaminate the tobacco product.

Subpart D – Equipment and Utensils

Section XXX.60(c) generally requires equipment to be adequately calibrated and controlled. That requirement applies to software used to control processes. The requirement to control certain software, including the requirement in Section XXX.60(e)(2) to control such software to ensure that specifications consistently are met, is not intended to require software validation. Such control may be achieved by a process of qualification, calibration, monitoring, verification, checks, other methods, or some combination thereof, as determined to be appropriate for the particular equipment and processes by the manufacturer.

Subpart E – Document Controls

Section XXX.70 requires a manufacturer to establish and maintain procedures to control documents required by the cGMP regulations. Such procedures shall include, among other things, controls for approving documents, making changes to documents, and approving those changes. Both Section XXX.70(a) and (b) require that the individuals approving documents or changes to them be identified. Identification of such individuals in the document control system, whether in electronic or paper form, or some combination thereof, is sufficient in lieu of such individuals’ signatures, provided that the document control procedures require the approving individual personally to identify him- or herself in some way and the identity of such individuals is not merely assigned automatically by the document control system or other personnel.
Subpart F – Purchasing Controls

Section XXX.80 requires manufacturers to have purchasing controls for incoming tobacco products, materials and packaging, as those terms are defined in Section XXX.3. Manufacturers have the flexibility under this provision to determine the type and extent of such controls based on the needs for their specific products and manufacturing processes.

Section XXX.85 requires manufacturers to establish and maintain the requirements that must be met by suppliers of tobacco products, materials and packaging. The specific requirements may vary based on an evaluation of the potential risk posed by the supplied material (e.g., tobacco ingredient vs. packaging component) but should include supplier evaluation criteria and maintaining a list of qualified suppliers.

Subpart G – Identification and Traceability

The identification requirements of Section XXX.90(a) are meant to apply wherever there is a reasonable possibility of mix-ups. It may not be necessary to identify the contents of some containers because the risks of mix-up, or the consequences of a mix-up, are small, such as where the use of a particular container or tobacco product is limited to one area of the manufacturing facility.

Section XXX.95 requires traceability that will assist manufacturers in identifying other potential batches or lots of finished tobacco products that might be affected by a product quality issue that arose during manufacturing and was detected in a particular finished tobacco product batch or lot, which, in turn, will assist manufacturers in conducting any necessary market withdrawals or recalls. For tobacco, by requiring traceability back only to the tobacco as first introduced into the manufacturing process, this provision makes clear that manufacturers are not required to establish traceability all the way back prior to its introduction into the manufacturing process, such as to the growers or sellers of the raw tobacco. This traceability requirement does not extend to farms because the tobacco is mixed after received from farms during leaf processing (or “stemmery”) operations, which are defined as “tobacco warehouses” in Section 900(21) of the FSPTCA. After such processing, the raw tobacco is typically stored for a few years prior to being introduced into the manufacturing process. Also, FDA does not have jurisdiction over tobacco farms or tobacco warehouses (with certain exceptions) under Chapter IX of the FSPTCA.

Subpart H – Manufacture and Process Controls

Under Section XXX.100, manufacturers are required to control their processes to ensure their tobacco products meet specifications. However, the specific control measures to be utilized are determined by the manufacturer so that it has the flexibility to identify and execute the control measures best suited to its manufacturing operations and tobacco products.

Section XXX.114 provides that a manufacturer should develop its sanitation control program by using a risk-based approach that is informed by an evaluation of potential biological, chemical,
and physical hazards. These criteria are consistent with those used in the food industry when applying "HACCP". While this section does not mandate a formal HACCP program, it does require manufacturers to undertake a HACCP-like evaluation to support its sanitation controls.

Section XXX.116 requires the development of a master manufacturing record, which is the key record documenting manufacturing controls. The development of the specifications in the master manufacturing record, beginning when the CGMP regulation takes effect, shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate to assure tobacco product requirements are met. This provision is intended to address the "preproduction design validation" language in FDCA Section 906(e)(1)(A).

The provisions in this Subpart II and the rest of this Part are not meant to require process validation. For tobacco products, adequate process controls might take the form of in-process control parameters, such as temperature or processing speed; equipment qualification and calibration; in-process quality checks; or other controls appropriate to the processes and tobacco products, as determined by the manufacturer.

Subpart I - Evaluation and Acceptance Activities

Section XXX.120 makes it incumbent on a manufacturer to establish appropriate procedures for the acceptance of incoming tobacco products, materials and packaging and the evaluation of in-process tobacco products to assure specified requirements are met. Acceptance activities may include visual checks, testing or verification of supplier Certificates of Analysis. Because of the unique nature of tobacco products, as explained in the introductory paragraph above, in-process or finished tobacco product testing is not required unless a manufacturer determines under other provisions of this Part that it is a necessary process control and makes such testing part of a specification in the master manufacturing record.

Subpart J - Nonconforming Tobacco Product

Under Section XXX.130, a tobacco product is nonconforming if it does not conform to the applicable specifications in the master manufacturing record or is contaminated, as that term is defined in Section XXX.3. A manufacturer must have a process to evaluate and handle nonconforming tobacco product as described in Section XXX.130.

Section XXX.130(c) requires that process to include a risk assessment and a determination of the need for an investigation into the cause of the nonconformance. A manufacturer's process for handling nonconforming tobacco product therefore should include criteria to evaluate the risk posed by the nonconformance and to determine how the tobacco product should be dispositioned. This provision gives direction to a manufacturer without specifying all of the criteria to be used for the investigation and disposition decisions because such criteria should be based on the attributes of the specific tobacco product and its manufacturing processes.
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

Under Section XXX.130(c), the disposition determination shall include an assessment of whether the nonconformance is a defect not ordinarily contained in the same category of tobacco products and whether that defect presents a risk of injury beyond that generally posed by the same category of tobacco products. That assessment already will have occurred in the case of contaminated product because of the definition of contamination in Section XXX.3, but such an assessment shall also be done in the case of a tobacco product that does not conform to specifications.

Subpart K – Labeling and Packaging Operations

Section XXX.140 requires a manufacturer to establish and maintain a process to control labeling and packaging activities. Provided that such process ensures that labels conform to specifications and that labels and packaging are managed to prevent mix-ups, a manufacturer is not required to quarantine or otherwise hold incoming labels prior to their introduction into labeling and packaging operations. This provision provides direction to a manufacturer to establish an effective process without specifying an evaluation and release process or other particular steps in the process.

Subpart L – Holding and Distribution

Although Sections XXX.150 and XXX.155 contain storage and distribution requirements, such requirements do not apply to a “distributor” as defined in Section 900(7) of the FDCA.

Subpart M – Complaints

Section XXX.160 requires a manufacturer to review all complaints. This provision does not attempt to specify all of the criteria a manufacturer must use to evaluate complaints or to determine whether an investigation is necessary. However, consistent with the language in the mandatory recall provisions of the FSPTCA, Section 908(c)(1), and the reporting provisions of the FSPTCA, Section 909(a), this provision requires quality assurance personnel or other qualified personnel, as described in XXX.31, to evaluate whether the complaint involves a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products and, in most cases, to investigate such complaints. Such complaints may not need to be investigated if they previously have been investigated and the cause of the defect is known. Additionally, given that smokers may experience certain transient effects (e.g. headaches) and consumers of smokeless tobacco products may as well (e.g. nausea), all complaints alleging health effects may not need to be investigated. This provision makes clear that an assessment of potential health hazards is a critical element of the complaint evaluation and investigation process. The term “acute” has been included in the description of the applicable health hazards for those purposes because the complaint handling process required by this section is not intended to handle allegations of chronic health effects related to the inherent risks of tobacco products as referenced in Section 1.B.
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

Effective date

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register. Consistent with FDCA Section 906(c)(B)(iv), the proposed effective date is necessary to provide a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein. The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.
Good morning!

The following link has a list of the industry folks attending next week's meeting and the proposed agenda. As soon as I receive industry's presentation, I will circulate it to the team.

Also, if you plan to participate via phone, please let me know. I will be setting up a dial-in number shortly.

Thanks!
A
From: Bautista, Andrea
Sent: Tuesday, May 01, 2012 10:31 AM
To: Akin, Ann; Bautista, Andrea; Boocker, Nancy; Buckler, Beth; Faranda, David; Fowler, Clarence (Grayson); Gerrity, Kevin T; Goldman, Tara D; Griffiths, Christopher *; Kaneva, Diana; Nguyen, Kiet; Perdue Jr, Paul; Price, Nakki; Raafa, Dina; Richter, Patricia; Schmidt, Rafael; Taylor, Larry; Tobias, Liridsey; Wang, Emil P; Wintershausen, Joanna; Whipp, Valerie
Subject: 04/27/2012 TPMP Meeting Minutes and Updates re: 5/1/2012 Industry Meeting

Good morning!

Here is a link to the meeting minutes from last week’s TPMP meeting:

Also, please find attached a copy of tomorrow's presentation:

May 2 2012
Industry Stakeh...

Thanks!
A
Bev, Nancy, and Beth,

Please find attached OCE's draft meeting minutes on the recent meeting with Reynolds et al re: their presentation of the proposed GMP regulation and preamble. We would appreciate any edits or additional input that OR may add. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil
CTP is bound by the Administrative Procedures Act; therefore, discussion of CTP’s timeframe for development of tobacco product GMPs and questions all out the proposed GMP regulations and preamble will be limited. There will be other opportunities for stakeholders to provide additional information and comments to FDA during the rulemaking process (e.g., TPSAC, oral hearing).

CTP is looking forward to hearing about the industry’s process and approach to developing the proposed GMP regulations and preamble.

**Dr. Charles Garner, R.J. Reynolds Tobacco Company**

Dr. Garner covered slides 1-5, which included the objectives of the meeting, the developmental process for the proposed GMP regulation, the industry stakeholders in support of the proposed GMP regulation, and the statutory requirements for the GMP regulation.

**Pamela Lieberman, Altria Client Services**

Ms. Lieberman covered slides 6-23. She described the purposes of the industry-proposed GMP regulation: the inherent risks associated with tobacco products require that the GMP regulation for tobacco products differ from the cGMPs for drugs and medical devices. Unlike drugs and medical devices, the tobacco product GMP cannot require tobacco manufacturers to assure their products are safe and/or effective. Rather, tobacco product GMPs are to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the FSPTCA. Accordingly, the purpose of the proposed GMP regulation is to assure that tobacco products are not contaminated and not adulterated or misbranded.

Further, Ms. Lieberman described how the inherent variability of tobacco requires tobacco manufacturers to periodically adjust the tobacco blend in a product in order to maintain product consistency. Accordingly, another purpose of the proposed GMP regulation is to allow manufacturers flexibility in the activities associated with tobacco product manufacturing while assuring all such activities are conducted in a controlled manner.
Ms. Lieberman described how the proposed rule covered areas in which the stakeholders found common ground. She then provided a brief overview of several subparts of the proposed GMP regulation, including general provisions, personnel, physical plant and grounds, equipment and utensils, manufacture and process controls, labeling and packaging operations, complaints. For example, Ms. Lieberman described how the proposed GMP regulation:

- Provides definitions for select terms such as "batch or lot," "contaminant," quality," or "specification." The definitions were written to cover a wide variety of tobacco products.
- Requires a manufacturer to provide adequate resources to comply with the regulations, including personnel designated to have certain quality assurance responsibility and authority.
- Would not require a formal quality control unit, so personnel can have overlapping responsibilities (dietary supplements approach)
- Includes requirements necessary to protect against contamination
- Incorporates HACCP principles (section 114)
- Requires manufacturers to use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained
- Requires manufacturers to develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to specifications
- Requires manufacturers to establish and maintain a process to control labeling and packaging activities
- Requires that quality assurance or other qualified personnel review all complaints and, where appropriate, investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products. This language is consistent with FDCA section 909's mandatory recall and reporting requirements.

Lastly, Ms. Lieberman discussed the statute’s requirement for the effective date of the future GMP regulation. The regulation would take effect a minimum of two years from the publication of the final rule in the Federal Register. Small tobacco manufacturers would not be required to comply for at least 4 years following the effective date of the regulation.

Ann Simoneau, Center for Tobacco Products, Office of Compliance and Enforcement

- We are educating ourselves on the GMP of the other Centers, but we are not bound by what other Centers have done.
- Although there is currently no docket or proposed rule associated with the 906(e) regulation to date, industry is encouraged to share additional data and science with the FDA.

Questions and Answers

(b) (5)
Boocker, Nancy

From: Chernaik, Beverly
Sent: Thursday, May 31, 2012 12:57 PM
To: Buckler, Beth; Boocker, Nancy
Subject: FW: GMP Industry Stakeholder Presentation Minutes.doc

Fyi

From: Chernaik, Beverly
Sent: Thursday, May 31, 2012 12:55 PM
To: Simoneau, Ann
Subject: FW: GMP Industry Stakeholder Presentation Minutes.doc

(b) (5)

From: Wang, Emil P
Sent: Tuesday, May 29, 2012 12:31 PM
To: Chernaik, Beverly; Boocker, Nancy; Buckler, Beth
Cc: Weitershausen, Joanna; Bautista, Andrea
Subject: GMP Industry Stakeholder Presentation Minutes.doc

Bev, Nancy, and Beth,

Please find attached OCE’s draft meeting minutes on the recent meeting with Reynolds et al. re: their presentation of the proposed GMP regulation and preamble. (b) (5) We would appreciate any edits or additional input that OR may add. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil

Industry Stakeholder Pres...
Boocker, Nancy

From: Chernaik, Beverly
Sent: Thursday, May 31, 2012 1:39 PM
To: Boocker, Nancy; Buckler, Beth
Subject: FW: GMP Industry Stakeholder Presentation Minutes.doc

Just a quick note. Bev, Nancy and Beth, I realize that I (b) (5) have taken a stab at making it really clear that this is just a summary of what was said (b) (5).

Indu

From: Wang, Emil P
Sent: Tuesday, May 29, 2012 12:31 PM
To: Chernaik, Beverly; Boocker, Nancy; Buckler, Beth
Cc: Weitershausen, Joanna; Bautista, Andrea
Subject: GMP Industry Stakeholder Presentation Minutes.doc

Bev, Nancy, and Beth,

Please find attached OCC’s draft meeting minutes on the recent meeting with Reynolds (b) (5). In re: their presentation of the proposed GMP regulation and preamble. (b) (5)

We would appreciate any edits or additional input that OR may add. Please let me know if you have any questions or would like to discuss. Thanks.

Emil

Indu
Industry Stakeholder Presentation to CTP
Proposed Good Manufacturing Practices for Tobacco Products
May 2, 2012

Note:
Ann Simoneau, Center for Tobacco Products, Office of Compliance and Enforcement

Ms. Simoneau explained that the purpose of the meeting was to provide an opportunity for industry to present their proposed GMP regulation to CTP. She explained that, because FDA rulemaking is conducted in a manner consistent with the Administrative Procedures Act, under which all members of the public are offered an opportunity to participate, CTP could not engage in any kind of substantive discussion of the merits of the proposal or any other matter regarding the development of the regulation. She explained that there will be other opportunities for stakeholders to provide additional information and comments to FDA during the rulemaking process (e.g., PSAC oral hearing).

Dr. Charles Garner, R.J. Reynolds Tobacco Company

Dr. Garner covered presented slides 1-5, which included the objectives of the meeting, the developmental process for the proposed GMP regulation, the industry stakeholders in support of the proposed GMP regulation, and the statutory requirements for the GMP regulation.

Pamela Lieberman, Attica Client Services

Ms. Lieberman covered presented slides 6-23. She described the purposes of the industry-proposed GMP regulation: the inherent risks associated with tobacco products require that the GMP regulation for tobacco products differ from the cGMPs for drugs and medical devices. She stated that, unlike drugs and medical devices, the tobacco product GMPs cannot require tobacco manufacturers to assure their products are safe and effective. Rather, she explained, tobacco product GMPs are to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the FSPTCA. Accordingly, Ms. Lieberman explained that the purpose of the proposed GMP regulation is to assure that tobacco products are not contaminated and not adulterated or misbranded.
Further, Ms. Lieberman described how the inherent variability of tobacco requires tobacco manufacturers to periodically adjust the tobacco blend in a product in order to maintain product consistency. Accordingly, according to Ms. Lieberman, another purpose of the proposed GMP regulation is to allow manufacturers flexibility in the activities associated with tobacco product manufacturing while assuring all such activities are conducted in a controlled manner.

Ms. Lieberman described how the proposed rule covered areas in which the stakeholders found common ground. She then provided a brief overview of several subparts of the proposed GMP regulation, including general provisions, personnel, physical plant and grounds, equipment and utensils, manufacture and process controls, labeling and packaging operations, complaints. For example, Ms. Lieberman described how the proposed GMP regulation:

- Provides definitions for select terms such as “batch or lot,” “contaminant,” “quality,” or “specification.” She explained that these definitions were written to cover a wide variety of tobacco products.
- Requires a manufacturer to provide adequate resources to comply with the regulations, including personnel designated to have certain quality assurance responsibility and authority.
- Would not require a formal quality control unit so personnel can have overlapping responsibilities (dietary supplements approach).
- Includes requirements necessary to protect against contamination.
- Incorporates HACCP principles (section 114).
- Requires manufacturers to use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.
- Requires manufacturers to develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to specifications.
- Requires manufacturers to establish and maintain a process to control labeling and packaging activities.
- Requires that quality assurance or other qualified personnel review all complaints and, where appropriate, investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products. Ms. Lieberman stated that this language is consistent with FDCA section 909’s mandatory recall and reporting requirements.

Lastly, Ms. Lieberman discussed the statute’s requirement for the effective date of the future GMP regulation. She said that the regulation would take effect a minimum of two years from the publication of the final rule in the Federal Register and that small tobacco manufacturers would not be required to comply for at least 4 years following the effective date of the regulation.

Ann Simoneau, Center for Tobacco Products, Office of Compliance and Enforcement
Ms. Simonon explained that CTP is educating ourselves about
the GMPs of the other Centers, but that we are not bound by what other Centers have
done. She also explained that,

• Although there is currently no docket or proposed rule associated with the 906(e)
  regulation to date, industry is encouraged to share additional data and science with the
  FDA.

Questions and Answers

Following the presentation, there was a short question and answer period. Following
that, the meeting was adjourned.
From: Boocker, Nancy
Sent: Thursday, May 31, 2012 1:47 PM
To: Chernaiik, Beverly; Boocker, Nancy
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

I just talked to Ann (b)(5) I've taken a stab at making it really clear that this is just a summary of what was said. I know we would appreciate any edits or additional input that DR may add. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil

<< File: Industry Stakeholder Presentation Minutes.doc >>
Boocker, Nancy

From: Chernaiik, Beverly
Sent: Thursday, May 31, 2012 2:38 PM
To: Buckler, Beth; Boocker, Nancy
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

Nancy, can you live with it?

From: Buckler, Beth
Sent: Thursday, May 31, 2012 1:47 PM
To: Chernaiik, Beverly; Boocker, Nancy
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

(b) (5) However, if you and Ann have agreed to this approach, then I'm ok with it.

Beth

From: Chernaiik, Beverly
Sent: Thursday, May 31, 2012 1:39 PM
To: Boocker, Nancy; Buckler, Beth
Subject: FW: GMP Industry Stakeholder Presentation Minutes.doc

I just talked to Ann. (b) (5) I've taken a stab at making it really clear that this is just a summary of what was said. I know (b) (5) Can you live with this?

<< File: Industry Stakeholder Presentation Minutes.doc >>

From: Wang, Emil P
Sent: Tuesday, May 29, 2012 12:31 PM
To: Chernaiik, Beverly; Boocker, Nancy; Buckler, Beth
Cc: Weitershausen, Joanna; Bautista, Andrea
Subject: GMP Industry Stakeholder Presentation Minutes.doc

Bev, Nancy, and Beth,

Please find attached OCF's draft meeting minutes on the recent meeting with Reynolds et al re: their presentation of the proposed GMP regulation and preamble. We would appreciate any edits or additional input that OR may add. Please let me know if you have any questions or would like to discuss. Thanks.

Emil
I agree. But since it's pretty innocuous I guess we can live with it. Thanks!

---

Nancy

---

Nancy, can you live with it?

---

However, if you and Ann have agreed to this approach, then I'm ok with it.

---

I just talked to Ann. I've taken a stab at making it really clear that this is just a summary of what was said. I know
can you live with this?

<< File: Industry Stakeholder Presentation Minutes.doc >>

---

From: Wang, Emil P  
Sent: Tuesday, May 29, 2012 12:31 PM  
To: Chernaik, Beverly; Boocker, Nancy; Buckler, Beth  
Cc: Wintershausen, Joanna; Bautista, Andrea  
Subject: GMP Industry Stakeholder Presentation Minutes.doc

Bev, Nancy, and Beth,

Please find attached OCE's draft meeting minutes on the recent meeting with Reynolds et al. re: their presentation of the proposed GMP regulation and preamble. We would appreciate any edits or additional input that Bev may add. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil

<< File: Industry Stakeholder Presentation Minutes.doc >>
Hi Emil. I've done a little tinkering just to make it clear in all places that this is what industry was saying. Please let me know if you have any questions. Thanks!

Emil

---

From: Wang, Emil P
Sent: Tuesday, May 29, 2012 12:31 PM
To: Cherniaik, Beverly; Boocker, Nancy; Buckler, Beth
Cc: Weitershausen, Joanna; Bautista, Andrea
Subject: GMP Industry Stakeholder Presentation Minutes.doc

Bev, Nancy, and Beth,

Please find attached OCE's draft meeting minutes on the recent meeting with Reynolds et al re: their presentation of the proposed GMP regulation and preamble. We would appreciate any edits or additional input that you may have. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil

<< File: Industry Stakeholder Presentation Minutes.doc >>
Thanks Bev

Hi Emil. I’ve done a little tinkering just to make it clear in all places that this is what industry was saying. Please let me know if you have any questions. Thanks!

Bev, Nancy, and Beth,

Please find attached OCE’s draft meeting minutes on the recent meeting with Reynolds et al re: their presentation of the proposed GMP regulation and preamble. (b) (5) We would appreciate any edits or additional input that OR may add. Please let me know if you have any questions or would like to discuss. Thanks.

- Emil

<< File: Industry Stakeholder Presentation Minutes.doc >>
Boocker, Nancy

From: Boocker, Nancy  
Sent: Thursday, May 31, 2012 4:37 PM  
To: Chernaik, Beverly; Buckler, Beth  
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

(b)(5)

Nancy, can you live with it?

(b)(5)

---

From: Chernaik, Beverly  
Sent: Thursday, May 31, 2012 2:38 PM  
To: Buckler, Beth; Boocker, Nancy  
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

Nancy, can you live with it?

From: Buckler, Beth  
Sent: Thursday, May 31, 2012 1:47 PM  
To: Chernaik, Beverly; Boocker, Nancy  
Subject: RE: GMP Industry Stakeholder Presentation Minutes.doc

(b)(5)

However, if you and Ann have agreed to this approach, then I’m ok with it.

Beth

From: Chernaik, Beverly  
Sent: Thursday, May 31, 2012 1:39 PM  
To: Boocker, Nancy; Buckler, Beth  
Subject: FW: GMP Industry Stakeholder Presentation Minutes.doc

I just talked to Ann. I’ve taken a stab at making it really clear that this is just a summary of what was said. I know we can you live with this?

<< File: Industry Stakeholder Presentation Minutes.doc >>

From: Wang, Emil P  
Sent: Tuesday, May 29, 2012 12:31 PM  
To: Chernaik, Beverly; Boocker, Nancy; Buckler, Beth
Bev. Nancy, and Beth,

Please find attached OCF's draft meeting minutes on the recent meeting with Reynolds et al re: their presentation of the proposed GMP regulation and preamble. We would appreciate any edits or additional input that ONS may add. Please let me know if you have any questions or would like to discuss. Thanks.

Emil

<< File: Industry Stakeholder Presentation Minutes.doc >>
Booccker, Nancy

From: Booccker, Nancy
Sent: Monday, December 03, 2012 1:16 PM
To: Buckler, Beth
Subject: Re: TPMP docket(s)

Bev didn’t say anything to me. (b) (5)

From: Buckler, Beth
Sent: Monday, December 03, 2012 12:39 PM
To: Booccker, Nancy
Subject: RE: TPMP docket(s)

Apparently Bev Ann and Bopper had a discussion about options for (b) (5)
According to Emil, (b) (5)
Bev recommended 2 options (b) (5)
(b) (5)

I only found this out because OCE tried to schedule a meeting with me today to discuss this further. I told Emil it was news to me (b) (5)

From: Booccker, Nancy
Sent: Monday, December 03, 2012 12:28 PM
To: Buckler, Beth
Subject: Re: TPMP docket(s)

Ok, let me guess. (b) (5)

From: Buckler, Beth
Sent: Monday, December 03, 2012 11:12 AM
To: Booccker, Nancy
Subject: FW: TPMP docket(s)

We need to touch base about this when you get back on Monday.

From: Bautista, Andrea
Sent: Monday, December 03, 2012 10:49 AM
To: Buckler, Beth
Subject: RE: TPMP docket(s)

Emil’s going to call you real quick!

From: Buckler, Beth
Sent: Monday, December 03, 2012 10:44 AM
To: Bautista, Andrea
Subject: RE: TPMP docket(s)
Ok. It will just be the (b) (5).

---

From: Bautista, Andrea
Sent: Monday, December 03, 2012 10:43 AM
To: Buckler, Beth
Subject: Re: TPMP docket(s)

We had a meeting with Ann this morning.

---

From: Buckler, Beth
Sent: Monday, December 03, 2012 10:06 AM
To: Bautista, Andrea
Subject: RE: TPMP docket(s)

Hey Andrea-

What is this meeting about?

Beth

-----Original Appointment-----
From: Bautista, Andrea
Sent: Monday, December 03, 2012 9:54 AM
To: Buckler, Beth; Wang, Emil P
Cc: Perdue Jr, Paul; Goldman, Tara D
Subject: TPMP docket(s)
When: Monday, December 03, 2012 2:30 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Emil's office
Hello All

Please find attached the proposed GMP from industry for the Center's consideration. The Center's Senior leadership will be discussing this industry's request for a meeting, and the Center's plan for GMPs on February 8th.

Thanks,
Mahala
January 10, 2012

Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Beverly Chernaik
Director, Office of Regulations
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Re: PROPOSED TOBACCO PRODUCT GOOD MANUFACTURING PRACTICES REGULATION AND REQUEST FOR MEETING

Dear Ms. Simoneau and Ms. Chernaik:

As indicated in its December 16, 2011 letter, R.J. Reynolds Tobacco Company ("RJRT"). has worked with various tobacco industry stakeholders to develop proposed current Good Manufacturing Practice ("cGMP") regulations pursuant to Section 906(e) of the Family Smoking Prevention and Tobacco Control Act. Specifically, the industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., and Hail & Cotton, Inc. (collectively referred to herein as the "Companies").

RJRT, on behalf of the Companies, submits to the United States Food and Drug Administration's ("FDA") Center for Tobacco Products ("CTP") for its review and consideration (1) proposed cGMP regulations and (2) a preamble to the proposed regulation. While each of the Companies reserves its right to express its own opinions regarding the proposed regulations and preamble, the preamble provides the Companies' common perspective and interpretation of the provisions of the proposed cGMP regulations. (See Attachments 1-2.)

The Companies believe the proposed cGMP regulations and preamble will help to facilitate a productive dialogue consistent with CTP's expressed goal to engage with and understand the tobacco product manufacturing industry. In that regard, the Companies
respectfully request a 2-hour meeting to discuss the proposed cGMP regulations and preamble attended by you and any other appropriate CTP representatives and representatives from the Companies. We will identify the specific Companies' representatives that plan to participate at least one week prior to the meeting. The Companies propose the following general agenda:

- Introductions and meeting objectives
- The Companies' approach to developing the proposed cGMP regulations and preamble
- Overview of the proposed cGMP regulations and preamble
- Discussion with CTP, including addressing CTP's questions regarding the proposed cGMP regulations and preamble.

Any planned presentations will be submitted to CTP at least one week prior to the meeting. In addition, should CTP wish to provide the Companies with questions in advance of the meeting, we will be prepared to address them.

The Companies are committed to working with the Agency to establish appropriate cGMP regulations for tobacco product manufacturers and look forward to discussing this matter with CTP. RJRT will contact you in the upcoming weeks to schedule a meeting at your earliest convenience. If you require any additional information or have any questions, please do not hesitate to contact me.

Respectfully Submitted,

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
Attachment
PART I—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO PRODUCTS

Subpart A — General Provisions
XXX.1 Applicability
XXX.3 Definitions
XXX.5 Good Manufacturing Practice Regulation

Subpart B — Personnel
XXX.20 Resources
XXX.30 Responsibility and Authority
XXX.31 Quality Assurance Personnel
XXX.35 Contamination Prevention
XXX.40 Qualification, Education, and Training

Subpart C — Physical Plant and Grounds
XXX.50 Plant Grounds, Facilities, and Sanitary Operations
XXX.53 Physical Plant Construction and Design

Subpart D — Equipment and Utensils
XXX.60 Equipment and Utensils
XXX.65 Procedures, Records and Recordkeeping

Subpart E — Document Controls
XXX.70 Procedures

Subpart F — Purchasing Controls
XXX.80 General
XXX.85 Evaluation of Suppliers

Subpart G — Identification and Traceability
XXX.90 Identification
XXX.95 Traceability

Subpart H — Manufacture and Process Controls
XXX.100 General Controls and Change Controls
XXX.110 Specifications
XXX.114 Sanitation Requirements
XXX.116 Master Manufacturing Record
XXX.118 Batch or Lot Manufacturing Records
Subpart I — Evaluation and Acceptance Activities
XXX.120 Receiving Acceptance and In-Process Evaluation

Subpart J — Nonconforming Tobacco Product
XXX.130 Procedures for Nonconforming Tobacco Product

Subpart K — Labeling and Packaging Operations
XXX.140 Labeling and Packaging
XXX.145 Repackaging and Relabeling

Subpart L — Holding and Distribution
XXX.150 Handling and Storage
XXX.155 Distribution

Subpart M — Complaints
XXX.160 Review and Investigation of Complaints
XXX.165 Required Records

Subpart N — Records and Recordkeeping
XXX.170 General
XXX.174 Record Retention
XXX.178 Confidentiality
XXX.1 Applicability

(a) Except as provided by paragraphs (b) and (c) of this section, you are subject to this Part if you manufacture, pack, label, repackage, relabel, store, or import cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, or any other tobacco products that the Secretary by regulations deems subject to this Part, for sale or distribution in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. The requirements in this part are intended to protect the public health by requiring the manufacture of tobacco products utilizing practices that protect against manufacturing defects not ordinarily contained in tobacco products that present a risk of injury beyond the risks generally posed by the same category of tobacco products. If you engage in only some operations subject to the requirements of this Part, and not in others, you need only comply with those requirements applicable to the operations in which you are engaged.

(b) The requirements pertaining to storing tobacco products shall not apply to you if you are storing those tobacco products at a retail establishment for the sole purpose of retail sale to individuals for personal consumption, including facilities where self-service displays of tobacco products are permitted.

(c) The requirements of this Part shall not apply to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, except to the extent such producer of tobacco leaf is engaged in an activity specified in paragraph (a) of this section or is controlled by a tobacco product manufacturer. A producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process shall not be subject to this Part. The requirements of this Part shall not apply to distributors as defined by Section 900(7) of the Tobacco Control Act, if the distributor is not also a tobacco product manufacturer and is not controlled by a tobacco product manufacturer.

(d) Any person who wishes to petition for a permanent or temporary exemption or variance from any requirement of this Part is subject to the requirements of Section 906(e)(2) of the Tobacco Control Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in 10.30 of this chapter, the United States Food and Drug Administration's administrative procedures.

XXX.3 Definitions

The definitions and interpretations of terms in Section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) apply to such terms when used in this Part. For the purpose of this Part, the following definitions also apply:

Batch or lot means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications.

Complaint means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco product.
Contact surface means any surface that contacts a tobacco product, material, or packaging during manufacture, processing, packaging or labeling.

Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminant or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface.

Finished tobacco product means any tobacco product that has completed the manufacturing and packaging process and is intended for commercial distribution.

Import means entry into the Customs territory of the United States for sale or distribution to consumers for consumption in the United States.

In-process tobacco product means any tobacco product that is fabricated, compounded, blended, ground, extracted, sifted, or processed in any other way by a tobacco product manufacturer for use in the manufacture of a finished tobacco product.

Label means a display of written, printed, or graphic matter upon the immediate package of any tobacco product.

Master manufacturing record means a compilation of records containing the procedure and specifications for manufacturing a finished tobacco product. A master manufacturing record may be prepared as a single document or file or may be prepared using an index system that specifies the location and identity of individual files, records, or documents that make up the master manufacturing record.

Material means any ingredient, additive or other substance other than tobacco incorporated into or added to a tobacco product during manufacturing.

Package means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including film), in which a tobacco product is offered for sale, sold, or otherwise distributed to adult tobacco product consumers. A shipping case is not included in the definition of package.

Pest means any objectionable insect or other animal including birds, rodents, flies, and beetles.

Physical plant means all or any part of a tobacco product manufacturer's building or facility used for or in connection with manufacturing, packaging, labeling, or holding of a tobacco product.

Quality means that the tobacco product meets the manufacturer's specifications and is not contaminated.

Reprocessing means using, in the manufacture of a tobacco product, uncontaminated tobacco product that has been previously removed from manufacturing and that is suitable for use in the...
subsequent manufacture of a tobacco product. Reprocessing is a routine manufacturing process.

Rework means action taken on a nonconforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

Specification means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform.

Tobacco product means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) that FDA has authority over pursuant to Section 901(b), 21 U.S.C. §387a(b), of the Tobacco Control Act.

Tobacco product manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States.

XXX.5 Good Manufacturing Practice Regulation

The regulations in this Part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, label, or hold tobacco products.

Subpart B — Personnel

XXX.20 Resources

You shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment of activities, to meet the requirements of this Part.

XXX.30 Responsibility and Authority

You shall establish the appropriate responsibility, authority, and reporting relationships of personnel who manage, perform, and assess work affecting the quality of tobacco products.

XXX.31 Quality Assurance Personnel

There shall be select individuals, who through appropriate education, experience and training, are specifically designated to perform quality assurance responsibilities. These personnel may have responsibilities in addition to their quality assurance responsibilities. These individuals shall assure all components, in-process materials, packaging material, labels and tobacco product meet specifications, as appropriate, and are not contaminated. Quality assurance personnel shall assure tobacco products manufactured, processed, packed, or held under contract by another company meet specifications. Quality assurance personnel shall be responsible for the review and evaluation of complaints under Subpart M, Section XXX.160.
PROPOSED TOBACCO PRODUCT GMP REGULATION

XXX 35 Contamination Prevention

You shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product packaging, or materials could reasonably be expected to result in contamination.

XXX.40 Qualification, Education, and Training

(a) Each person engaged in manufacturing, testing, packaging, labeling, or holding, or in performing any quality control operations, shall have the education, background, training, and/or experience to adequately perform the person's assigned functions.

(b) You shall assign personnel qualified by education, training, and/or experience to supervise the manufacturing, testing, packaging, labeling, or holding of tobacco products.

(c) You shall establish procedures for identifying training needs and ensure that appropriate personnel are trained to adequately perform their assigned functions. Training shall be documented to assure that personnel have a thorough understanding of their jobs, including the date of the training, the type or title of the training, and the person(s) trained.

Subpart C — Physical Plant and Grounds

XXX.50 Plant Grounds, Facilities, and Sanitary Operations

(a) Grounds. You shall keep the grounds of your physical plant in a condition that protects against contamination.

(b) Physical plant facilities. You shall maintain your physical plant in a clean and sanitary condition and repair to the extent necessary to protect against contamination.

(c) Cleaning compounds, pesticides, and other toxic chemicals. You shall use cleaning compounds and pesticides in a manner that does not result in contamination. Other toxic chemicals shall be used and stored in a manner that prevents them from coming into contact with tobacco products, materials, packaging, or contact surfaces.

(d) Pest control.

(1) You shall not allow animals in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination.

(2) You shall take effective measures to minimize pests from the physical plant and to protect against contamination.

(3) When monitoring indicates the need for the use of insecticides, fumigant, fungicides, or rodenticides, such products shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination.
PROPOSED TOBACCO PRODUCT GMP REGULATION

(c) Water supply.

(1) You shall provide water that is safe and sanitary at suitable temperatures and under pressure as needed for all uses where water does not become a component of the tobacco product.

(2) Water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product, e.g., when such water is used as an ingredient or otherwise contacts tobacco products or any contact surface, shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product.

(f) Plumbing. The plumbing used in your physical plant shall be of an adequate size and design and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant into an adequate sewage system or through other adequate means;

(3) Avoid being a source of contamination or creating an unsanitary condition (e.g., not allow backflow or cross connection with wastewater or sewage); and

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(g) Bathrooms. You shall provide your employees with adequate, readily accessible bathrooms that are kept clean so as not to be a potential source of contamination.

(h) Hand-washing facilities. You shall provide adequate and accessible hand-washing facilities for manufacturing personnel.

(i) Trash disposal. You shall collect, store, and dispose of trash in a manner that protects against contamination. The handling, storage and disposal of trash shall not create malodors that contaminate tobacco products or result in an attraction, harborage or breeding place for pests.

(j) Sanitation supervisors. You shall assign one or more employees to supervise overall sanitation. Each of these supervisors shall be qualified by education, training and/or experience related to the development or supervision of sanitation programs.

(k) Procedures. You shall establish procedures for cleaning the physical plant and for pest control.

XXX.53 Physical Plant Construction and Design

(a) Any physical plant you use in the manufacture of tobacco products shall

(1) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitary operations necessary to protect against contamination; and
(2) Have adequate space for the placement of equipment and holding of tobacco products, packaging, and materials as is necessary to protect against contamination or mix-ups of components during manufacturing, packaging, labeling, or holding.

Subpart D — Equipment and Utensils

XXX.60 Equipment and Utensils

(a) You shall use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.

(b) Equipment and utensils shall be maintained and cleaned to prevent contamination.

(c) Instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination shall be:

1. Accurate and precise for their intended use;
2. Adequately maintained;
3. Adequate in number for their designated uses; and
4. Calibrated before first use and at a frequency specified by the manufacturer of the instrument or control or at intervals necessary to ensure their accuracy and precision.

(d) Equipment and utensils shall be removed, replaced or repaired when they no longer perform as designed or do not conform to the applicable reference standard.

(e) Automated, mechanical, and electronic equipment (including software for computer controlled processes), shall be:

1. Appropriate for, and function in accordance with, its intended use;
2. Controlled to consistently meet specifications, including controls to account for any changes to such equipment; and
3. Routinely calibrated, inspected, or checked to ensure proper performance.

XXX.65 Procedures, Records and Recordkeeping

(a) You shall establish procedures for fulfilling the requirements of this subpart, including procedures for:

1. Calibrating instruments and controls that you use in manufacturing or testing a tobacco product;
2. Calibrating, inspecting, and checking automated, mechanical, and electronic equipment;
(3) Maintaining, repairing, and cleaning, as necessary, all equipment, utensil, and any other contact surfaces that are used to manufacture, package, label, or hold tobacco products; and

(4) Identifying what actions are to be taken if calibration accuracy or precision is not met or post-maintenance/repair testing does not meet performance requirements.

(b) Where the performance or accuracy of equipment and instruments may be necessary to assure that tobacco products meet specifications, you shall document any calibration, maintenance, and/or repair, each time it is performed, for instruments and controls that you use in manufacturing or testing a tobacco product.

(c) You shall make and keep records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment.

(d) Where the performance of equipment may be necessary to assure that tobacco products meet specifications, you shall make and keep records of the controls that you use to ensure that equipment functions in accordance with its intended use.

Subpart E — Document Controls

XXX.70 Procedures

You shall establish and maintain procedures to control all documents that are required by this Part. The procedures shall provide for the following:

(a) Document approval and distribution. Quality assurance or other qualified personnel shall review for adequacy and approve prior to issuance all documents established to meet the requirements of this Part. The approval, including the date and identification of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this Part shall be available at all locations for which they are designated, used, or otherwise necessary, and all documents established under this Part that are obsolete shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) Document changes. Changes to documents shall be reviewed and approved. Approved changes shall be communicated to the appropriate personnel in a timely manner. You shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the identification of the approving individual(s), the approval date, and when the change becomes effective.

Subpart F — Purchasing Controls

XXX.80 General

(a) You shall establish and maintain procedures to confirm that all purchased or otherwise received tobacco products, materials, and packaging conform to your specified requirements.

(b) You shall establish and maintain data that clearly describe or reference the specifications for purchased or otherwise received tobacco products, materials, and packaging. Purchasing
documents shall include, where possible, an agreement that the suppliers agree to notify the manufacturer of changes in the tobacco product, material, or packaging so that manufacturers may determine whether the changes may affect the specifications of a finished tobacco product.

XXX.85 Evaluation of Suppliers

(a) You shall establish and maintain the requirements that must be met by suppliers of tobacco products, materials and packaging.

(b) You shall evaluate and select suppliers on the basis of their ability to meet your specified requirements. The evaluation shall be documented.

(c) You shall define the type and extent of control to be exercised over the tobacco products, materials, and packaging suppliers based on the evaluation results.

(d) You shall establish and maintain a list of qualified suppliers.

Subpart G — Identification and Traceability

XXX.90 Identification

You shall establish and maintain procedures for identifying tobacco products, materials, and packaging during all stages of manufacture to prevent mix-ups. The procedures shall include where appropriate:

(a) Identifying electronically, by signage, or other method of identification all containers to identify their contents and, where necessary, the stage of processing of the batch or lot; and

(b) Identifying electronically, by signage, or other method of identification all processing lines and major equipment used during manufacturing, as necessary, to indicate their contents, including the name of the tobacco product and the specific batch number, control number, or lot number and, when necessary, the stage of processing of the batch or lot.

XXX.95 Traceability

You shall establish and maintain procedures providing for traceability between a finished tobacco product and its materials, packaging, and tobacco used to produce a given lot or batch of finished tobacco product. For tobacco, traceability extends to the tobacco as it was first introduced into the manufacturing process.

Subpart H — Manufacture and Process Controls

XXX.100 General Controls and Change Controls

(a) You shall develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to your specifications. Where deviations from specifications could occur as a result of the manufacturing process, you shall establish and maintain adequate process
control procedures to ensure conformance to specifications. Where process control procedures are necessary they shall include:

(1) Documented instructions or procedures that define and control the manner of manufacture;

(2) Monitoring and control of manufacturing processes to ensure conformance to specifications during manufacture; and

(3) A process for approving, in writing, new processes and process equipment or modifications thereto.

(b) You shall establish and maintain procedures for changes to a specification, process, or procedure. Prior to implementation, such changes shall be properly qualified where appropriate.

XXX.110 Specifications

You shall establish specifications for any point, step, or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged and labeled as intended by the manufacturer. Such specifications shall be contained or referenced in the master manufacturing record.

XXX.114 Sanitation Requirements

You shall conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions determined by your evaluation of potential biological, chemical, and physical hazard to prevent contamination.

XXX.116 Master Manufacturing Record

You shall prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate for tobacco products. The master manufacturing record shall include, or reference the location of, the following information, where appropriate:

(a) Specifications;

(b) Manufacturing methods, manufacturing procedures or any manufacturing environment requirements;

(c) Quality control procedures;

(d) Evaluation criteria and quality control measures associated with any reprocessing activities; and
PROPOSED TOBACCO PRODUCT GMP REGULATION

(e) Label and packaging specifications and methods and processes used to ensure conformance with such specifications.

XXX. 118 Batch or Lot Manufacturing Records

You shall establish and maintain procedures to ensure a batch or lot manufacture record is prepared for each batch or lot of a tobacco product that includes complete information relating to the manufacture and control of each batch or lot and accurately follows the appropriate master manufacturing record and each step taken in the manufacture of the batch or lot. The batch or lot manufacturing record shall include, or refer to the location of, the following information:

(a) The date(s) of manufacture;
(b) The quantity of tobacco product manufactured;
(c) The quantity of tobacco product distributed;
(d) The records demonstrating the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record;
(e) Any identification and control number(s) for the finished tobacco product and components, materials, and any labels and packaging included in the finished tobacco product; and
(f) A description of any reprocessing or rework activity associated with such batch or lot including records demonstrating the reprocessing conformed to the master manufacturing record.

Subpart I — Evaluation and Acceptance Activities

XXX. 120 Receiving Acceptance and In-Process Evaluation

(a) You shall establish and maintain procedures for the acceptance of incoming tobacco products, materials, and packaging to assure specified requirements are met.

(b) You shall establish and maintain evaluation procedures, where appropriate, to ensure that specified requirements for in-process tobacco product are met.

(c) You shall maintain records of in-process tobacco product failing evaluation activities and their disposition required by this Part. These records shall include:

(1) Identification of such in-process tobacco product failing evaluation,
(2) The dates such in-process tobacco product failed the evaluations;
(3) The results of such evaluations;
(4) The identity of the individual(s) conducting the evaluation; and
(5) Where appropriate, the equipment used.
Subpart J — Nonconforming Tobacco Product

XXX.130 Procedures for Nonconforming Tobacco Product

(a) You shall establish and maintain a process to control tobacco products that do not meet specifications or are contaminated. The process shall address the identification, documentation, evaluation, segregation, and appropriate disposition of such nonconforming tobacco products.

(b) Identification of nonconforming tobacco products shall include documentation of the identity and quantity of the nonconforming tobacco product, the date the tobacco product was identified as nonconforming, the nonconformance, and the identity of the person who determined the tobacco product to be nonconforming.

(c) Evaluation of the nonconformance shall include an assessment of the risk posed by the nonconformance and a determination of the need for an investigation into the cause of the nonconformance. Where an investigation is conducted, it shall include a review of relevant manufacturing records, data, and any other relevant information necessary to determine the cause of the nonconformance and to eliminate other possible causes.

(d) Segregation of the nonconforming tobacco product shall include clearly identifying and holding nonconforming tobacco product in a manner that prevents mix-ups.

(e) Disposition of nonconforming tobacco product that is nonconforming due to being out of specification may include an assessment of whether the nonconformance presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Personnel responsible for making such disposition determinations shall be identified.

(f) You may rework nonconforming tobacco product to bring it into conformance with specifications only if you can establish and verify a plan for ensuring the tobacco product meets specifications and is not contaminated.

(g) You shall establish and maintain a corrective action and preventive action program to address nonconforming tobacco products, when the risk posed by the nature of the nonconformance or the frequency of the nonconformance warrants such action. Such a program shall include the following:

(1) An investigation of the root cause of the nonconformance;

(2) Identification of the action(s) needed to correct and prevent recurrence of the nonconformance;

(3) Implementing such action(s); and

(4) Assessment and confirmation of the effectiveness of such action(s).

(h) You shall keep and maintain records of all activities required under this section.
PROPOSED TOBACCO PRODUCT GMP REGULATION

Subpart K — Labeling and Packaging Operations

XXX.140 Labeling and Packaging

You shall establish and maintain a process to control labeling and packaging activities.

(a) Labels shall be printed and applied to finished tobacco products so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and sale.

(b) You shall establish a process to ensure that labels received from suppliers conform to the label specifications.

(c) You shall manage label storage, label application, and packaging operations to prevent mix-ups.

(d) You shall ensure that any numbers, codes, and/or markings used to identify the tobacco product batch or lot are adequately applied to labels or packaging on finished tobacco products.

(e) Tobacco product packaging and shipping cases or containers shall be designed and constructed to protect against the contamination of finished tobacco products during customary conditions of processing, storage, handling, distribution and sale.

XXX.145 Repackaging and Relabeling

You shall establish and maintain a process to manage repackaging and relabeling operations that meet the requirements set forth in Section XXX.140.

Subpart L — Holding and Distribution

XXX.150 Handling and Storage

You shall establish and maintain procedures to ensure tobacco products are held under appropriate conditions to protect against the possibility of mix-up or contamination.

XXX.155 Distribution

You shall establish and maintain a process to ensure finished tobacco products are distributed under appropriate conditions to protect against contamination. You shall establish and maintain records that include:

(a) The identification of the initial consignee;

(b) The identification and quantity of the finished tobacco product shipped;

(c) The date of shipment; and

(d) Any code used to identify the finished tobacco product and/or batch or lot.
Subpart M — Complaints

XXX.160 Review and Investigation of Complaints

Quality assurance or other qualified personnel shall:

(a) Review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products;

(b) Evaluate the need for an investigation; and

(c) Where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and an other investigation is not necessary.

XXX.165 Required Records

(a) You shall make and keep the following complaint records:

(1) Procedures for fulfilling the requirements of this subpart.

(2) A record of every complaint. The record of the complaint shall include, where available, the following:

(i) The name and description of the finished tobacco product;

(ii) The batch, lot, or control number of the finished tobacco product;

(iii) The date the complaint was received and the name, address, or telephone number of the complainant;

(iv) The nature of the complaint including, if known, how the finished tobacco product was used;

(v) The reply to the complainant, if any; and

(vi) The identification of the person receiving the complaint.

(3) Where complaints are investigated, the record of the investigation shall include:

(i) A record of the investigational activities performed; and

(ii) The findings of the investigation and follow up action(s) taken as a result of the investigation.
XXX.170 General

(a) You shall establish procedures to fulfill the requirements of this Part.

(b) You shall make and keep records required under this Part in accordance with this subpart.

(c) All records required by this Part shall be maintained at the establishment where the operations were conducted or other location that is reasonably accessible to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available during the retention period to FDA employee(s) for inspection and copying when requested. Such records shall be legible and shall be stored to minimize deterioration and to protect against loss. Those records stored in automated data processing systems shall be backed up.

(d) Records shall be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, you shall make suitable reader and photocopying equipment readily available to FDA.

XXX.174 Record Retention

You shall keep records for at least 2 years beyond the date of manufacture of the last batch or lot of finished tobacco products associated with those records.

XXX.178 Confidentiality

Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in Part 20 of this chapter.

Effective Date:

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register.
Attachment 2
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

PART __ — CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO PRODUCTS

AGENCY: Food and Drug Administration, HHS

SUMMARY: The Food and Drug Administration ("FDA") is proposing to establish current good manufacturing practice ("cGMP") regulations for tobacco products. The proposed rule establishes cGMP requirements for the manufacture, labeling, packing, and storage of tobacco products to ensure that the tobacco products are not adulterated or misbranded. The proposed rule is one of many actions related to tobacco products that FDA is taking pursuant to the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (the "Tobacco Control Act" or "Act"). The Tobacco Control Act added authorities to the Federal Food, Drug and Cosmetic Act ("FDCA") to enhance public health protection.

1. Background and Related Information

A. Purpose

The Tobacco Control Act became law on June 22, 2009. This Act gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. To that end, FDA is empowered to prescribe regulations to protect the public health and assure that tobacco products are in compliance with the provisions of the Act by requiring good manufacturing practices or hazard analysis and critical control point methodology. Accordingly, certain members of the tobacco industry ("Identified Companies")1 are proposing the attached cGMP regulations for consideration by the FDA.

The tobacco industry produces a diverse array of tobacco products, many of which involve different manufacturing processes. Even the manufacturing processes within the same category of tobacco product may vary in numerous ways. Thus the Identified Companies are proposing cGMPs that provide sufficient direction for the establishment of adequate manufacturing controls without providing detailed instruction for what specific criteria should be used to implement the controls. This framework will enable the Agency to protect the public health with respect to this unique product category while giving individual manufacturers the opportunity to meet the goal of the cGMPs in an effective manner that allows for flexibility and innovation. More specifically, the cGMPs require each manufacturer to identify and establish certain procedures and practices but allow the specific practices and procedures to be tailored to the category of tobacco product, and the attributes of the specific tobacco products, produced by the manufacturer. The extent and nature of documentation and practices necessary to meet the

---

requirements of the proposed cGMPs will vary according to the complexity of the manufacturing operations and the risks associated with the failure to implement a given practice.

The proposed cGMPs take into account that tobacco products are unique when compared to other products regulated by the FDA because of the inherent variability of tobacco (as an agricultural crop) and the inherent risk to users of the products. For example, the cGMP regulations for drugs and medical devices were established in part to ensure that the drug or device meets the safety requirements of the FDCA. See 43 Fed. Reg. 45014 (Sept. 29, 1978) (a drug is deemed adulterated unless it “conforms to cGMP” so that the drug meets the safety requirements of the Act and has the identity and strength and meets the quality and purity characteristics that it is represented to have”); 43 Fed Reg. 31508 (July 21, 1978) (medical devices must “conform to [cGMP] requirements, as prescribed in the regulation, to assure that devices are safe and effective and otherwise in compliance with the act.”). FDA found that many device recalls “resulted from manufacturers’ failure to follow good manufacturing practices” and, therefore, found it “vitaly important that devices be manufactured in accordance with quality assurance principles that help prevent the production of defective products that can endanger consumers.” Id. The cGMP regulations for dietary supplements were established to ensure that consumers do not suffer harm and obtain the purported health benefit from the consumption of dietary supplements. 68 Fed Reg. 12159 (Mar. 13, 2003) (a dietary supplement is adulterated if it “contains contaminants because [the supplement does] not contain the dietary ingredient it is represented to contain or because the amount of the dietary ingredient thought to provide a health benefit is not actually present in the supplement”). Unlike the cGMPs for drugs, medical devices, and dietary supplements, cGMP regulations for tobacco products are not meant to assure the safety and effectiveness of a tobacco product—because of their inherent risk to users of the products—but rather to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the Act. Tobacco Control Act, §906(e)(1).

Therefore, the purpose of the proposed cGMP regulation is threefold: (1) to protect the public health by providing assurance that tobacco products are not contaminated (prohibiting the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product); (2) to prevent misbranded tobacco products; and (3) to allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.

B. Inherent Risks Associated With the Use of Tobacco Products

Underpinning the proposed cGMP regulation for tobacco products is an acknowledgment that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products. When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was “to continue to permit the sale of tobacco products to
adults.” FDCA § 907(d)(3)(A) (FDA is expressly "prohibited" from issuing a regulation “banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products.”).

Thus the cGMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks and, given the purpose of the cGMPs, not require manufacturers to address those risks in this context. Unlike for drugs, medical devices, dietary supplements, and food, the tobacco product cGMPs cannot require tobacco manufacturers to assure their products are safe and/or effective.

In light of these considerations, the Identified Companies’ proposed cGMP regulation provides direction to tobacco product manufacturers to control their manufacturing processes in a manner that would prevent the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products. Further, the proposed regulation directs tobacco product manufacturers to control their manufacturing processes so that the tobacco product is not misbranded. The Identified Companies believe that these elements are central to meeting the Congressional intent as expressed in Section 906(e) of the Tobacco Control Act.

C. Inherent Variability of Tobacco Products

Tobacco — the main ingredient in tobacco products — is of an agricultural or gin, and therefore tobacco products are subject to natural variation. Each type of tobacco, e.g., flue-cured, dark air-cured, fire cured, burley, and oriental, has its own particular taste and aroma. Moreover, there are variations in these attributes within each type according to the tobacco’s grade (i.e., quality), stalk position, geographic origin, and year of harvest. Tobacco product manufacturers combine different types of tobacco to produce a distinctive “blend” that is primarily responsible for giving each tobacco product its distinctive sensory characteristics (similar to the blending processes that occur in other agricultural based consumer products, such as coffee, wine, and beer). Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

This inherent variability of tobacco results in unavoidable variations in the tobacco blends. To compensate for these natural variations and maintain the consistency of the tobacco product, a tobacco product manufacturer must routinely adjust the tobacco blends — for example, by blending across several crop years of one type of tobacco. FDA acknowledges that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco ... in order to maintain a consistent product” in a recent guidance document. CENTER FOR TOBACCO PRODUCTS, GUIDANCE FOR INDUSTRY AND FDA STAFF: SECTION 905(j) REPORTS: DEMONSTRATING SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS 4 (2011). FDA has also acknowledged that such adjustments to the tobacco blend are not “intended to alter the chemical or perception properties” of a tobacco product, but rather maintain a consistent product. Id.
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

Therefore, the direction to manufacturers provided by the proposed cGMP regulation recognizes the inherent variability unique to tobacco products. This is achieved by providing tobacco product manufacturers the flexibility necessary to manufacture, label, pack, and store in a manner allowing for such variability but not permitting (a) the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products or (b) misbranding.

II. Proposed Rule

Subpart A – General Provisions

XXX.1 Applicability

The language in subsection (a) of this section essentially tracks the Tobacco Control Act authority over tobacco product manufacturers. In other words, if a facility meets the Tobacco Control Act definition of a tobacco product manufacturer, then it will be covered by the proposed cGMP regulation to the extent it manufactures tobacco products within FDA’s jurisdiction under Section 901(b). While the storage of tobacco products by a tobacco product manufacturer is within the scope of the regulation, a distributor as defined in Section 900(7) of the FDCA is exempt from these regulations. Subsection (b) provides further clarity with respect to the non-applicability of the requirements to storage activities at retail. The other subsections essentially restate other provisions of the Tobacco Control Act. Also, small tobacco product manufacturers, as defined by Section 900(16) of the Tobacco Control Act, are not required to comply with the cGMP regulation for at least 4 years following the effective date of the regulation. See Section 906(e)(1)(B)(v).

XXX.3 Definitions

This section provides definitions for certain relevant terms used in the proposed cGMP regulation that are not defined in Section 201 of the FDCA or the Tobacco Control Act. While the defined terms in the regulation speak for themselves, we have elaborated on the intent of certain of the defined terms below.

The definition for “batch or lot” provides the tobacco manufacturer with the flexibility to define “any specific quantity or manufacturing period” as a “batch or lot” as long as tobacco product being manufactured during such a “batch or lot” is intended to meet the same specifications. Such flexibility is necessary for tobacco product manufacturers because some tobacco products are not made in discrete “batches” but are manufactured by continuous production.

The definition of “contaminant” recognizes the unique risk profile of tobacco products. They are agricultural products that, for that reason, naturally include substances other than tobacco. This definition also acknowledges the inherent risks associated with tobacco products, as described in Section 1.8. Thus, a substance becomes a “contaminant” only when it has been added to a tobacco product, is not intended to be in the tobacco product, and presents a risk beyond that generally posed by the same category of tobacco products. This concept is consistent with the...
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

language in the mandatory recall provisions of Section 908(c)(1). It is not necessary to eliminate from tobacco products added substances that ordinarily are contained in tobacco products because of their agricultural nature or that do not increase the health risk of the tobacco products. The “master manufacturing record” is where the procedures and specifications for manufacturing a finished tobacco product are found. It is the key repository of manufacturing requirements and controls and may comprise several documents or files or an index identifying them and their location.

The “quality” of a tobacco product refers to whether the product meets the manufacturer’s specifications and is not contaminated. Because of the inherent risks posed by tobacco products, those are the two elements of what is ordinarily considered product quality that need to be addressed by this Part in order to protect the public health.

“Rework” means action taken on a nonconforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

A “specification” is any requirement that a manufacturer defines as a specification in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform. The manufacturer defines what the product and processing specifications should be. What the manufacturer may describe as parameters, limits, criteria or like terms are not specifications unless the manufacturer defines them as such in the master manufacturing record. This provision also recognizes that tobacco product manufacturers may use in-process rather than finished product specifications if the manufacturer otherwise is in compliance with this Part.

Subpart B – Personnel

Sections XXX.20, XXX.30, and XXX.31 require a manufacturer to have adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority. At the same time, these provisions recognize that no formal quality unit is required. In the case of tobacco products, such personnel may have duties other than quality assurance as well, as long as the quality assurance duties are well-defined and adequately carried out, as specified in the regulation.

Section XXX.35 requires a manufacturer to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

Subpart C – Physical Plant and Grounds

The terms “clean and sanitary”, as used in Section XXX.50(b), mean a manufacturer’s physical plant shall be kept clean to the extent necessary to protect against contamination, taking into account the inherent risks of tobacco products and an analysis of the risks of contamination, as
that term is defined in Section XXX.3. The term "sanitary" is not intended to require sanitation, sterilization, or any other specific form of cleaning beyond what the risk analysis determines is necessary. This requirement is consistent with the application of the concepts associated with hazard analysis and critical control point (HACCP) methodology to sanitation in Section XXX.114.

Section XXX.50(d)(3) requires that insecticides, fumigants, fungicides, or rodenticides, used for pest control activities shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination. Foreign manufacturers not subject to the Federal Insecticide, Fungicide and Rodenticide Act shall comply with their own national or local requirements governing the use of such pesticides and shall not contaminate the tobacco product.

Section XXX.50(e)(2) requires that water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product. Foreign manufacturers shall comply with their own national or local requirements governing water quality and shall not contaminate the tobacco product.

Subpart D – Equipment and Utensils

Section XXX.60(e) generally requires equipment to be adequately calibrated and controlled. That requirement applies to software used to control processes. The requirement to control certain software, including the requirement in Section XXX.60(e)(2) to control such software to ensure that specifications consistently are met, is not intended to require software validation. Such control may be achieved by a process of qualification, calibration, monitoring, verification checks, other methods, or some combination thereof, as determined to be appropriate for the particular equipment and processes by the manufacturer.

Subpart E – Document Controls

Section XXX.70 requires a manufacturer to establish and maintain procedures to control documents required by the cGMP regulations. Such procedures shall include, among other things, controls for approving documents, making changes to documents, and approving those changes. Both Section XXX.70(a) and (b) require that the individuals approving documents or changes to them be identified. Identification of such individuals in the document control system, whether in electronic or paper form or some combination thereof, is sufficient in lieu of such individuals' signatures, provided that the document control procedures require the approving individual personally to identify him or herself in some way and the identity of such individuals is not merely assigned automatically by the document control system or other personnel.
Subpart F - Purchasing Controls

Section XXX.80 requires manufacturers to have purchasing controls for incurring tobacco products, materials and packaging, as those terms are defined in Section XXX 3. Manufacturers have the flexibility under this provision to determine the type and extent of such controls based on the needs for their specific products and manufacturing processes.

Section XXX.85 requires manufacturers to establish and maintain the requirements that must be met by suppliers of tobacco products, materials and packaging. The specific requirements may vary based on an evaluation of the potential risk posed by the supplied material (e.g. tobacco ingredient vs. packaging component) but should include supplier evaluation criteria and maintaining a list of qualified suppliers.

Subpart G - Identification and Traceability

The identification requirements of Section XXX.90(a) are meant to apply whenever there is a reasonable possibility of mix-ups. It may not be necessary to identify the contents of some containers because the risks of mix-up, or the consequences of a mix-up, are small, such as where the use of a particular container or tobacco product is limited to one area of the manufacturing facility.

Section XXX.95 requires traceability that will assist manufacturers in identifying other potential batches or lots of finished tobacco products that might be affected by a product quality issue that arose during manufacturing and was detected in a particular finished tobacco product batch or lot, which, in turn, will assist manufacturers in conducting any necessary market withdrawals or recalls. For tobacco, by requiring traceability back only to the tobacco as first introduced into the manufacturing process, this provision makes clear that manufacturers are not required to establish traceability all the way back prior to its introduction into the manufacturing process, such as to the growers or sellers of the raw tobacco. This traceability requirement does not extend to farms because the tobacco is mixed after received from farms during leaf processing (or "stemmery") operations, which are defined as "tobacco warehouses" in Section 900(21) of the FSPTCA. After such processing, the raw tobacco is typically stored for a few years prior to being introduced into the manufacturing process. Also, FDA does not have jurisdiction over tobacco farms or tobacco warehouses (with certain exceptions) under Chapter IX of the FSPTCA.

Subpart H - Manufacture and Process Controls

Under Section XXX.100, manufacturers are required to control their processes to ensure their tobacco products meet specifications. However, the specific control measures to be utilized are determined by the manufacturer so that it has the flexibility to identify and execute the control measures best suited to its manufacturing operations and tobacco products.

Section XXX.114 provides that a manufacturer should develop its sanitation control program by using a risk based approach that is informed by an evaluation of potential biological, chemical,
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

and physical hazards. These criteria are consistent with those used in the food industry when applying "HACCP". While this section does not mandate a formal HACCP program, it does require manufacturers to undertake a HACCP-like evaluation to support its sanitation controls.

Section XXX.116 requires the development of a master manufacturing record, which is the key record documenting manufacturing controls. The development of the specifications in the master manufacturing record, beginning when the cGMP regulation takes effect, shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate to assure tobacco product requirements are met. This provision is intended to address the "preproduction design validation" language in FDCA Section 906(c)(1)(A).

The provisions in this Subpart II and the rest of this Part are not meant to require process validation. For tobacco products, adequate process controls might take the form of in-process control parameters, such as temperature or processing speed, equipment qualification and calibration, in-process quality checks; or other controls appropriate to the processes and tobacco products, as determined by the manufacturer.

Subpart I - Evaluation and Acceptance Activities

Section XXX.120 makes it incumbent on a manufacturer to establish appropriate procedures for the acceptance of incoming tobacco products, materials and packaging and the evaluation of in-process tobacco products to assure specified requirements are met. Acceptance activities may include visual checks, testing or verification of supplier Certificates of Analysis. Because of the unique nature of tobacco products, as explained in the introductory paragraphs above, in-process or finished tobacco product testing is not required unless a manufacturer determines, under other provisions of this Part that it is a necessary process control and makes such testing part of a specification in the master manufacturing record.

Subpart J - Nonconforming Tobacco Product

Under Section XXX.130, a tobacco product is nonconforming if it does not conform to the applicable specifications in the master manufacturing record or is contaminated, as that term is defined in Section XXX.3. A manufacturer must have a process to evaluate and handle nonconforming tobacco product as described in Section XXX.130.

Section XXX.130(c) requires that process to include a risk assessment and a determination of the need for an investigation into the cause of the nonconformance. A manufacturer's process for handling nonconforming tobacco product therefore should include criteria to evaluate the risk posed by the nonconformance and to determine how the tobacco product should be dispositioned. This provision gives direction to a manufacturer without specifying all of the criteria to be used for the investigation and disposition decisions because such criteria should be based on the attributes of the specific tobacco product and its manufacturing processes.
Under Section XXX.130(c), the disposition determination shall include an assessment of whether the nonconformance is a defect not ordinarily contained in the same category of tobacco products and whether that defect presents a risk of injury beyond that generally posed by the same category of tobacco products. That assessment already will have occurred in the case of contaminated product because of the definition of contamination in Section X.X.3, but such an assessment shall also be done in the case of a tobacco product that does not conform to specifications.

Subpart K – Labeling and Packaging Operations

Section XXX.140 requires a manufacturer to establish and maintain a process to control labeling and packaging activities. Provided that such process ensures that labels conform to specifications and that labels and packaging are managed to prevent mix-ups, the manufacturer is not required to quarantine or otherwise hold incoming labels prior to their introduction into labeling and packaging operations. This provision provides direction to a manufacturer to establish an effective process without specifying an evaluation and release process or other particular steps in the process.

Subpart L – Holding and Distribution

Although Sections XXX.150 and XXX.155 contain storage and distribution requirements, such requirements do not apply to a “distributor” as defined in Section 900(7) of the FDCA.

Subpart M – Complaints

Section XXX.160 requires a manufacturer to review all complaints. This provision does not attempt to specify all of the criteria a manufacturer must use to evaluate complaints or to determine whether an investigation is necessary. However, consistent with the language in the mandatory recall provisions of the FSPTCA, Section 908(c)(1), and the reporting provisions of the FSPTCA, Section 909(a), this provision requires quality assurance personnel or other qualified personnel, as described in XXX.31, to evaluate whether the complaint involves a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products and, in most cases, to investigate such complaint. Such complaints may not need to be investigated if they previously have been investigated and the cause of the defect is known. Additionally, given that smokers may experience certain transient effects (e.g., headaches) and consumers of smokeless tobacco products may as well (e.g., nausea), all complaints alleging health effects may not need to be investigated. This provision makes clear that an assessment of potential health hazards is a critical element of the complaint evaluation and investigation process. The term “acute” has been included in the description of the applicable health hazards for those purposes because the complaint handling process required by this section is not intended to handle allegations of chronic health effects related to the inherent risks of tobacco products as referenced in Section 1.B.
Effective date

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register. Consistent with FDCA Section 906(e)(B)(iv), the proposed effective date is necessary to provide a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein. The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.
June 20, 2012

Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Beverly Chernaiik
Director, Office of Regulations
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Re: MAY 2, 2012 MEETING WITH INDUSTRY STAKEHOLDER TO DISCUSS PROPOSED GMPs

Dear Ms. Simoneau and Ms. Chernaiik:

R.J. Reynolds Tobacco Company ("RJRT"), on behalf of the industry stakeholders1 who participated in the May 2, 2012 meeting, would like to thank the United States Food and Drug Administration’s Center for Tobacco Products ("CTP") for the opportunity to meet on May 2, 2012 and discuss the Companies’ proposed Good Manufacturing Practice ("GMP") regulations and preamble.

While the Companies believed that the proposed GMP regulations and preamble would facilitate a productive dialogue consistent with CTP’s expressed goal to engage with and understand the industry, we recognize that CTP was not prepared to engage in a dialogue at the May 2, 2012 meeting. Should CTP wish to meet with the Companies again during its development of GMP regulations, we welcome the opportunity as we are committed to working with the Agency to establish appropriate GMP regulations for tobacco product manufacturers.

---

1 The industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., Ha & Cotten, Inc., and CI/MA (collectively referred to herein as the "Companies").
If you have any questions, please do not hesitate to contact me.

Respectfully Submitted,

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Atria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group L.L.C
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
CITMA
Please find attached correspondence from R.J. Reynolds Tobacco Company and the various industry stakeholders that participated in the May 2, 2012 meeting.

Thank you,

Amanda J. Klingler
King & Spalding LLP
1700 Pennsylvania Avenue, NW
Washington, DC 20006
Tel. 202-626-9255
Fax. 202-626-3737
aklingler@kslaw.com
Proposed Good Manufacturing Practices for Tobacco Products:

Industry Stakeholder Presentation to CTP

May 2, 2012
Meeting Objectives

- Share with CTP:
  - The process the industry stakeholders used to develop the proposed GMP
  - Industry stakeholder perspective on the proposed GMP and preamble
- Help the industry stakeholders understand the CTP’s current thinking on the process and timing for the development of tobacco product GMPs
- Begin a dialogue with CTP on development of tobacco product GMPs
Developmental Process for Proposed GMP Regulation

- Diverse group of stakeholders including large and small manufacturers and suppliers
- Began initial discussions spring-2011 to develop a GMP approach appropriate for tobacco product manufacturing
- Considered the scope and range of both tobacco products and manufacturing processes
- Submitted proposed GMP regulation and preamble to the Agency, January 10, 2012
- In the ensuing period, other tobacco product manufacturers and suppliers have been supportive of this approach
- General consensus-current version appropriate for tobacco products
Supporting Industry Stakeholders

- R.J. Reynolds Tobacco Company
- Santa Fe Natural Tobacco Company, Inc.
- American Snuff Company, LLC
- Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company
- Lorillard, Inc.
- Commonwealth Brands, Inc
- Liggett Group LLC
- The SMAJ TT Coalition, which includes Nat Sherman, Commonwealth Brands, Inc, Japan Tobacco International, King Maker Marketing, Inc.
- Vector Tobacco Inc.
- National Tobacco Company, L.P.
- Hail & Cotton, Inc.
- Swedish Match North America
- CITMA
- Mundet
Statutory Requirements for GMP Regulation

- The FSPTCA* requires that the FDA prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing and storage of tobacco products conform to (i) cGMPs or (ii) hazard analysis and critical control point methodology ("HACCP").

* Federal Food, Drug, and Cosmetic Act ("FDCA") Section 906(e), as amended by the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").
Proposed GMP Regulation and Preamble

- The proposed GMP Regulation is intended to meet the statutory requirements of the FSPTCA and draw from existing cGMP regulations where controls were deemed appropriate.

- The proposed GMP Regulation provides direction without a high degree of specificity, requiring a controlled manufacturing process but allowing each manufacturer discretion as to the types of controls and level of control (e.g., specifications).

- Such flexibility will also allow manufacturers to adopt additional controls in the future in the event tobacco product standards are promulgated by the FDA.
Proposed GMP Preamble

- Background and Related Information
  - Purpose
  - Inherent risks associated with the use of tobacco products
  - Inherent variability of tobacco products

- Proposed Rule
  - Rationale for key tobacco-related definitions
  - Explanation of key elements of the “proposed rule”
Proposed GMP Regulation

• Unlike the FDA cGMPs for drugs and medical devices, the proposed GMP regulations for tobacco products are not meant to assure the “safety and effectiveness” of a tobacco product (as those terms are traditionally used by FDA) – because of the inherent risks associated with the use of different categories of tobacco products – but rather to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the Act. Tobacco Control Act, §906(e)(1).
Purpose of Proposed GMP Regulation

* To protect the public health by providing assurance that tobacco products are not contaminated (prohibiting the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product);

* To provide assurance that the manufacturing of tobacco products does not result in such products being adulterated or misbranded; and

* To allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.
Proposed GMP Regulation: Inherent Risks of Tobacco Products

- Underpinning the proposed GMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products.

- When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was “to continue to permit the sale of tobacco products to adults.” Tobacco Control Act, §907(d)(3)(A).

- Thus the GMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks.

- Unlike drugs and medical devices, the tobacco product GMPs cannot require tobacco manufacturers to assure their products are safe and/or effective as those terms are traditionally used by FDA.
Proposed GMP Regulation:
Inherent Variability of Tobacco Products

- Tobacco is of an agricultural origin and therefore tobacco products are subject to natural variation.

- Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

- FDA acknowledged that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco... in order to maintain a consistent product” in a recent guidance document.*

---

* Center For Tobacco Products, Guidance for Industry And FDA Staff: Section 905(j) Reports Demonstrating Substantial Equivalence For Tobacco Products 4 (2011).
Proposed GMP Regulation: Subparts

A. General Provisions
B. Personnel
C. Physical Plant and Grounds
D. Equipment and Utensils
E. Document Controls
F. Purchasing Controls
G. Identification and Traceability
H. Manufacture and Process Controls
I. Evaluation and Acceptance Activities
J. Nonconforming Tobacco Product
K. Labeling and Packaging Operations
L. Holding and Distribution
M. Complaints
N. Records and Recordkeeping
Subpart A: General Provisions

XXX.3 Definitions

- Batch or Lot
- Complaint
- Contact Surface
- Contaminant
- Finished tobacco product
- Import
- In-process tobacco product
- Label
- Master Manufacturing Record
- Material
- Package
- Pest
- Physical Plant
- Quality
- Reprocessing
- Rework
- Specification
- Tobacco Product
- Tobacco Product Manufacturer
Proposed GMP Regulation:
XXX.3 Definitions - Select Terms

- **"Batch or lot"** means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications.

- **"Contaminant"** means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminate or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface.

- **"Quality"** means that the tobacco product meets the manufacturer’s specifications and is not contaminated.

- **"Specification"** means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform.

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation:
Illustrative Examples

- Subpart B - Personnel (similar to dietary supp approach)

  - Requires a manufacturer to “provide adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority.”

  - For example, “quality assurance personnel shall assure all components, in-process materials, packaging materials, labels, and tobacco products meet specifications, as appropriate, and are not contaminated.”

  - Requires a manufacturer to “establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.”

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

- Subpart C – Physical Plant and Grounds
  - Includes requirements necessary to protect against contamination for:
    - Grounds,
    - Physical plant facilities.
    - Cleaning compounds, pesticides and other toxic chemicals,
    - Pest control,
    - Water supply,
    - Plumbing, bathrooms and hand-washing facilities,
    - Trash disposal,
    - Sanitation Supervisors
  - Requires establishment of procedures for cleaning and pest control.

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

• Subpart D – Equipment and Utensils
  
  - Requires manufacturers to “use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.”

  - Establishes requirements for “instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination.”

  - Requires that manufacturers establish and maintain procedures and maintain records for such controls (e.g. calibration).

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

• Subpart H – Manufacture and Process Control;
  – Requires manufacturers to:
    • “develop, conduct, control and monitor manufacturing processes to ensure that tobacco products conform to specifications.”
    • “establish and maintain procedures for changes to a specification, process or procedure.”
    • “establish specifications for any point, step or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged and labeled as intended by the manufacturer.”
    • “conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions to prevent contamination” (e.g. application of HACCP concepts).

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: 
Illustrative Examples

- Subpart H – Manufacture and Process Controls -continued
  - Requires manufacturers to:
    - “prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes.”
    - “ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate” for the category of tobacco product.
    - “establish and maintain procedures to ensure a batch or lot manufacture record is prepared for each batch or lot of a tobacco product”; including “records demonstrating that the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record.”

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulations: Illustrative Examples

- Subpart K – Labeling and Packaging Operations
  - Requires manufacturers to “establish and maintain a process to control labeling and packaging activities”:
    - Printing and application of labels to finished tobacco products
    - Ensuring labels received from suppliers conform to label specifications
    - Preventing mix-ups
    - Assuring numbers, codes or markings used to identify the tobacco product batch or lot are adequately applied

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

- Subpart M - Complaints

  - *Complaint* means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco product.

  - Requires that “quality assurance or other qualified personnel”:
    - review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products; and
    - evaluate the need for an investigation; and
    - where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.”

  - Defines required complaint records. (Info required to be maintained.)
Proposed GMP Regulation: Effective Date

- GMP regulations would take effect a minimum of two years from publication of the final rule in the Federal Register.

- The proposed effective date provides a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein.

- The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.

- Small tobacco manufacturers as defined by Section 906(16) of the FSPTCA are not required to comply with the GMP regulation for at least 4 years following the effective date of the regulation (See Section 906(e)(1)(B)(v))
Questions?
Good morning!

The following link has a list of the industry folks attending next week's meeting and the proposed agenda: [non-responsive link]. As soon as I receive industry's presentation, I will circulate it to the team.

Also, if you plan to participate via phone, please let me know. I will be setting up a dial-in number shortly.

Thanks!

A
Good morning!

Here is a link to the meeting minutes from last week's TPMP meeting:
non-responsive

Also, please find attached a copy of tomorrow's presentation:
non-responsive

Thanks!
A
FYI.

From: Bautista, Andrea
Sent: Wednesday, January 11, 2012 7:31 PM
To: Boocker, Nancy; Faranda, David; Raafat, Dina; Shillingford, Mahala
Subject: RJR GMP PDF

Happy reading!
Thanks,
A
FYI to all, CTP received the attached letter from RJR today. As a result of Bopper's suggestion at the December Stakeholder Discussion series, RJR and various tobacco industry stakeholders are working collaboratively to develop GMPs. The stakeholders plan to provide CTP their proposed GMP regulations in January 2012 and will include a formal meeting request with their proposal.

Anne M. Henig
Office of the Center Director
Center for Tobacco Products/FDA
anne.henig@fda.hhs.gov
301-796-9212
December 16, 2011

Ann Simoneau, J.D.                          Beverly Chernaik
Director, Office of Compliance and Enforcement  Director, Office of Regulations
U.S. Food and Drug Administration              U.S. Food and Drug Administration
Center for Tobacco Products                  Center for Tobacco Products
9200 Corporate Boulevard                     9200 Corporate Boulevard
Rockville, MD 20850                           Rockville, MD 20850

Re: PROPOSED TOBACCO PRODUCT GOOD MANUFACTURING PRACTICES REGULATION

Dear Ms. Simoneau and Ms. Chernaik:

At the United States Food and Drug Administration’s ("FDA") Center for Tobacco Products ("CTP") December 2010 Stakeholder Discussion Series for large and small tobacco product manufacturers, tobacco growers, and warehouses, Dr. Dayton encouraged these diverse tobacco industry stakeholder groups to work collaboratively and engage with CTP as it implements the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") as CTP continues to develop regulatory experience with tobacco products. As such, various tobacco industry stakeholders are developing (1) proposed current Good Manufacturing Practice ("cGMP") regulations pursuant to Section 906(e) of the FSPTCA and (2) a preamble to the proposed regulations that provides the group’s common perspective and interpretation of the provisions of the proposed cGMP regulations. The industry stakeholders include, but are not limited to, the following companies: R.J. Reynolds Tobacco Company ("RJRT"), Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services (on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company), Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, and the SMARTT Coalition (collectively referred to herein as the "Companies").

RJRT, on behalf of the Companies, takes this opportunity to inform CTP of the Companies’ plan to provide CTP for its review and consideration the proposed cGMP
regulations and preamble on or about January 10, 2012. The Companies believe that the proposed cGMP regulations and preamble will help to facilitate a productive dialogue with CTP consistent with CTP's expressed goal to engage with and understand the tobacco product industry. As such, the Companies' January 10, 2012 submission will include a formal request to meet with CTP to discuss the proposed cGMP regulations and preamble.

The Companies look forward to discussing this matter with CTP. If you require any additional information or have any questions, please do not hesitate to contact RJRT at your convenience.

Respectfully Submitted,

[Signature]

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
PART — CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO PRODUCTS

Subpart A — General Provisions
  XXX.1 Applicability
  XXX.3 Definitions
  XXX.5 Good Manufacturing Practice Regulation

Subpart B — Personnel
  XXX.20 Resources
  XXX.30 Responsibility and Authority
  XXX.31 Quality Assurance Personnel
  XXX.35 Contamination Prevention
  XXX.40 Qualification, Education, and Training

Subpart C — Physical Plant and Grounds
  XXX.50 Plant Grounds, Facilities, and Sanitary Operations
  XXX.53 Physical Plant Construction and Design

Subpart D — Equipment and Utensils
  XXX.60 Equipment and Utensils
  XXX.65 Procedures, Records and Recordkeeping

Subpart E — Document Controls
  XXX.70 Procedures

Subpart F — Purchasing Controls
  XXX.80 General
  XXX.85 Evaluation of Suppliers

Subpart G — Identification and Traceability
  XXX.90 Identification
  XXX.95 Traceability

Subpart H — Manufacture and Process Controls
  XXX.100 General Controls and Change Controls
  XXX.110 Specifications
  XXX.114 Sanitation Requirements
  XXX.116 Master Manufacturing Record
  XXX.118 Batch or Lot Manufacturing Records
Subpart I — Evaluation and Acceptance Activities
XXX.120 Receiving Acceptance and In-Process Evaluation

Subpart J — Nonconforming Tobacco Product
XXX.130 Procedures for Nonconforming Tobacco Product

Subpart K — Labeling and Packaging Operations
XXX.140 Labeling and Packaging
XXX.145 Repackaging and Relabeling

Subpart L — Holding and Distribution
XXX.150 Handling and Storage
XXX.155 Distribution

Subpart M — Complaints
XXX.160 Review and Investigation of Complaints
XXX.165 Required Records

Subpart N — Records and Recordkeeping
XXX.170 General
XXX.174 Record Retention
XXX.178 Confidentiality
Subpart A — General Provisions

XXX.1 Applicability

(a) Except as provided by paragraphs (b) and (c) of this section, you are subject to this Part if you manufacture, pack, label, repackage, relabel, store, or import cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, or any other tobacco products that the Secretary by regulations deems subject to this Part, for sale or distribution in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. The requirements in this part are intended to protect the public health by requiring the manufacture of tobacco products utilizing practices that protect against manufacturing defects not ordinarily contained in tobacco products that present a risk of injury beyond the risks generally posed by the same category of tobacco products. If you engage in only some operations subject to the requirements of this Part, and not in others, you need only comply with those requirements applicable to the operations in which you are engaged.

(b) The requirements pertaining to storing tobacco products shall not apply to you if you are storing those tobacco products at a retail establishment for the sole purpose of retail sale to individuals for personal consumption, including facilities where self-service displays of tobacco products are permitted.

(c) The requirements of this Part shall not apply to producers of tobacco leaf, including tobacco growers, tobacco warehouses, and tobacco grower cooperatives, except to the extent such producer of tobacco leaf is engaged in an activity specified in paragraph (a) of this section or is controlled by a tobacco product manufacturer. A producer of tobacco leaf who grows tobacco under a contract with a tobacco product manufacturer and who is not otherwise engaged in the manufacturing process shall not be subject to this Part. The requirements of this Part shall not apply to distributors as defined by Section 900(7) of the Tobacco Control Act if the distributor is not also a tobacco product manufacturer and is not controlled by a tobacco product manufacturer.

(d) Any person who wishes to petition for a permanent or temporary exemption or variance from any requirement of this Part is subject to the requirements of Section 906(e)(2) of the Tobacco Control Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in 10.30 of this chapter, the United States Food and Drug Administration’s administrative procedures.

XXX.3 Definitions

The definitions and interpretations of terms in Section 201 of the Federal Food, Drug, and Cosmetic Act (the Act) apply to such terms when used in this Part. For the purpose of this Part, the following definitions also apply:

* Batch or lot* means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications.

* Complaint* means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco product.
Contact surface means any surface that contacts a tobacco product, material, or packaging during manufacture, processing, packaging or labeling.

Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminate or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface.

Finished tobacco product means any tobacco product that has completed the manufacturing and packaging process and is intended for commercial distribution.

Import means entry into the Customs territory of the United States for sale or distribution to consumers for consumption in the United States.

In-process tobacco product means any tobacco product that is fabricated, compounded, blended, ground, extracted, sifted, or processed in any other way by a tobacco product manufacturer for use in the manufacture of a finished tobacco product.

Label means a display of written, printed, or graphic matter upon the immediate package of any tobacco product.

Master manufacturing record means a compilation of records containing the procedure and specifications for manufacturing a finished tobacco product. A master manufacturing record may be prepared as a single document or file or may be prepared using an index system that specifies the location and identity of individual files, records, or documents that make up the master manufacturing record.

Material means any ingredient, additive or other substance other than tobacco incorporated into or added to a tobacco product during manufacturing.

Package means a pack, box, carton, or container of any kind or, if no other container, any wrapping (including film), in which a tobacco product is offered for sale, sold, or otherwise distributed to adult tobacco product consumers. A shipping case is not included in the definition of package.

Pest means any objectionable insect or other animal including birds, rodents, flies, and beetles.

Physical plant means all or any part of a tobacco product manufacturer’s building or facility used for or in connection with manufacturing, packaging, labeling, or holding of a tobacco product.

Quality means that the tobacco product meets the manufacturer’s specifications and is not contaminated.

Reprocessing means using, in the manufacture of a tobacco product, uncontaminated tobacco product that has been previously removed from manufacturing and that is suitable for use in the
subsequent manufacture of a tobacco product. Reprocessing is a routine manufacturing process.

*Rework* means action taken on a nonconforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

*Specification* means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform.

*Tobacco product* means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product) that FDA has authority over pursuant to Section 901(b), 21 U.S.C. § 387a(b), of the Tobacco Control Act.

*Tobacco product manufacturer* means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, or labels a tobacco product, or imports a finished tobacco product for sale or distribution in the United States.

**XXX.5 Good Manufacturing Practice Regulation**

The regulations in this Part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, label, or hold tobacco products.

**Subpart B — Personnel**

**XXX.20 Resources**

You shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment of activities, to meet the requirements of this Part.

**XXX.30 Responsibility and Authority**

You shall establish the appropriate responsibility, authority, and reporting relationships of personnel who manage, perform, and assess work affecting the quality of tobacco products.

**XXX.31 Quality Assurance Personnel**

There shall be select individuals, who through appropriate education, experience and training, are specifically designated to perform quality assurance responsibilities. These personnel may have responsibilities in addition to their quality assurance responsibilities. These individuals shall assure all components, in-process materials, packaging material, labels, and tobacco product meet specifications, as appropriate, and are not contaminated. Quality assurance personnel shall assure tobacco products manufactured, processed, packed, or held under contract by another company meet specifications. Quality assurance personnel shall be responsible for the review and evaluation of complaints under Subpart M, Section XXX.160.
XXX.35 Contamination Prevention

You shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

XXX.40 Qualification, Education, and Training

(a) Each person engaged in manufacturing, testing, packaging, labeling, or holding, or in performing any quality control operations, shall have the education, background, training, and/or experience to adequately perform the person's assigned functions.

(b) You shall assign personnel qualified by education, training, and/or experience to supervise the manufacturing, testing, packaging, labeling, or holding of tobacco products.

(c) You shall establish procedures for identifying training needs and ensure that appropriate personnel are trained to adequately perform their assigned functions. Training shall be documented to assure that personnel have a thorough understanding of their jobs, including the date of the training, the type or title of the training, and the person(s) trained.

Subpart C — Physical Plant and Grounds

XXX.50 Plant Grounds, Facilities, and Sanitary Operations

(a) Grounds. You shall keep the grounds of your physical plant in a condition that protects against contamination.

(b) Physical plant facilities. You shall maintain your physical plant in a clean and sanitary condition and repair to the extent necessary to protect against contamination.

(c) Cleaning compounds, pesticides, and other toxic chemicals. You shall use cleaning compounds and pesticides in a manner that does not result in contamination. Other toxic chemicals shall be used and stored in a manner that prevents them from coming into contact with tobacco products, materials, packaging, or contact surfaces.

(d) Pest control.

(1) You shall not allow animals in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination.

(2) You shall take effective measures to minimize pests from the physical plant and to protect against contamination.

(3) When monitoring indicates the need for the use of insecticides, fumigants, fungicides, or rodenticides, such products shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination.
(c) Water supply.

(1) You shall provide water that is safe and sanitary at suitable temperatures and under pressure as needed for all uses where water does not become a component of the tobacco product.

(2) Water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product, e.g., when such water is used as an ingredient or otherwise contacts tobacco products or any contact surface, shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product.

(f) Plumbing. The plumbing used in your physical plant shall be of an adequate size and design and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant into an adequate sewage system or through other adequate means;

(3) Avoid being a source of contamination or creating an unsanitary condition (e.g., not allow backflow or cross connection with wastewater or sewage); and

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.

(g) Bathrooms. You shall provide your employees with adequate, readily accessible bathrooms that are kept clean so as not to be a potential source of contamination.

(h) Hand-washing facilities. You shall provide adequate and accessible hand-washing facilities for manufacturing personnel.

(i) Trash disposal. You shall collect, store, and dispose of trash in a manner that protects against contamination. The handling, storage and disposal of trash shall not create malodors that contaminate tobacco products or result in an attraction, harborage or breeding place for pests.

(j) Sanitation supervisors. You shall assign one or more employees to supervise overall sanitation. Each of these supervisors shall be qualified by education, training, and/or experience related to the development or supervision of sanitation programs.

(k) Procedures. You shall establish procedures for cleaning the physical plant and for pest control.

XXX.53 Physical Plant Construction and Design

(a) Any physical plant you use in the manufacture of tobacco products shall:

(1) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitary operations necessary to protect against contamination; and
(2) Have adequate space for the placement of equipment and holding of tobacco products, packaging, and materials as is necessary to protect against contamination or mix-ups of components during manufacturing, packaging, labeling, or holding.

**Subpart D — Equipment and Utensils**

XXX.60 Equipment and Utensils

(a) You shall use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.

(b) Equipment and utensils shall be maintained and cleaned to prevent contamination.

(c) Instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination shall be:

(1) Accurate and precise for their intended use;

(2) Adequately maintained;

(3) Adequate in number for their designated uses; and

(4) Calibrated before first use and at a frequency specified by the manufacturer of the instrument or control or at intervals necessary to ensure their accuracy and precision.

(d) Equipment and utensils shall be removed, replaced or repaired when they no longer perform as designed or do not conform to the applicable reference standard.

(e) Automated, mechanical, and electronic equipment (including software for computer controlled processes), shall be:

(1) Appropriate for, and function in accordance with, its intended use;

(2) Controlled to consistently meet specifications, including controls to account for any changes to such equipment; and

(3) Routinely calibrated, inspected, or checked to ensure proper performance.

XXX.65 Procedures, Records and Recordkeeping

(a) You shall establish procedures for fulfilling the requirements of this subpart, including procedures for:

(1) Calibrating instruments and controls that you use in manufacturing or testing a tobacco product;

(2) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment;
(3) Maintaining, repairing, and cleaning, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold tobacco products, and

(4) Identifying what actions are to be taken if calibration accuracy or precision is not met or post-maintenance/repair testing does not meet performance requirements.

(b) Where the performance or accuracy of equipment and instruments may be necessary to assure that tobacco products meet specifications, you shall document any calibration, maintenance, and/or repair, each time it is performed, for instruments and controls that you use in manufacturing or testing a tobacco product.

(c) You shall make and keep records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment.

(d) Where the performance of equipment may be necessary to assure that tobacco products meet specifications, you shall make and keep records of the controls that you use to ensure that equipment functions in accordance with its intended use.

Subpart E — Document Controls

XXX.70 Procedures

You shall establish and maintain procedures to control all documents that are required by this Part. The procedures shall provide for the following:

(a) Document approval and distribution. Quality assurance or other qualified personnel shall review for adequacy and approve prior to issuance all documents established to meet the requirements of this Part. The approval, including the date and identification of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this Part shall be available at all locations for which they are designated, used, or otherwise necessary, and all documents established under this Part that are obsolete shall be promptly removed from all points of use or otherwise prevented from unintended use.

(b) Document changes. Changes to documents shall be reviewed and approved. Approved changes shall be communicated to the appropriate personnel in a timely manner. You shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the identification of the approving individual(s), the approval date, and when the change becomes effective.

Subpart F — Purchasing Controls

XXX.80 General

(a) You shall establish and maintain procedures to confirm that all purchased or otherwise received tobacco products, materials, and packaging conform to your specified requirements.

(b) You shall establish and maintain data that clearly describe or reference the specifications for purchased or otherwise received tobacco products, materials, and packaging. Purchasing
documents shall include, where possible, an agreement that the suppliers agree to notify the manufacturer of changes in the tobacco product, material, or packaging so that manufacturers may determine whether the changes may affect the specifications of a finished tobacco product.

XXX.85 Evaluation of Suppliers

(a) You shall establish and maintain the requirements that must be met by suppliers of tobacco products, materials and packaging.

(b) You shall evaluate and select suppliers on the basis of their ability to meet your specified requirements. The evaluation shall be documented.

(c) You shall define the type and extent of control to be exercised over the tobacco products, materials, and packaging suppliers based on the evaluation results.

(d) You shall establish and maintain a list of qualified suppliers.

Subpart G — Identification and Traceability

XXX.90 Identification

You shall establish and maintain procedures for identifying tobacco products, materials, and packaging during all stages of manufacture to prevent mix-ups. The procedures shall include where appropriate:

(a) Identifying electronically, by signage, or other method of identification all containers to identify their contents and, where necessary, the stage of processing of the batch or lot; and

(b) Identifying electronically, by signage, or other method of identification all processing lines and major equipment used during manufacturing, as necessary, to indicate their contents, including the name of the tobacco product and the specific batch number, control number, or lot number and, when necessary, the stage of processing of the batch or lot.

XXX.95 Traceability

You shall establish and maintain procedures providing for traceability between a finished tobacco product and its materials, packaging, and tobacco used to produce a given lot or batch of finished tobacco product. For tobacco, traceability extends to the tobacco as it was first introduced into the manufacturing process.

Subpart H — Manufacture and Process Controls

XXX.100 General Controls and Change Controls

(a) You shall develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to your specifications. Where deviations from specifications could occur as a result of the manufacturing process, you shall establish and maintain adequate process
control procedures to ensure conformance to specifications. Where process control procedures are necessary they shall include:

(1) Documented instructions or procedures that define and control the manner of manufacture;

(2) Monitoring and control of manufacturing processes to ensure conformance to specifications during manufacture; and

(3) A process for approving, in writing, new processes and process equipment or modifications thereto.

(b) You shall establish and maintain procedures for changes to a specification, process, or procedure. Prior to implementation, such changes shall be properly qualified, where appropriate.

XXX.110 Specifications

You shall establish specifications for any point, step, or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged and labeled as intended by the manufacturer. Such specifications shall be contained or referenced in the master manufacturing record.

XXX.114 Sanitation Requirements

You shall conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions determined by your evaluation of potential biological, chemical, and physical hazard to prevent contamination.

XXX.116 Master Manufacturing Record

You shall prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate for tobacco products. The master manufacturing record shall include, or reference the location of, the following information, where appropriate:

(a) Specifications;

(b) Manufacturing methods, manufacturing procedures or any manufacturing environment requirements;

(c) Quality control procedures;

(d) Evaluation criteria and quality control measures associated with any reprocessing activities; and
(e) Label and packaging specifications and methods and processes used to ensure conformance with such specifications.

XXX. 118 Batch or Lot Manufacturing Records

You shall establish and maintain procedures to ensure a batch or lot manufacture record is prepared for each batch or lot of a tobacco product that includes complete information relating to the manufacture and control of each batch or lot and accurately follows the appropriate master manufacturing record and each step taken in the manufacture of the batch or lot. The batch or lot manufacturing record shall include, or refer to the location of, the following information:

(a) The date(s) of manufacture;

(b) The quantity of tobacco product manufactured;

(c) The quantity of tobacco product distributed;

(d) The records demonstrating the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record;

(e) Any identification and control number(s) for the finished tobacco product and components, materials, and any labels and packaging included in the finished tobacco product; and

(f) A description of any reprocessing or rework activity associated with such batch or lot including records demonstrating the reprocessing conformed to the master manufacturing record.

Subpart I — Evaluation and Acceptance Activities

XXX.120 Receiving Acceptance and In-Process Evaluation

(a) You shall establish and maintain procedures for the acceptance of incoming tobacco products, materials, and packaging to assure specified requirements are met.

(b) You shall establish and maintain evaluation procedures, where appropriate, to ensure that specified requirements for in-process tobacco product are met.

(c) You shall maintain records of in-process tobacco product failing evaluation activities and their disposition required by this Part. These records shall include:

(1) Identification of such in-process tobacco product failing evaluation;

(2) The dates such in-process tobacco product failed the evaluations;

(3) The results of such evaluations;

(4) The identity of the individual(s) conducting the evaluation; and

(5) Where appropriate, the equipment used.
Subpart J — Nonconforming Tobacco Product

XXX.130 Procedures for Nonconforming Tobacco Product

(a) You shall establish and maintain a process to control tobacco products that do not meet specifications or are contaminated. The process shall address the identification, documentation, evaluation, segregation, and appropriate disposition of such nonconforming tobacco products.

(b) Identification of nonconforming tobacco products shall include documentation of the identity and quantity of the nonconforming tobacco product, the date the tobacco product was identified as nonconforming, the nonconformance, and the identity of the person who determined the tobacco product to be nonconforming.

(c) Evaluation of the nonconformance shall include an assessment of the risk posed by the nonconformance and a determination of the need for an investigation into the cause of the nonconformance. Where an investigation is conducted, it shall include a review of relevant manufacturing records, data and any other relevant information necessary to determine the cause of the nonconformance and to eliminate other possible causes.

(d) Segregation of the nonconforming tobacco product shall include clearly identifying and holding nonconforming tobacco product in a manner that prevents mix-ups.

(e) Disposition of nonconforming tobacco product that is nonconforming due to being out of specification may include an assessment of whether the nonconformance presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Personnel responsible for making such disposition determinations shall be identified.

(f) You may rework nonconforming tobacco product to bring it into conformance with specifications only if you can establish and verify a plan for ensuring the tobacco product meets specifications and is not contaminated.

(g) You shall establish and maintain a corrective action and preventive action program to address nonconforming tobacco products, when the risk posed by the nature of the nonconformance or the frequency of the nonconformance warrants such action. Such a program shall include the following:

(1) An investigation of the root cause of the nonconformance;

(2) Identification of the action(s) needed to correct and prevent recurrence of the nonconformance;

(3) Implementing such action(s); and

(4) Assessment and confirmation of the effectiveness of such action(s).

(h) You shall keep and maintain records of all activities required under this section.
Subpart K — Labeling and Packaging Operations

XXX.140 Labeling and Packaging

You shall establish and maintain a process to control labeling and packaging activities.

(a) Labels shall be printed and applied to finished tobacco products so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and sale.

(b) You shall establish a process to ensure that labels received from suppliers conform to the label specifications.

(c) You shall manage label storage, label application and packaging operations to prevent mix-ups.

(d) You shall ensure that any numbers, codes and/or markings used to identify the tobacco product batch or lot are adequately applied to labels or packaging on finished tobacco products.

(e) Tobacco product packaging and shipping cases or containers shall be designed and constructed to protect against the contamination of finished tobacco products during customary conditions of processing, storage, handling, distribution and sale.

XXX.145 Repackaging and Relabeling

You shall establish and maintain a process to manage repackaging and relabeling operations that meets the requirements set forth in Section XXX.140.

Subpart L — Holding and Distribution

XXX.150 Handling and Storage

You shall establish and maintain procedures to ensure tobacco products are held under appropriate conditions to protect against the possibility of mix-up or contamination.

XXX.155 Distribution

You shall establish and maintain a process to ensure finished tobacco products are distributed under appropriate conditions to protect against contamination. You shall establish and maintain records that include:

(a) The identification of the initial consignee;

(b) The identification and quantity of the finished tobacco product shipped;

(c) The date of shipment; and

(d) Any code used to identify the finished tobacco product and/or batch or lot.
Subpart M—Complaints

XXX.160 Review and Investigation of Complaints

Quality assurance or other qualified personnel shall:

(a) Review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products;

(b) Evaluate the need for an investigation; and

(c) Where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

XXX.165 Required Records

(a) You shall make and keep the following complaint records:

(1) Procedures for fulfilling the requirements of this subpart.

(2) A record of every complaint. The record of the complaint shall include, where available, the following:

(i) The name and description of the finished tobacco product;

(ii) The batch, lot, or control number of the finished tobacco product;

(iii) The date the complaint was received and the name, address, or telephone number of the complainant;

(iv) The nature of the complaint including, if known, how the finished tobacco product was used;

(v) The reply to the complainant, if any; and

(vi) The identification of the person receiving the complaint.

(3) Where complaints are investigated, the record of the investigation shall include:

(i) A record of the investigational activities performed; and

(ii) The findings of the investigation and follow up action(s) taken as a result of the investigation.
Subpart N — Records and Recordkeeping

XXX.170 General

(a) You shall establish procedures to fulfill the requirements of this Part.

(b) You shall make and keep records required under this Part in accordance with this subpart.

(c) All records required by this Part shall be maintained at the establishment where the operations were conducted or other location that is reasonably accessible to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available during the retention period to FDA employee(s) for inspection and copying when requested. Such records shall be legible and shall be stored to minimize deterioration and to protect against loss. Those records stored in automated data processing systems shall be backed up.

(d) Records shall be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, you shall make suitable reader and photocopying equipment readily available to FDA.

XXX.174 Record Retention

You shall keep records for at least 2 years beyond the date of manufacture of the last batch or lot of finished tobacco products associated with those records.

XXX.178 Confidentiality

Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in Part 20 of this chapter.

Effective Date:

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register.
Attachment 2
PART __ — CURRENT GOOD MANUFACTURING PRACTICE IN
MANUFACTURING, PACKING, AND STORAGE OPERATIONS FOR TOBACCO
PRODUCTS

AGENCY: Food and Drug Administration, HHS

SUMMARY: The Food and Drug Administration ("FDA") is proposing to establish current
good manufacturing practice ("cGMP") regulations for tobacco products. The proposed rule
establishes cGMP requirements for the manufacture, labeling, packing, and storage of tobacco
products to ensure that the tobacco products are not adulterated or misbranded. The proposed
rule is one of many actions related to tobacco products that FDA is taking pursuant to the Family
Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (the "Tobacco Control Act" or
"Act"). The Tobacco Control Act added authorities to the Federal Food, Drug, and Cosmetic
Act ("FDCA") to enhance public health protection.

I. Background and Related Information

A. Purpose

The Tobacco Control Act became law on June 22, 2009. This Act gives FDA the authority to
regulate the manufacture, distribution, and marketing of tobacco products. To that end, FDA is
empowered to prescribe regulations to protect the public health and assure that tobacco products
are in compliance with the provisions of the Act by requiring good manufacturing practices or
hazard analysis and critical control point methodology. Accordingly, certain members of the
tobacco industry ("Identified Companies")\(^1\) are proposing the attached cGMP regulations for
consideration by the FDA.

The tobacco industry produces a diverse array of tobacco products, many of which involve
different manufacturing processes. Even the manufacturing processes within the same category
of tobacco product may vary in numerous ways. Thus the Identified Companies are proposing
cGMPs that provide sufficient direction for the establishment of adequate manufacturing controls
without providing detailed instruction for what specific criteria should be used to implement the
controls. This framework will enable the Agency to protect the public health with respect to this
unique product category while giving individual manufacturers the opportunity to meet the goal
of the cGMPs in an effective manner that allows for flexibility and innovation. More
specifically, the cGMPs require each manufacturer to identify and establish certain procedures
and practices but allow the specific practices and procedures to be tailored to the category of
tobacco product, and the attributes of the specific tobacco products, produced by the
manufacturer. The extent and nature of documentation and practices necessary to meet the

\(^1\) The industry stakeholders include the following companies: R.J. Reynolds Tobacco Company, Santa Fe Natural
Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA
America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., and
Hail & Cotton, Inc.
requirements of the proposed cGMPs will vary according to the complexity of the manufacturing operations and the risks associated with the failure to implement a given practice.

The proposed cGMPs take into account that tobacco products are unique when compared to other products regulated by the FDA because of the inherent variability of tobacco (as an agricultural crop) and the inherent risk to users of the products. For example, the cGMP regulations for drugs and medical devices were established in part to ensure that the drug or device meets the safety requirements of the FDCA. See 43 Fed. Reg. 45014 (Sept. 29, 1978) (a drug is deemed adulterated unless it "conforms to [cGMP] so that the drug meets the safety requirements of the Act and has the identity and strength and meets the quality and purity characteristics that it is represented to have."); 43 Fed Reg. 31508 (July 21, 1978) (medical devices must "conform to [cGMP] requirements, as prescribed in the regulation, to assure that devices are safe and effective and otherwise in compliance with the act.").

FDA found that many device recalls "resulted from manufacturers’ failure to follow good manufacturing practices" and, therefore, found it "vitaly important that devices be manufactured in accordance with quality assurance principles that help prevent the production of defective products that can endanger consumers." Id. The cGMP regulations for dietary supplements were established to ensure that consumers do not suffer harm and obtain the purported health benefit from the consumption of dietary supplements. 68 Fed Reg. 12159 (Mar. 13, 2003) (a dietary supplement is adulterated if it "contains contaminants because [the supplement does] not contain the dietary ingredient it is represented to contain or because the amount of the dietary ingredient thought to provide a health benefit is not actually present in the supplement"). Unlike the cGMPs for drugs, medical devices, and dietary supplements, cGMP regulations for tobacco products are not meant to assure the safety and effectiveness of a tobacco product—because of their inherent risk to users of the products—but rather to "assure that the public health is protected and that the tobacco product is manufactured in compliance" with the Act. Tobacco Control Act, §906(c)(1).

Therefore, the purpose of the proposed cGMP regulation is threefold: (1) to protect the public health by providing assurance that tobacco products are not contaminated (prohibiting the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product); (2) to prevent misbranded tobacco products; and (3) to allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.

B. Inherent Risks Associated With the Use of Tobacco Products

Underpinning the proposed cGMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products. When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was "to continue to permit the sale of tobacco products to
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

adults." FDCA § 907(d)(3)(A) (FDA is expressly "prohibited" from issuing a regulation "banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products.").

Thus the cGMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks and, given the purpose of the cGMPs, not require manufacturers to address those risks in this context. Unlike for drugs, medical devices, dietary supplements, and food, the tobacco product cGMPs cannot require tobacco manufacturers to assure their products are safe and/or effective.

In light of these considerations, the Identified Companies’ proposed cGMP regulation provides direction to tobacco product manufacturers to control their manufacturing processes in a manner that would prevent the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products. Further, the proposed regulation directs tobacco product manufacturers to control their manufacturing processes so that the tobacco product is not misbranded. The Identified Companies believe that these elements are central to meeting the Congressional intent as expressed in Section 906(e) of the Tobacco Control Act.

C. Inherent Variability of Tobacco Products

Tobacco — the main ingredient in tobacco products — is of an agricultural origin, and therefore tobacco products are subject to natural variation. Each type of tobacco, e.g., flue-cured, dark air-cured, fire cured, burley, and oriental, has its own particular taste and aroma. Moreover, there are variations in these attributes within each type according to the tobacco’s grade (i.e., quality), stalk position, geographic origin, and year of harvest. Tobacco product manufacturers combine different types of tobacco to produce a distinctive “blend” that is primarily responsible for giving each tobacco product its distinctive sensory characteristics (similar to the blending processes that occur in other agricultural based consumer products, such as coffee, wine, and beer). Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

This inherent variability of tobacco results in unavoidable variations in the tobacco blends. To compensate for these natural variations and maintain the consistency of the tobacco product, a tobacco product manufacturer must routinely adjust the tobacco blends — for example, by blending across several crop years of one type of tobacco. FDA acknowledged that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco ... in order to maintain a consistent product” in a recent guidance document. CENTER FOR TOBACCO PRODUCTS, GUIDANCE FOR INDUSTRY AND FDA STAFF: SECTION 905(j) REPORTS: DEMONSTRATING SUBSTANTIAL EQUIVALENCE FOR TOBACCO PRODUCTS 4 (2011). FDA has also acknowledged that such adjustments to the tobacco blend are not “intended to alter the chemical or perception properties” of a tobacco product, but rather maintain a consistent product. Id.
Therefore, the direction to manufacturers provided by the proposed cGMP regulation recognizes the inherent variability unique to tobacco products. This is achieved by providing tobacco product manufacturers the flexibility necessary to manufacture, label, pack, and store in a manner allowing for such variability but not permitting (a) the introduction of substances not ordinarily contained in tobacco products that would present a risk of injury to the consumer beyond that generally posed by the same category of tobacco products or (b) misbranding.

II. Proposed Rule

Subpart A – General Provisions

XXX.1 Applicability

The language in subsection (a) of this section essentially tracks the Tobacco Control Act authority over tobacco product manufacturers. In other words, if a facility meets the Tobacco Control Act definition of a tobacco product manufacturer, then it will be covered by the proposed cGMP regulation to the extent it manufactures tobacco products within FDA’s jurisdiction under Section 901(b). While the storage of tobacco products by a tobacco product manufacturer is within the scope of the regulation, a distributor as defined in Section 900(7) of the FDCA is exempt from these regulations. Subsection (b) provides further clarity with respect to the non-applicability of the requirements to storage activities at retail. The other subsections essentially restate other provisions of the Tobacco Control Act. Also, small tobacco product manufacturers, as defined by Section 900(16) of the Tobacco Control Act, are not required to comply with the cGMP regulation for at least 4 years following the effective date of the regulation. See Section 906(e)(1)(B)(v).

XXX.3 Definitions

This section provides definitions for certain relevant terms used in the proposed cGMP regulation that are not defined in Section 201 of the FDCA or the Tobacco Control Act. While the defined terms in the regulation speak for themselves, we have elaborated on the intent of certain of the defined terms below.

The definition for “batch or lot” provides the tobacco manufacturer with the flexibility to define “any specific quantity or manufacturing period” as a “batch or lot” as long as tobacco product being manufactured during such a “batch or lot” is intended to meet the same specifications. Such flexibility is necessary for tobacco product manufacturers because some tobacco products are not made in discrete “batches” but are manufactured by continuous production.

The definition of “contaminant” recognizes the unique risk profile of tobacco products. They are agricultural products that, for that reason, naturally include substances other than tobacco. This definition also acknowledges the inherent risks associated with tobacco products, as described in Section I.B. Thus, a substance becomes a “contaminant” only when it has been added to a tobacco product, is not intended to be in the tobacco product, and presents a risk beyond that generally posed by the same category of tobacco products. This concept is consistent with the
language in the mandatory recall provisions of Section 908(c)(1). It is not necessary to eliminate from tobacco products added substances that ordinarily are contained in tobacco products because of their agricultural nature or that do not increase the health risk of the tobacco products. The "master manufacturing record" is where the procedures and specifications for manufacturing a finished tobacco product are found. It is the key repository of manufacturing requirements and controls and may comprise several documents or files or an index identifying them and their location.

The "quality" of a tobacco product refers to whether the product meets the manufacturer's specifications and is not contaminated. Because of the inherent risks posed by tobacco products, those are the two elements of what is ordinarily considered product quality that need to be addressed by this Part in order to protect the public health.

"Rework" means action taken on a nonconforming tobacco product so that it is suitable for use before it is released for further processing or distribution. Tobacco products to be reworked require an evaluation and disposition prior to use.

A "specification" is any requirement that a manufacturer defines as a specification in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform. The manufacturer defines what the product and processing specifications should be. What the manufacturer may describe as parameters, limits, criteria, or like terms are not specifications unless the manufacturer defines them as such in the master manufacturing record. This provision also recognizes that tobacco product manufacturers may use in-process rather than finished product specifications if the manufacturer otherwise is in compliance with this Part.

Subpart B — Personnel

Sections XXX.20, XXX.30, and XXX.31 require a manufacturer to have adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority. At the same time, these provisions recognize that no formal quality unit is required. In the case of tobacco products, such personnel may have duties other than quality assurance as well, as long as the quality assurance duties are well-defined and adequately carried out, as specified in the regulation.

Section XXX.35 requires a manufacturer to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.

Subpart C — Physical Plant and Grounds

The terms "clean and sanitary", as used in Section XXX.50(b), mean a manufacturer's physical plant shall be kept clean to the extent necessary to protect against contamination, taking into account the inherent risks of tobacco products and an analysis of the risks of contamination, as
that term is defined in Section XXX.3. The term “sanitary” is not intended to require sanitization, sterilization, or any other specific form of cleaning beyond what the risk analysis determines is necessary. This requirement is consistent with the application of the concepts associated with hazard analysis and critical control point (HACCP) methodology to sanitation in Section XXX.114.

Section XXX.50(d)(3) requires that insecticides, fumigants, fungicides, or rodenticides, used for pest control activities shall be used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act as applicable, and the use shall follow label directions including any required precautions when directed to protect against contamination. Foreign manufacturers not subject to the Federal Insecticide, Fungicide and Rodenticide Act shall comply with their own national or local requirements governing the use of such pesticides and shall not contaminate the tobacco product.

Section XXX.50(c)(2) requires that water that is used in the manufacturing process in a manner such that the water will or may become a component of the tobacco product, shall, at a minimum, be supplied from sources required to comply with applicable Federal, State, and local requirements and shall not contaminate the tobacco product. Foreign manufacturers shall comply with their own national or local requirements governing water quality and shall not contaminate the tobacco product.

**Subpart D – Equipment and Utensils**

Section XXX.60(e) generally requires equipment to be adequately calibrated and controlled. That requirement applies to software used to control processes. The requirement to control certain software, including the requirement in Section XXX.60(c)(2) to control such software to ensure that specifications consistently are met, is not intended to require software validation. Such control may be achieved by a process of qualification, calibration, monitoring, verification checks, other methods, or some combination thereof, as determined to be appropriate for the particular equipment and processes by the manufacturer.

**Subpart E – Document Controls**

Section XXX.70 requires a manufacturer to establish and maintain procedures to control documents required by the cGMP regulations. Such procedures shall include, among other things, controls for approving documents, making changes to documents, and approving those changes. Both Section XXX.70(a) and (b) require that the individuals approving documents or changes to them be identified. Identification of such individuals in the document control system, whether in electronic or paper form, or some combination thereof, is sufficient in lieu of such individuals' signatures, provided that the document control procedures require the approving individual personally to identify him- or herself in some way and the identity of such individuals is not merely assigned automatically by the document control system or other personnel.
Subpart F – Purchasing Controls

Section XXX.80 requires manufacturers to have purchasing controls for incoming tobacco products, materials and packaging, as those terms are defined in Section XXX.3. Manufacturers have the flexibility under this provision to determine the type and extent of such controls based on the needs for their specific products and manufacturing processes.

Section XXX.85 requires manufacturers to establish and maintain the requirements that must be met by suppliers of tobacco products, materials and packaging. The specific requirements may vary based on an evaluation of the potential risk posed by the supplied material (e.g. tobacco ingredient vs. packaging component) but should include supplier evaluation criteria and maintaining a list of qualified suppliers.

Subpart G – Identification and Traceability

The identification requirements of Section XXX.90(a) are meant to apply wherever there is a reasonable possibility of mix-ups. It may not be necessary to identify the contents of some containers because the risks of mix-up, or the consequences of a mix-up, are small, such as where the use of a particular container or tobacco product is limited to one area of the manufacturing facility.

Section XXX.95 requires traceability that will assist manufacturers in identifying other potential batches or lots of finished tobacco products that might be affected by a product quality issue that arose during manufacturing and was detected in a particular finished tobacco product batch or lot, which, in turn, will assist manufacturers in conducting any necessary market withdrawals or recalls. For tobacco, by requiring traceability back only to the tobacco as first introduced into the manufacturing process, this provision makes clear that manufacturers are not required to establish traceability all the way back prior to its introduction into the manufacturing process, such as to the growers or sellers of the raw tobacco. This traceability requirement does not extend to farms because the tobacco is mixed after received from farms during leaf processing (or “stemmaery”) operations, which are defined as “tobacco warehouses” in Section 900(21) of the FSPTCA. After such processing, the raw tobacco is typically stored for a few years prior to being introduced into the manufacturing process. Also, FDA does not have jurisdiction over tobacco farms or tobacco warehouses (with certain exceptions) under Chapter IX of the FSPTCA.

Subpart H – Manufacture and Process Controls

Under Section XXX.100, manufacturers are required to control their processes to ensure their tobacco products meet specifications. However, the specific control measures to be utilized are determined by the manufacturer so that it has the flexibility to identify and execute the control measures best suited to its manufacturing operations and tobacco products.

Section XXX.114 provides that a manufacturer should develop its sanitation control program by using a risk based approach that is informed by an evaluation of potential biological, chemical,
and physical hazards. These criteria are consistent with those used in the food industry when applying “HACCP”. While this section does not mandate a formal HACCP program, it does require manufacturers to undertake a HACCP-like evaluation to support its sanitation controls.

Section XXX.116 requires the development of a master manufacturing record, which is the key record documenting manufacturing controls. The development of the specifications in the master manufacturing record, beginning when the cGMP regulation takes effect, shall be based upon defined tobacco product development and manufacturing scale-up processes. The manufacturer shall ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate to assure tobacco product requirements are met. This provision is intended to address the “preproduction design validation” language in FDCA Section 906(e)(1)(A).

The provisions in this Subpart H and the rest of this Part are not meant to require process validation. For tobacco products, adequate process controls might take the form of in-process control parameters, such as temperature or processing speed; equipment qualification and calibration; in-process quality checks; or other controls appropriate to the processes and tobacco products, as determined by the manufacturer.

Subpart I – Evaluation and Acceptance Activities

Section XXX.120 makes it incumbent on a manufacturer to establish appropriate procedures for the acceptance of incoming tobacco products, materials and packaging and the evaluation of in process tobacco products to assure specified requirements are met. Acceptance activities may include visual checks, testing or verification of supplier Certificates of Analysis. Because of the unique nature of tobacco products, as explained in the introductory paragraphs above, in-process or finished tobacco product testing is not required unless a manufacturer determines under other provisions of this Part that it is a necessary process control and makes such testing part of a specification in the master manufacturing record.

Subpart J – Nonconforming Tobacco Product

Under Section XXX.130, a tobacco product is nonconforming if it does not conform to the applicable specifications in the master manufacturing record or is contaminated, as that term is defined in Section XXX.3. A manufacturer must have a process to evaluate and handle nonconforming tobacco product as described in Section XXX.130.

Section XXX.130(c) requires that process to include a risk assessment and a determination of the need for an investigation into the cause of the nonconformance. A manufacturer’s process for handling nonconforming tobacco product therefore should include criteria to evaluate the risk posed by the nonconformance and to determine how the tobacco product should be dispositioned. This provision gives direction to a manufacturer without specifying all of the criteria to be used for the investigation and disposition decisions because such criteria should be based on the attributes of the specific tobacco product and its manufacturing processes.
Under Section XXX.130(e), the disposition determination shall include an assessment of whether the nonconformance is a defect not ordinarily contained in the same category of tobacco products and whether that defect presents a risk of injury beyond that generally posed by the same category of tobacco products. That assessment already will have occurred in the case of contaminated product because of the definition of contamination in Section XXX.3, but such an assessment shall also be done in the case of a tobacco product that does not conform to specifications.

**Subpart K – Labeling and Packaging Operations**

Section XXX.140 requires a manufacturer to establish and maintain a process to control labeling and packaging activities. Provided that such process ensures that labels conform to specifications and that labels and packaging are managed to prevent mix-ups, a manufacturer is not required to quarantine or otherwise hold incoming labels prior to their introduction into labeling and packaging operations. This provision provides direction to a manufacturer to establish an effective process without specifying an evaluation and release process or other particular steps in the process.

**Subpart L – Holding and Distribution**

Although Sections XXX.150 and XXX.155 contain storage and distribution requirements, such requirements do not apply to a “distributor” as defined in Section 900(7) of the FDCA.

**Subpart M – Complaints**

Section XXX.160 requires a manufacturer to review all complaints. This provision does not attempt to specify all of the criteria a manufacturer must use to evaluate complaints or to determine whether an investigation is necessary. However, consistent with the language in the mandatory recall provisions of the FSPTCA, Section 908(c)(1), and the reporting provisions of the FSPTCA, Section 909(a), this provision requires quality assurance personnel or other qualified personnel, as described in XXX.31, to evaluate whether the complaint involves a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products and, in most cases, to investigate such complaints. Such complaints may not need to be investigated if they previously have been investigated and the cause of the defect is known. Additionally, given that smokers may experience certain transient effects (e.g. headaches) and consumers of smokeless tobacco products may as well (e.g. nausea), all complaints alleging health effects may not need to be investigated. This provision makes clear that an assessment of potential health hazards is a critical element of the complaint evaluation and investigation process. The term “acute” has been included in the description of the applicable health hazards for those purposes because the complaint handling process required by this section is not intended to handle allegations of chronic health effects related to the inherent risks of tobacco products as referenced in Section I.B.
PREAMBLE FOR PROPOSED TOBACCO PRODUCT GMP REGULATION

Effective date

This rule takes effect a minimum of two years from publication of the final rule in the Federal Register. Consistent with FDCA Section 906(e)(B)(iv), the proposed effective date is necessary to provide a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein. The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.
January 10, 2012

Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Beverly Chernaik
Director, Office of Regulations
U.S. Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850

Re: PROPOSED TOBACCO PRODUCT GOOD MANUFACTURING PRACTICES REGULATION AND REQUEST FOR MEETING

Dear Ms. Simoneau and Ms. Chernaik:

As indicated in its December 16, 2011 letter, R.J. Reynolds Tobacco Company ("RJRT") has worked with various tobacco industry stakeholders to develop proposed current Good Manufacturing Practice ("cGMP") regulations pursuant to Section 906(e) of the Family Smoking Prevention and Tobacco Control Act. Specifically, the industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., and Hail & Cotton, Inc. (collectively referred to herein as the "Companies").

RJRT, on behalf of the Companies, submits to the United States Food and Drug Administration's ("FDA") Center for Tobacco Products ("CTP") for its review and consideration (1) proposed cGMP regulations and (2) a preamble to the proposed regulations. While each of the Companies reserves its right to express its own opinions regarding the proposed regulations and preamble, the preamble provides the Companies' common perspective and interpretation of the provisions of the proposed cGMP regulations. (See Attachments 1-2.)

The Companies believe the proposed cGMP regulations and preamble will help to facilitate a productive dialogue consistent with CTP's expressed goal to engage with and understand the tobacco product manufacturing industry. In that regard, the Companies
respectfully request a 2-hour meeting to discuss the proposed cGMP regulations and preamble attended by you and any other appropriate CTP representatives and representatives from the Companies. We will identify the specific Companies' representatives that plan to participate at least one week prior to the meeting. The Companies propose the following general agenda:

- Introductions and meeting objectives
- The Companies' approach to developing the proposed cGMP regulations and preamble
- Overview of the proposed cGMP regulations and preamble
- Discussion with CTP, including addressing CTP's questions regarding the proposed cGMP regulations and preamble.

Any planned presentations will be submitted to CTP at least one week prior to the meeting. In addition, should CTP wish to provide the Companies with questions in advance of the meeting, we will be prepared to address them.

The Companies are committed to working with the Agency to establish appropriate cGMP regulations for tobacco product manufacturers and look forward to discussing this matter with CTP. RJRT will contact you in the upcoming weeks to schedule a meeting at your earliest convenience. If you require any additional information or have any questions, please do not hesitate to contact me.

Respectfully Submitted,

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
June 15, 2012

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R.J. Reynolds Tobacco Company
401 N. Main St.
P.O. Box 2959
Winston-Salem, NC 27102

Re: May 2, 2012 Industry Stakeholder Presentation to the Center for Tobacco Products

Dear Dr. Swauger:

Enclosed please find minutes to the May 2, 2012 meeting regarding proposed good manufacturing practices for tobacco products, with attachments (presentation slides and attendee list). Please ensure all who attended receive a copy of this correspondence. Feel free to contact me if you have any questions. I can be reached at 301-796-5533 or via email at Joanna.Weitershausen@fda.hhs.gov.

Sincerely,

Joanna Weitershausen
Enforcement and Manufacturing Group
Office of Compliance and Enforcement
Center for Tobacco Products

Enclosures:
(1) Meeting Minutes
(2) Presentation Slides
(3) Attendee List
Industry Stakeholder Presentation to CTP
Proposed Good Manufacturing Practices for Tobacco Products
May 2, 2012

Ann Simoneau, Center for Tobacco Products, Office of Compliance and Enforcement
Ms. Simoneau explained that the purpose of the meeting was to provide an opportunity for industry to present their proposed GMP regulation to CTP. She explained that, because FDA rulemaking is conducted in a manner consistent with the Administrative Procedure Act, under which all members of the public are offered an opportunity to participate, CTP could not engage in any kind of substantive discussion of the merits of the proposal or any other matter regarding the development of the regulation. She explained that there will be other opportunities for stakeholders to provide additional information and comments to FDA during the rulemaking process.

Dr. Charles Garner, R.J. Reynolds Tobacco Company
Dr. Garner presented slides 1-5, which included the objectives of the meeting, the developmental process for the proposed GMP regulation, the industry stakeholders in support of the proposed GMP regulation, and the statutory requirements for the GMP regulation.

Pamela Lieberman, Altria Client Services
Ms. Lieberman presented slides 6-23. She described the purposes of the industry-proposed GMP regulation: the inherent risks associated with tobacco products require that the GMP regulation for tobacco products differ from the cGMPs for drugs and medical devices. She stated that, unlike drugs and medical devices, the tobacco product GMPs cannot require tobacco manufacturers to assure their products are safe and/or effective. Rather, she explained, tobacco product GMPs are to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the FSPTCA. Accordingly, Ms. Lieberman explained that the purpose of the proposed GMP regulation is to assure that tobacco products are not contaminated and not adulterated or misbranded.

Further, Ms. Lieberman described how the inherent variability of tobacco requires tobacco manufacturers to periodically adjust the tobacco blend in a product in order to maintain product consistency. Accordingly, according to Ms. Lieberman, another purpose of the proposed GMP regulation is to allow manufacturers flexibility in the activities associated with tobacco product manufacturing while assuring all such activities are conducted in a controlled manner.

Ms. Lieberman described how the proposed rule covered areas in which the stakeholders found common ground. She then provided a brief overview of several subparts of the proposed GMP regulation, including general provisions, personnel, physical plant and grounds, equipment and utensils, manufacture and process controls, labeling and packaging operations, complaints. For example, Ms. Lieberman described how the proposed GMP regulation:
• Provides definitions for select terms such as “batch or lot,” “contaminant,” “quality,” or “specification.” She explained that the definitions were written to cover a wide variety of tobacco products.

• Requires a manufacturer to provide adequate resources to comply with the regulations, including personnel designated to have certain quality assurance responsibility and authority.

• Would not require a formal quality control unit, so personnel can have overlapping responsibilities (dietary supplements approach)

• Includes requirements necessary to protect against contamination

• Incorporates HACCP principles (section 114)

• Requires manufacturers to use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained

• Requires manufacturers to develop, conduct, control, and monitor manufacturing processes to ensure that tobacco products conform to specifications

• Requires manufacturers to establish and maintain a process to control labeling and packaging activities

• Requires that quality assurance or other qualified personnel review all complaints and, where appropriate, investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products. Ms. Lieberman stated that this language is consistent with FDCA section 909's mandatory recall and reporting requirements.

Lastly, Ms. Lieberman discussed the statute’s requirement for the effective date of the future GMP regulation. She said that the regulation would take effect a minimum of two years from the publication of the final rule in the Federal Register and that small tobacco manufacturers would not be required to comply for at least 4 years following the effective date of the regulation.

Ann Simoneau, Center for Tobacco Products, Office of Compliance and Enforcement

Ms. Simoneau explained that CTP is educating itself about the GMPs of the other Centers, but that we are not bound by what other Centers have done. She also explained that, although there is currently no docket or proposed rule associated with the 906(e) regulation to date, industry is encouraged to share additional data and science with the FDA.

Questions and Answers
Following the presentation, there was a short question and answer period. Following that, the meeting was adjourned.
Proposed Good Manufacturing Practices for Tobacco Products:
Industry Stakeholder Presentation to CTP

May 2, 2012
Meeting Objectives

- Share with CTP:
  - The process the industry stakeholders used to develop the proposed GMP
  - Industry stakeholder perspective on the proposed GMP and preamble

- Help the industry stakeholders understand the CTP's current thinking on the process and timing for the development of tobacco product GMPs

- Begin a dialogue with CTP on development of tobacco product GMPs
Developmental Process for Proposed GMP Regulation

- Diverse group of stakeholders including large and small manufacturers and suppliers
- Began initial discussions spring-2011 to develop a GMP approach appropriate for tobacco product manufacturing
- Considered the scope and range of both tobacco products and manufacturing processes
- Submitted proposed GMP regulation and preamble to the Agency, January 10, 2012
- In the ensuing period, other tobacco product manufacturers and suppliers have been supportive of this approach
- General consensus-current version appropriate for tobacco products
Supporting Industry Stakeholders

- R.J. Reynolds Tobacco Company
- Santa Fe Natural Tobacco Company, Inc.
- American Snuff Company, LLC
- Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company
- Lorillard, Inc.
- Commonwealth Brands, Inc
- Ligget Group LLC

- The SMARTT Coalition, which includes Nat Sherman, Commonwealth Brands, Inc. Japan Tobacco International, King Maker Marketing, Inc.
- Vector Tobacco Inc.
- National Tobacco Company, L.P.
- Hail & Cotton, Inc.
- Swedish Match North America
- CITMA
- Mundet
Statutory Requirements for GMP Regulation

• The FSPTCA* requires that the FDA prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing and storage of tobacco products conform to (i) cGMPs or (ii) hazard analysis and critical control point methodology ("HACCP").

* Federal Food, Drug, and Cosmetic Act ("FDCA") Section 906(e), as amended by the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").
Proposed GMP Regulation and Preamble

- The proposed GMP Regulation is intended to meet the statutory requirements of the FSPTCA and draw from existing cGMP regulations where controls were deemed appropriate.

- The proposed GMP Regulation provides direction without a high degree of specificity, requiring a controlled manufacturing process but allowing each manufacturer discretion as to the types of controls and level of control (e.g. specifications).

- Such flexibility will also allow manufacturers to adopt additional controls in the future in the event tobacco product standards are promulgated by the FDA.
Proposed GMP Preamble

- Background and Related Information
  - Purpose
  - Inherent risks associated with the use of tobacco products
  - Inherent variability of tobacco products

- Proposed Rule
  - Rationale for key tobacco-related definitions
  - Explanation of key elements of the “proposed rule”
Proposed GMP Regulation

• Unlike the FDA cGMPs for drugs and medical devices, the proposed GMP regulations for tobacco products are not meant to assure the “safety and effectiveness” of a tobacco product (as those terms are traditionally used by FDA) – because of the inherent risks associated with the use of different categories of tobacco products – but rather to “assure that the public health is protected and that the tobacco product is manufactured in compliance” with the Act. Tobacco Control Act, §906(e)(1).
Purpose of Proposed GMP Regulation

- To protect the public health by providing assurance that tobacco products are not contaminated (prohibiting the introduction of substances in the tobacco product not ordinarily contained in tobacco products that present a risk of injury beyond that generally posed by the same category of tobacco product);

- To provide assurance that the manufacturing of tobacco products does not result in such products being adulterated or misbranded; and

- To allow tobacco product manufacturers the flexibility to manufacture, label, pack, and store tobacco products to account for different categories of tobacco products, different manufacturing processes, and the inherent variability of tobacco, while assuring all such activities are conducted in a controlled manner.
Proposed GMP Regulation: Inherent Risks of Tobacco Products

- Underpinning the proposed GMP regulation for tobacco products is an acknowledgement that the U.S. Surgeon General and other public health authorities have identified certain inherent risks associated with the use of different categories of such products.

- When Congress enacted the Tobacco Control Act, it acknowledged such inherent risks but did not ban such products, clearly stating that the intent of the act was "to continue to permit the sale of tobacco products to adults." Tobacco Control Act, §907(d)(3)(A).

- Thus the GMP regulation for tobacco product manufacturers must take into account that tobacco products have inherent risks.

- Unlike drugs and medical devices, the tobacco product GMPs cannot require tobacco manufacturers to assure their products are safe and/or effective as those terms are traditionally used by FDA.
Proposed GMP Regulation: 
Inherent Variability of Tobacco Products

• Tobacco is of an agricultural origin and therefore tobacco products are subject to natural variation.

• Tobacco product manufacturers must use a combination of science and art to (1) achieve a tobacco blend that delivers a distinctive adult tobacco product consumer experience, and (2) adjust the blend to maintain consistency of that tobacco product to account for natural tobacco variability.

• FDA acknowledged that tobacco manufacturers are “required” to periodically adjust the tobacco blend in a product “to address the natural variation of tobacco . . . in order to maintain a consistent product” in a recent guidance document.*

* Center For Tobacco Products, Guidance For Industry And FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence For Tobacco Products 4 (2011).
Proposed GMP Regulation: Subparts

A. General Provisions
B. Personnel
C. Physical Plant and Grounds
D. Equipment and Utensils
E. Document Controls
F. Purchasing Controls
G. Identification and Traceability
H. Manufacture and Process Controls
I. Evaluation and Acceptance Activities
J. Nonconforming Tobacco Product
K. Labeling and Packaging Operations
L. Holding and Distribution
M. Complaints
N. Records and Recordkeeping
Subpart A: General Provisions

XXX.3 Definitions

- Batch or Lot
- Complaint
- Contact Surface
- Contaminant
- Finished tobacco product
- Import
- In-process tobacco product
- Label
- Master Manufacturing Record
- Material
- Package
- Pest
- Physical Plant
- Quality
- Reprocessing
- Rework
- Specification
- Tobacco Product
- Tobacco Product Manufacturer
Proposed GMP Regulation: XXX.3 Definitions - Select Terms

- "Batch or lot means any specific quantity or manufacturing period of a tobacco product defined as a batch or lot by a tobacco product manufacturer in the master manufacturing record that is intended to meet the same specifications."

- "Contaminant means any added substance not ordinarily contained in tobacco products that presents a risk of injury beyond the risks generally posed by the same category of tobacco products. Contaminate or Contamination refers to a contaminant in a tobacco product, material, packaging, or on a contact surface."

- "Quality means that the tobacco product meets the manufacturer’s specifications and is not contaminated."

- "Specification means any requirement defined as a specification by a tobacco product manufacturer in the master manufacturing record to which a finished or in-process tobacco product or manufacturing process must conform."

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

- Subpart B - Personnel

  - Requires a manufacturer to “provide adequate resources, including personnel, to comply with the regulations and, specifically, personnel designated to have certain quality assurance responsibility and authority.”

  - For example, “quality assurance personnel shall assure all components, in-process materials, packaging materials, labels, and tobacco products meet specifications, as appropriate, and are not contaminated.”

  - Requires a manufacturer to “establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and tobacco product, packaging, or materials could reasonably be expected to result in contamination.”

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation: Illustrative Examples

• Subpart C – Physical Plant and Grounds
  – Includes requirements necessary to protect against contamination for:
    • Grounds,
    • Physical plant facilities,
    • Cleaning compounds, pesticides and other toxic chemicals,
    • Pest control,
    • Water supply,
    • Plumbing, bathrooms and hand-washing facilities,
    • Trash disposal,
    • Sanitation Supervisors
  – Requires establishment of procedures for cleaning and pest control.

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

• Subpart D – Equipment and Utensils
  
  – Requires manufacturers to “use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained.”

  – Establishes requirements for “instruments or controls used in the manufacturing or holding of tobacco products, packaging, and materials that are used to measure, regulate, or record any information that is necessary to determine conformance with specifications or protect against contamination.”

  – Requires that manufacturers establish and maintain procedures and maintain records for such controls (e.g. calibration).

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

• Subpart H – Manufacture and Process Controls
  - Requires manufacturers to:
  • “develop, conduct, control and monitor manufacturing processes to ensure that tobacco products conform to specifications.”
  • “establish and maintain procedures for changes to a specification, process or procedure.”
  • “establish specifications for any point, step or stage in the manufacturing process where necessary to ensure that the finished tobacco product is manufactured, packaged and labeled as intended by the manufacturer.”
  • “conduct manufacturing operations in accordance with adequate sanitation principles and take necessary precautions to prevent contamination” (e.g. application of HACCP concepts).

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

- Subpart H – Manufacture and Process Controls -continued
  - Requires manufacturers to:
    - “prepare and approve a master manufacturing record for each tobacco product manufactured as distinguished by category, brand, subcategory or subbrand. The information in the master manufacturing record shall be based upon defined tobacco product development and manufacturing scale-up processes.”
    - “ensure that controls utilized in the tobacco product development and manufacturing scale-up processes are appropriate” for the category of tobacco product.
    - “establish and maintain procedures to ensure a batch or lot manufacture record is prepared for each batch or lot of a tobacco product”; including “records demonstrating that the tobacco product in the batch or lot was manufactured in accordance with the master manufacturing record.”

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulations: Illustrative Examples

- Subpart K – Labeling and Packaging Operations
  - Requires manufacturers to “establish and maintain a process to control labeling and packaging activities”:
    - Printing and application of labels to finished tobacco products
    - Ensuring labels received from suppliers conform to label specifications
    - Preventing mix-ups
    - Assuring numbers, codes or markings used to identify the tobacco product batch or lot are adequately applied

Refer to the proposed GMP for the complete requirements
Proposed GMP Regulation: Illustrative Examples

- Subpart M – Complaints
  - *Complaint* means any written, electronic, or oral communication received by the tobacco product manufacturer that alleges a deficiency related to the quality of a finished tobacco product.
  - Requires that “quality assurance or other qualified personnel”:
    - “review all complaints to determine whether the complaint involves a reasonable probability that a finished tobacco product contains a manufacturing or other defect not ordinarily contained in the same category of tobacco products on the market that would cause an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products;
    - evaluate the need for an investigation; and
    - where appropriate investigate any complaint that involves an acute, serious, adverse health consequence not otherwise associated with use of the same category of tobacco products, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.”
  - Defines required complaint records.

Refer to the proposed GMP for the complete requirements.
Proposed GMP Regulation:
Effective Date

- GMP regulations would take effect a minimum of two years from publication of the final rule in the Federal Register.

- The proposed effective date provides a reasonable period of time for manufacturers to conform to the good manufacturing practices required herein.

- The period of time to comply is based on the differences in the manner in which the different types of tobacco products have historically been produced, the financial resources of the different tobacco product manufacturers, the state of their existing manufacturing facilities, and a consideration of what would constitute a reasonable period of time to comply with the requirements in this Part.

- Small tobacco manufacturers as defined by Section 900(16) of the FSPTCA are not required to comply with the GMP regulation for at least 4 years following the effective date of the regulation (See Section 906(e)(1)(B)(v))
Questions?
April 23, 2012

Ann Simoneau, J.D. 
Director, Office of Compliance and Enforcement  
U.S. Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850

Beverly Chernaik  
Director, Office of Regulations  
U.S. Food and Drug Administration  
Center for Tobacco Products  
9200 Corporate Boulevard  
Rockville, MD 20850

Re: **MAY 2, 2012 MEETING PARTICIPANTS AND PROPOSED AGENDA**

Dear Ms. Simoneau and Ms. Chernaik:

As requested, R.J. Reynolds Tobacco Company (“RJRT”) hereby respectfully submits this letter to the United States Food and Drug Administration’s Center for Tobacco Product (“CTP”) to provide CTP with the specific representatives from the various industry stakeholders who plan to participate in the May 2, 2012 meeting with CTP to discuss the Companies’ proposed Good Manufacturing Practice (“GMP”) regulations and preamble. We also take this opportunity to provide CTP with the Companies’ proposed agenda.

The following Company representatives will attend the May 2, 2012 meeting:

- James E. Swauger, Ph.D., DABT  
  Vice-President – Regulatory Oversight  
  R. J. Reynolds Tobacco Company

- Charles D. Garner, Ph.D., DABT, CIH  
  Sr. Director – Regulatory Oversight  
  R. J. Reynolds Tobacco Company

- Mitchell A. Neuhauser  
  Managing Counsel – Regulatory  
  R. J. Reynolds Tobacco Company

---

Mark S. Brown
King & Spalding LLP
Representing R. J. Reynolds Tobacco Company

Amanda J. Klingler
King & Spalding LLP
Representing R. J. Reynolds Tobacco Company

Gregory H. Ray
Vice President, Quality Compliance
Altria Client Services

Pamela D. Lieberman
Director, Quality Compliance Management
Altria Client Services

Ronald Gahagan
Assistant General Counsel
Altria Client Services

Stephen C. Payne
Gibson, Dunn & Crutcher LLP
Representing Altria Client Services

Sam Eich
Director, Quality Management
Lorillard Tobacco Company

Patricia Kovacevic, JD
Director Regulatory Affairs, Associate General Counsel
Lorillard Tobacco Company

Frank Howell
Vice President, Manufacturing
Commonwealth Brands, Inc.

Rob Wilkey
Vice President & General Counsel
Commonwealth Brands, Inc.

Billy T. Turner, Jr.
Vice President Operations
Liggett Group LLC
T. Jeffrey Clark, PhD, MBA  
Director Science & Quality Assurance  
Liggett Group LLC

John R. Long  
Vice President & General Counsel  
Liggett Vector Brands

Susan R. H. Gernert  
Assistant General Counsel  
National Tobacco Company, L.P.

Jaimison D. Schellenger  
Associate General Counsel  
Swedish Match North America, Inc.

J. Benneville (Ben) Haas  
Latham & Watkins LLP  
 Representing Swedish Match North America, Inc. and the SMARTT Coalition

Kevin Altman  
CITMA

As discussed in our January 10, 2012 submission, the Companies propose the following agenda for the 90-minute meeting:

- Introductions and meeting objectives
- Discussion of the Companies’ approach to developing the proposed GMP regulations and preamble
- Overview of the proposed GMP regulations and preamble
- Discussion with CTP, including addressing CTP’s questions regarding the proposed GMP regulations and preamble

We will submit our planned presentation and any specific questions to CTP prior to the meeting. In addition, should CTP wish to provide the Companies with questions by April 25, 2012, we will be prepared to discuss them. If possible, please let us know who will be representing CTP at the meeting.
The Companies are committed to working with the Agency to establish appropriate GMP regulations for tobacco product manufacturers and look forward to discussing this matter with CTP. If you require any additional information or have any questions, please do not hesitate to contact me.

Respectfully Submitted,

[Signature]

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
January 26, 2012

James E. Swauger, Ph.D., DABT  
Vice President – Regulatory Oversight  
R.J. Reynolds Tobacco Company  
401 N. Main St.  
P.O. Box 2959  
Winston-Salem, NC 27102  

Re: Proposed Tobacco Product Good Manufacturing Practices Regulation and Request for Meeting

Dear Dr. Swauger:

This letter acknowledges the Center for Tobacco Products’ (CTP) receipt of your “Proposed Tobacco Product Good Manufacturing Practices Regulations and Request for Meeting,” dated January 10, 2012. After we have had the opportunity to review the documents, CTP will contact you regarding your meeting request.

If you have any questions please contact Emil Wang at 301-796-9244 or at Emil.Wang@fda.hhs.gov.

Sincerely,

Ann Simoneau, J.D.  
Director  
Office of Compliance and Enforcement  
Center for Tobacco Products
June 20, 2012

Ann Simoneau, J.D. Beverly Chernaik
Director, Office of Compliance and Enforcement Director, Office of Regulations
U.S. Food and Drug Administration U.S. Food and Drug Administration
Center for Tobacco Products Center for Tobacco Products
9200 Corporate Boulevard 9200 Corporate Boulevard
Rockville, MD 20850 Rockville, MD 20850

Re: MAY 2, 2012 MEETING WITH INDUSTRY STAKEHOLDERS TO DISCUSS PROPOSED GMPs

Dear Ms. Simoneau and Ms. Chernaik:

R.J. Reynolds Tobacco Company ("RJRT"), on behalf of the industry stakeholders1 who participated in the May 2, 2012 meeting, would like to thank the United States Food and Drug Administration’s Center for Tobacco Products ("CTP") for the opportunity to meet on May 2, 2012 and discuss the Companies’ proposed Good Manufacturing Practice ("GMP") regulations and preamble.

While the Companies believed that the proposed GMP regulations and preamble would facilitate a productive dialogue consistent with CTP’s expressed goal to engage with and understand the industry, we recognize that CTP was not prepared to engage in a dialogue at the May 2, 2012 meeting. Should CTP wish to meet with the Companies again during its development of GMP regulations, we welcome the opportunity as we are committed to working with the Agency to establish appropriate GMP regulations for tobacco product manufacturers.

---

1 The industry stakeholders include the following companies: RJRT, Santa Fe Natural Tobacco Company, Inc., American Snuff Company, LLC, Altria Client Services on behalf of Philip Morris USA Inc. and U.S. Smokeless Tobacco Company, Lorillard, Inc., Commonwealth Brands, Inc., Swedish Match North America, the SMARTT Coalition, Liggett Group LLC, Vector Tobacco Inc., National Tobacco Company, L.P., Hail & Cotton, Inc., and CITMA (collectively referred to herein as the "Companies").
If you have any questions, please do not hesitate to contact me.

Respectfully Submitted,

James E. Swauger, Ph.D., DABT
Vice President – Regulatory Oversight
R. J. Reynolds Tobacco Company

cc: Lawrence R. Deyton, M.D., M.S.P.H
David L. Ashley, Ph.D., CAPT, USPHS
James E. Dillard, III, Senior Vice President, Regulatory Affairs, Altria Client Services
Lorillard, Inc.
Commonwealth Brands, Inc.
Swedish Match North America
SMARTT Coalition
Liggett Group LLC
Vector Tobacco Inc.
National Tobacco Company, L.P.
Hail & Cotton, Inc.
CITMA