

October 20, 2016

Commissioner Robert Califf, MD  
Division of Dockets Management  
HFA-305  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Refuse to Accept Procedures for Premarket Tobacco Product Submissions

**Docket No. FDA-2016-N-1555**

Dear Commissioner Califf:

The Tobacco Control Legal Consortium is pleased to submit these comments to the U.S. Food and Drug Administration (FDA) on the FDA's procedures for refusing to accept premarket tobacco product submissions. The Tobacco Control Legal Consortium is a national network of nonprofit legal centers providing technical assistance to public officials, health professionals and advocates concerning legal issues related to tobacco and public health.<sup>1</sup>

The premarket review process is an incredibly important element in the FDA's regulation of tobacco products and this rule represents a sensible step towards effective tobacco product regulation. We are encouraged that the rule addresses some of the problems with the premarket review process and that the agency is seeking out solutions to those problems. However, the FDA must take many more steps in order to reform the process into one that maximizes the protection of public health.

**I. The premarket review process is intended to prevent harmful new tobacco products from entering the marketplace.**

Congress passed the Family Smoking Prevention and Tobacco Control Act to give the FDA comprehensive regulatory authority over tobacco products and the tobacco industry. This was a necessary delegation of power because the industry's history of business practices, rooted in deception, misinformation, and manipulation, are well-established.<sup>2</sup> The largest cigarette manufacturers have spent decades fine-tuning the addictiveness and attractiveness of their

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<sup>1</sup> 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 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.

<sup>2</sup> See e.g., *U.S. v. Philip Morris, Inc.*, 449 F. Supp. 2d 1 (D.D.C. 2006), *aff'd in relevant part*, 566 F.2d 1095 (D.C. Cir. 2009), *cert. denied*, 130 S.Ct. 3501 (2010).

products to ensure that as many people as possible experiment with their products and that those who experiment have a greater chance of becoming addicted to nicotine. After decades expending tremendous resources to cast doubt on the scientific evidence linking smoking with cancer, heart disease, COPD, and many other diseases, it eventually became clear that the growing body of scientific evidence would prompt many smokers to attempt to quit smoking. In order to preserve its profits, the industry developed and marketed so-called “light” and “low-tar” cigarettes to provide smokers with an alternative to quitting that was allegedly less harmful than continuing to smoke so-called “full-flavored” cigarettes. However, in reality not only were these cigarettes just as harmful, but the tobacco industry knew it. Judge Kessler’s 2006 opinion in *U.S. v. Philip Morris* analyzed millions of pages of internal documents from tobacco industry defendants<sup>3</sup> and concluded that:

Even as they engaged in a campaign to market and promote filtered and low tar cigarettes as less harmful than conventional ones, Defendants either lacked evidence to substantiate their claims or knew them to be false. Indeed, internal industry documents reveal Defendants’ awareness by the late 1960s/early 1970s that, because low tar cigarettes do not actually deliver the low levels of tar and nicotine which are advertised, they are unlikely to provide any clear health benefit to human smokers, as opposed to the FTC smoking machine, when compared to regular, full flavor cigarettes.

As Defendants have long been aware, nicotine delivered by cigarettes is addictive. Defendants’ internal documents demonstrate their understanding that, in order to obtain an amount of nicotine sufficient to satisfy their addiction, smokers of low tar cigarettes modify their smoking behavior, or “compensate,” for the reduced nicotine yields by taking more frequent puffs, inhaling smoke more deeply, holding smoke in their lungs longer, covering cigarette ventilation holes with fingers or lips, and/or smoking more cigarettes.

As a result of this nicotine-driven smoker behavior, smokers of light cigarettes boost their intake of tar, thus negating what Defendants have long promoted as the primary health-related benefit of light cigarettes: lower tar intake.

Defendants did not disclose the full extent and depth of their knowledge and understanding of smoker compensation to the public health community or to government regulators.

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<sup>3</sup> Philip Morris, Inc., now Philip Morris USA, Inc., a division of Altria Group Inc.; R.J. Reynolds Tobacco Co., now a division of Reynolds American, Inc.; Brown & Williamson Tobacco Co., a wholly owned subsidiary of British American Tobacco plc, which merged with R.J. Reynolds Tobacco Co. and became part of Reynolds American, Inc.; Lorillard Tobacco Company, now a part of Reynolds American, Inc.; The Liggett Group, now part of Vector Group Ltd.; American Tobacco Co., which merged with Brown & Williamson, prior to the merger between Brown & Williamson and R.J. Reynolds Tobacco Co.; Philip Morris Cos., now Altria Group, Inc.; British American Tobacco Investments Ltd.; The Council for Tobacco Research U.S.A., Inc.; and The Tobacco Institute, Inc.

Defendants' conduct relating to low tar cigarettes was intended to further their overarching economic goal: to keep smokers smoking; to stop smokers from quitting; to encourage people, especially young people, to start smoking; and to maintain or increase corporate profits.<sup>4</sup>

Perhaps even more disturbing, not only was this unchecked product manipulation an industry-wide fraud perpetuated against the public, but the marketing of “light” cigarettes had a dramatic impact on the rates of various types of lung cancer. The Health Consequences of Smoking—50 Years of Progress concludes that:

The design and composition of cigarettes have changed substantively since the first major wave of evidence linking smoking to lung cancer in the 1950s. Although the details of these changes are only partially understood, changes in design—notably the addition of ventilated filters—have clearly changed the pattern of smoking, including more intense puffing. In addition, changes in the composition of cigarettes have resulted in incompletely characterized alterations in the chemical composition of cigarette smoke. Documented changes include increases in tobacco-specific nitrosamines and decreases in [polycyclic aromatic hydrocarbons] in the smoke of U.S. cigarettes. Substantial differences between U.S. cigarettes and those of many other nations include the use of blended tobacco in U.S. cigarettes and the use of unblended, flue-cured tobacco in cigarettes in Australia, Canada, and the United Kingdom. The United States has somewhat preceded most other developed countries in the adoption of filtered and low-yield, machine-tested cigarettes, but U.S. products are also used widely in most countries. These changes raise a question of whether rates of lung cancer have been altered by the changes in the design and composition of cigarettes—changes that were accompanied by an initial belief that lower yields of machine-tested tar might signal a lower risk for lung cancer. In fact, the risk of lung cancer in the United States may have increased as a result of such changes.

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Compensatory changes in the patterns of puffing and inhaling smoke by smokers switching to cigarettes with low yields of toxicants may increase the deposition of smoke particles in the alveolar region of the lung. This is supported by modeling of particle deposition in the lung that suggests this effect likely increases the deposition of particles in the alveolar region. Increased alveolar deposition and increasing tobacco-specific nitrosamine levels over time may have combined to increase the risk for adenocarcinoma.<sup>5</sup>

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<sup>4</sup> *Philip Morris*, 449 F. Supp. 2d at 430-31 (internal citation omitted).

<sup>5</sup> U.S. Dep't of Health & Human Servs., *The Health Consequences of Smoking – 50 Years of Progress A Report of The Surgeon General 185-86* (2014) [hereinafter SGR 2014]. *available at* <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

In weighing the body of scientific evidence, the report further concludes that, “[t]he evidence is sufficient to conclude that the increased risk of adenocarcinoma of the lung in smokers results from changes in the design and composition of cigarettes since the 1950s.”<sup>6</sup>

It comes as no surprise, then, that in attempting to protect public health, Congress specifically targeted the health fraud associated with “light” cigarettes and also gave the FDA important tools to prevent the industry from further manipulating its products without oversight.

Section 911 of the Tobacco Control Act attempts to end the tobacco industry’s “light” cigarette fraud by prohibiting the terms “light,” “low,” and “mild.”<sup>7</sup> Perhaps equally important, Section 905(j) and 910 establish a regulatory scheme, commonly referred to as premarket review, whereby all new and modified tobacco products are subject to thorough scientific analysis by the FDA *before* the products can be sold at retail.<sup>8</sup> When enforced with fidelity, this authority should prevent the tobacco industry from perpetuating the kind of health fraud that has been a hallmark of its past business practices. Unfortunately, in implementing the premarket review process for tobacco products, the FDA has made numerous decisions that have benefitted the tobacco industry at the expense of public health. This rule takes one small step to address one of the problems with this process but more is needed to fully realize the potential health benefits.

## II. The FDA must do more to maximize the public health benefits of this rule.

We applaud the FDA for recognizing that one of the most important problems with the current premarket review process is the lack of established criteria that allow the agency to dispose of marketing applications that are completely and utterly deficient. However, in order to make the most of this rule, the FDA must add additional criteria to its list of deficiencies that will result in a refusal to accept an application, and clarify the rule’s effect on marketing applications that have provisional status.<sup>9</sup>

The FDA correctly recognizes that in order to efficiently and effectively dispose of the thousands of deficient marketing applications currently pending, it must establish criteria that allow the

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<sup>6</sup> *Id.* at 186.

<sup>7</sup> 21 U.S.C. § 387k. However, the industry has had little difficulty in compromising the potential benefits to public health and preserving its profits by using color-coded packages rather than the prohibited terms. *See*, Letter from Ann Simoneau, Acting Dir., Office of Compliance, Ctr. for Tobacco Products, Food and Drug Admin., to William Melton, Vice President – Compliance and Regulations, Commonwealth Brands, Inc. (July 20, 2010) *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM284126.pdf>; Letter from Ann Simoneau, Acting Dir., Office of Compliance, Ctr. for Tobacco Products, Food and Drug Admin., to Denise F. Keane, Exec. Vice President, Altria Group, Inc. (June 17, 2010) *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM284131.pdf>; Gregory N. Connolly & Hillel R. Alpert, *Has the Tobacco Industry Evaded the FDA’s Ban on ‘Light’ Cigarette Descriptors?*, 23 TOBACCO CONTROL 140 (2014) *available at* <http://tobaccocontrol.bmj.com/content/23/2/140>; Hua-Hie Yong et al., *U.S. Smokers’ Beliefs, Experiences and Perceptions of Different Cigarette Variants Before and After the FSPTCA Ban on Misleading Descriptors Such as “Light,” “Mild,” or “Low”* 18 NICOTINE & TOBACCO RESEARCH 2115 (2016) *available at* <http://ntr.oxfordjournals.org/content/18/11/2115>; M. Falcone et al., *Awareness of FDA-Mandated Cigarette Packaging Changes Among Smokers of ‘Light’ Cigarettes*, 30 HEALTH EDUC. RESEARCH 81 (2015) *available at* <http://her.oxfordjournals.org/content/30/1/81.full>.

<sup>8</sup> 21 U.S.C. § 387e(j); 21 U.S.C. § 387j.

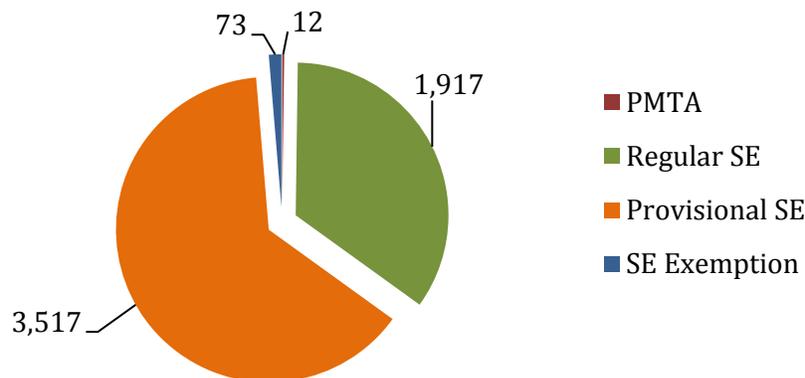
<sup>9</sup> Desmond Jenson, Joelle Lester & Micah L. Berman, *FDA’s Misplaced Priorities: Premarket Review Under the Family Smoking Prevention and Tobacco Control Act*, 25 TOBACCO CONTROL 246 (2016).

agency to refuse to accept these deficient applications. In doing so, the agency does not need to apply the required scientific review to an application that would inevitably be rejected. Instead, the FDA can determine that the application is lacking sufficient evidence to allow the agency to make a scientific conclusion. Removing the application from the scientific review track allows the agency to commit fewer resources to reviewing these types of applications which in turn allows for quicker and more effective review of all applications. This is a prudent step that is long overdue. While we support this effort, it is unclear whether this action will address the most significant category of deficient applications: Provisional Substantial Equivalence reports.

**A. The FDA must apply the new rule to currently pending Provisional Substantial Equivalence reports.**

The Tobacco Control Act establishes three pathways to market new and modified tobacco products. So far, the tobacco industry has almost exclusively utilized the Substantial Equivalence (SE) pathway to attempt to market new products. Because the Tobacco Control Act allows manufacturers to continue marketing products that were introduced by March 22, 2011, so long as an SE report was filed by that date, the tobacco industry took this opportunity to maximize its ability to keep products on the market without premarket review. These so-called Provisional SE reports are subject to review while the products that they represent are already on the market. This “postmarket” review is distinct from the “premarket” review that Regular SE reports, submitted after March 22, 2011, are subject to.<sup>10</sup> All SE reports submitted after that date represent products that cannot be introduced to the market until *after* the agency issues an affirmative order. Figure 1 shows the tobacco industry’s clear efforts to maximize the introduction of products subject to postmarket, rather than premarket review. Even a full five years after the deadline for Provisional SE reports, these postmarket reports make up two-thirds of all marketing applications received by the agency. In five months, the industry submitted 3,517 Provisional SE reports; in the fifty-five months that followed, the industry has only submitted 1,917 Regular SE reports.<sup>11</sup>

**Figure 1: Premarket Submissions to the FDA**

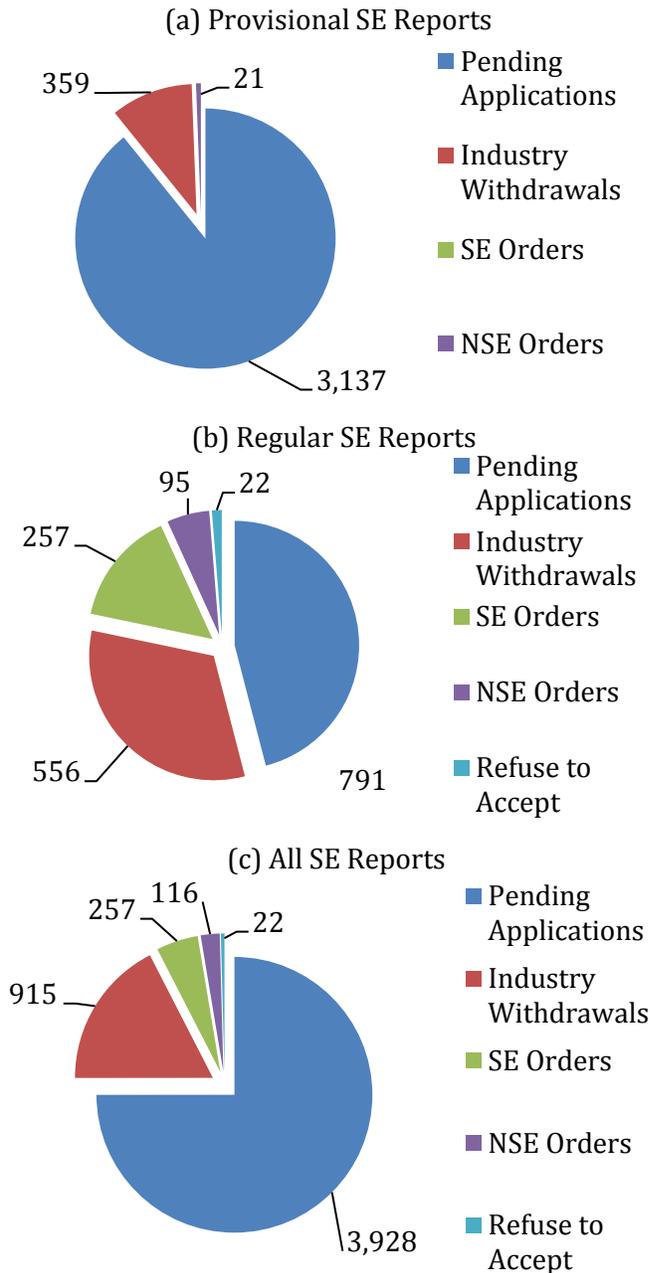


<sup>10</sup> The term “postmarket review” as it is used here is intended to provide a counter to the term “premarket review.” It is not intended to capture any of the FDA’s authority with respect to postmarket surveillance.

<sup>11</sup> All data related to applications submitted and FDA actions taken is current as of September 2015. Records from that point forward are kept in a different fashion and the data cannot be represented with sufficient level of detail. However, there is little evidence that the overall picture has changed dramatically.

Provisional SE reports represent a potential public health problem the scope of which is entirely dependent on the swiftness of FDA action. Because of the disparate nature of Provisional and

**Figure 2: Status of Premarket Submissions to the FDA**



Regular SE reports and the effect of the FDA's action on those reports, FDA action can have dramatic consequences on the tobacco product market.

Provisional SE products are currently on the market, so FDA action on these reports can result in the removal of products that are currently marketed and thus currently causing disease and death. Regular SE products are not yet on the market and thus causing no harm. FDA action on Regular SE reports facilitates the introduction of new products that will eventually cause disease and death.

Given the volume of Provisional SE reports, the fact that they were received by the agency earlier than Regular SE reports, the potential for the FDA to remove non-compliant products from the market by acting on these reports, and the agency's mandate to protect public health, one would expect the FDA to prioritize the review of Provisional over Regular SE reports. Instead, the FDA has done the opposite; the agency has prioritized the review of Regular SE reports. Figure 2 shows the FDA's disparate action on Regular and Provisional SE reports. The FDA has also publicly stated its priority of reviewing Regular, rather than Provisional, SE reports several times.<sup>12</sup> The agency has not offered a justification for its priority.

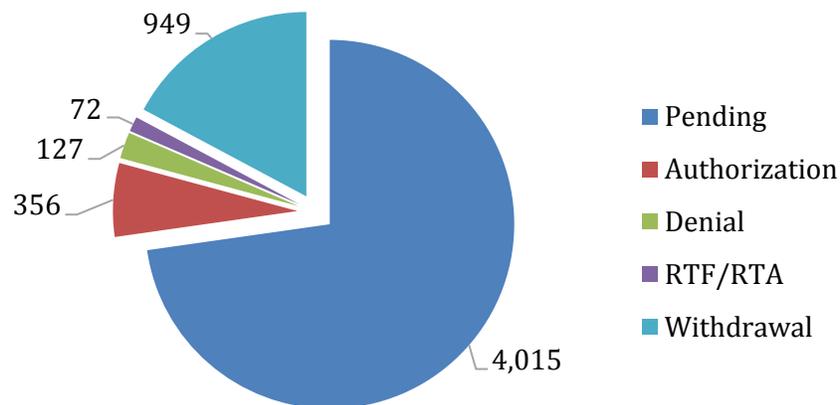
In order to maximize the public health benefit of the agency's premarket review of tobacco products, the FDA

<sup>12</sup> U. S. GOV'T ACCOUNTABILITY OFF., GAO-13-723, NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIME FRAMES FOR ITS REVIEW PROCESS 25 (2013) available at <http://www.gao.gov/assets/660/657451.pdf>; Cristi Stark, *Reports on Substantial Equivalence (905(j)(1)(A)(i) Reports): One Year Later* 15 (2012) available at

must reverse its priorities and begin focusing its SE report review resources on Provisional rather than Regular SE reports. In addition, the FDA must use this rule to significantly reduce the backlog of Provisional SE reports. While it has refused to accept twenty-two Regular SE reports, it has yet to refuse to accept any Provisional SE reports. We urge the agency to either begin enforcing this new rule against Provisional SE reports or expand the rule so that the criteria established to allow the FDA to refuse to accept a deficient application can also be applied to Provisional SE reports. This would allow the agency to issue a Not Substantially Equivalent order letter to manufacturers who have submitted deficient reports but to do so without conducting a full scientific review. The scope of the problem clearly supports this action.

Of all of the FDA’s actions on marketing applications thus far, refusals to accept<sup>13</sup> comprise the smallest portion of the agency’s actions. Figure 3 shows that most of the dispositive action on marketing applications has come from the industry withdrawing applications of its own volition. A significant portion of the FDA’s actions have been to authorize new products for sale. The agency has issued modest number of orders denying the marketing of new products but has only refused to accept a handful of applications. Even more significant, of all of the applications that the FDA has received, almost three quarters are still pending before the agency and have yet to receive any agency review.

**Figure 3: Status of All Marketing Applications**



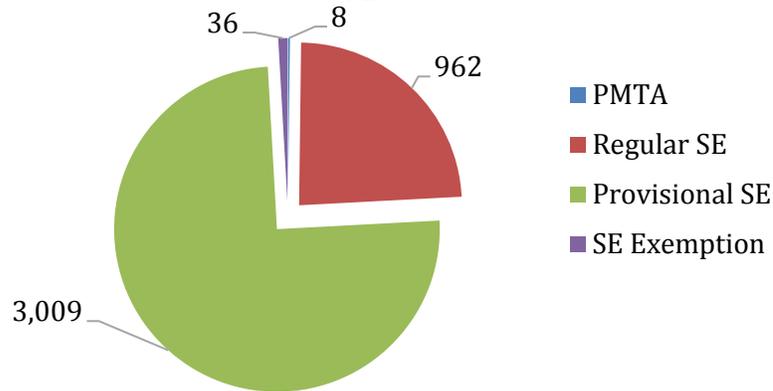
Clearly, there is a significant backlog of applications that require the FDA to act. However, as is suggested above, if the FDA is not intending to begin refusing to accept Provisional SE reports, the public health impact of this rule will be significantly reduced. Figure 4 shows the proportion of the currently pending marketing applications that are represented by each type of application. Unsurprisingly, the vast majority of pending applications are Provisional SE reports. These are

<http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/ForIndustry/Retailer/UCM301597.pdf>; David L. Ashley & Matthew Holman, *Reports on Substantial Equivalence (905(j)(1)(A)(i) Reports): An Update 5* (2012) available at <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/BreakTheChain/UCM316450.pdf>; Cristi Stark & Matthew Holman, *Update on Review of Substantial Equivalence Reports (SE Reports) 2* (2013) available at <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/BreakTheChain/UCM347933.pdf>.

<sup>13</sup> For the purposes of Figure 3, this category also encompasses “refusal to file” which the FDA has indicated that it has done for PMTAs but has not clarified how this is different for “refusing to accept” SE reports and requests for SE exemption.

the applications that require immediate attention. Not only are they the largest group of pending applications but they are the only group that represents products that are currently on the market.

**Figure 4: Pending Marketing Applications by Type**



The FDA must make any necessary changes to this rule so that it can apply these criteria to Provisional SE reports. There is good reason to believe that these reports represent some of the most deficient reports that are pending before the agency. The Provisional SE reports were the earliest marketing applications received by the agency and so they are the reports which benefit the least from manufacturer and agency experience with the premarket review process. In addition, of the Provisional SE reports that the agency has reviewed, there has been a clear pattern of significant deficiencies and most of these deficiencies have not been corrected despite multiple attempts by the agency to solicit amendments and corrections. Before this rule, the FDA had been committing far too many resources to assisting report submitters correct deficient applications. Figure 5 illustrates the Provisional SE reports that have received Not Substantially Equivalent orders thus far and clearly demonstrates the significant drag on FDA resources.

**Figure 5: Provisional SE Report Deficiencies**

Manufacturer	Number of SE Reports	Number of Contacts Initiated by FDA	Nature of Deficiency	Date of First Contact	Date of Final Contact	Date of NSE Order	Days on the Market with Known Deficiency	Notes
Jash International, Inc.	4	8	New and predicate products not uniquely identified.	3/19/2013	8/23/2013	2/21/2014	339	Products discontinued, reports abandoned.
Star Scientific, Inc.	7	4	No side-by-side quantitative comparison of “other features.”	11/1/2012	6/13/14	6/28/2014	665	Manufacturing activities ceased.
Eagle River Importers, Inc.	10	5	New and predicate products not uniquely identified.	5/6/2013	2/12/2015	5/20/2015	744	
California Clinical Supply Company	1	16	New and predicate products not uniquely identified.	12/20/2012	4/24/2015	8/6/2015	959	Applicant answered none of the FDA’s 16 contact attempts.
Pacific Standard Manufacturing Corporation	1	10	New and predicate products not uniquely identified.	11/14/2012	5/19/2015	9/4/2015	1024	Applicant notified FDA that business had closed upon first contact. FDA requested applicant withdraw report and applicant refused. FDA continued to contact applicant and request information.
R.J. Reynolds Tobacco Company	4	7	Deficient predicate product information.	3/29/13	3/31/2015	9/15/2015	900	Applicant attempted to utilize as a predicate “a composite of all cigarettes commercially marketed in the United States as of February 15, 2007.”
LIT Distributor, Inc.	10	12	New and predicate products not uniquely identified.	4/4/2013	5/8/15	10/14/15	923	Initial contact and amendment made by applicant.
Southern Tobacco Company	11	13	New and predicate products not uniquely identified, no scientific data.	10/10/12	5/26/15	2/19/16	1,227	Applicant notified FDA that it no longer sold tobacco products. FDA initiated nine subsequent contacts.

Of the manufacturers of Provisional SE products who have received an NSE order, only Star Scientific, Inc., provided enough information for the FDA to identify both the predicate and new products in its initial applications. All of the other manufacturers failed to identify the new and predicate products. In the case of the R.J. Reynolds Tobacco Company, the manufacturer attempted to pass off “a composite of all cigarettes commercially marketed in the United States as of February 15, 2007” as a predicate. This is clearly in defiance of the statutory language and guidance issued by the FDA before the reports were submitted. Manufacturers must identify a single predicate product and a single new product and provide an analysis of the differences to allow the agency to determine if the new product raises different questions of public health.<sup>14</sup> Such a comparison is not possible if a manufacturer utilizes hundreds of predicate products.

Rather than initiate the swift removal of products with deficient reports, the FDA contacted report submitters multiple times to negotiate the submission of additional information. Only RJR eventually submitted enough information to identify predicate products. In all other cases, the FDA’s extended dialogs with manufacturers proved entirely fruitless. In some cases, these dialogs went on for months and even years.

It is also worth noting that by the time the FDA began its review of some of these reports, the products were no longer on the market. There was no longer any incentive on the manufacturer’s end to correct deficiencies. In some cases, the FDA was unable to make any contact with former manufacturers and yet the agency persisted in requesting additional information. In the case of the Pacific Standard Manufacturing Corporation, when first contacted by the agency, the company representative informed the FDA that the manufacturer had “closed its operations over two years ago.”<sup>15</sup> Rather than immediately issue an NSE order or refuse to accept the report, actions that would essentially have no effect and would not be challenged, the FDA “informed the applicant that it will need to submit a formal withdrawal request.”<sup>16</sup> The company did not bother to request a withdrawal. After two and a half years of attempting to solicit a withdrawal request and failing to make contact with a representative of the company, the agency received a response that indicated that “the company has been closed for four years.”<sup>17</sup> In another case, the FDA spent two and a half years attempting to make contact with a report submitter that never responded to at least 16 attempts to make contact. These cases paint a painful picture of needlessly wasted agency resources. This time and energy could have been spent reviewing applications for products that are on the market and currently harming public health.

That the agency was committing any resources to ensure that a manufacturer submitted enough information for the FDA to begin a scientific review of an SE report is outrageous. It is the manufacturer’s burden under the law to establish enough evidence to allow the agency to make a final decision; the burden is not on the FDA to help manufacturers gather that information. This degree of hand-holding incentivizes the submission of deficient reports and further slows the FDA’s review process. The agency must stop coddling the industry by helping it through the agency’s processes and start refusing to accept such grossly deficient applications.

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<sup>14</sup> 21 U.S.C. § 387e(j)(1)(A)(i); 21 U.S.C. §387j(a)(3).

<sup>15</sup> U.S. Food & Drug Admin., Technical Project Lead (TPL) Review: SE0002648 3 (2015) *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM461525.pdf>.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

In addition, whether or not these applications are corrected, the FDA has been conducting scientific reviews of the deficient applications. There is no logical reason for the FDA to review the merits of an application that has failed to properly identify products. The agency must begin refusing to accept these applications to swiftly and efficiently reduce the tremendous backlog of deficient applications. Refusing to accept these applications and removing them from the scientific queue will significantly reduce the agency resources being used to review deficient applications.

**B. The FDA must apply this rule to applications that receive provisional status under the deeming rule.**

While it is critically important that the agency deal with the vast number of Provisional SE reports that have been languishing for more than five years, it is equally important that this new rule apply to the thousands of provisional marketing applications that will flood the agency for products covered by the deeming regulation. The FDA's implementation of the deeming regulation will allow manufacturers to submit marketing applications that grant products provisional status for a period of time that is dictated by the application pathway chosen, 24 months for PMTAs, 18 months for SE reports, and 12 months for requests for SE exemption. The agency will also extend the provisional period for an additional 12 months for all products that have submitted an application before the deadline and has noted that it can extend the provisional status even further on a case-by-case basis. If the agency cannot refuse to accept these new marketing applications, the FDA will be crippled by deficient applications that will require thousands of hours contacting manufacturers and conducting fruitless scientific reviews. According to the agency's own estimates, in the first two years following the implementation of the deeming regulation, the agency will receive somewhere between 5,424 to 6,764 marketing applications.<sup>18</sup> This is roughly the same number of applications that the agency has received over the course of the last seven years, most of which are still pending. The volume may be much greater; while the agency assumes that many products will not seek continued marketing, the FDA has determined that as many as 36,621 to 100,761 products will be affected by the deeming regulation.<sup>19</sup> It is entirely possible, then, that the agency's estimate regarding the number of marketing applications that it will receive is significantly lower than it has predicted. If this is the case, it is all the more crucial that the FDA can dispense with clearly deficient applications quickly and with minimal expenditure of resources.

**C. The FDA must expand the rule's criteria for applications that the agency refuses to accept.**

In addition to clarifying or expanding the rule so that it can be applied to Provisional SE reports and all provisional marketing applications for products regulated after the implementation of the deeming regulation, there are three more criteria that the FDA should add to the list of deficiencies that will result in a refusal to accept.

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<sup>18</sup> U.S. FOOD AND DRUG ADMIN., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS, 84, Table 9 (2016) *available at* <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/UCM500254.pdf>.

<sup>19</sup> *Id.* at 78, Table 6.

First, section 1105.10(a)(7) of the new rule indicates that the agency can refuse to accept a submission that “does not contain the following product-identifying information: The manufacturer of the tobacco product; the product name, including the brand and subbrand; the product category and subcategory; packages type and package quantity; and characterizing flavor.” Because most of the Provisional SE reports that eventually received NSE orders failed to identify the new product or predicate product, this is a prudent addition to the list of criteria for refusing to accept an application. However, the agency should make clear that the identification requirement applies to both new and predicate products. If an SE report properly identifies the new product, but fails to properly identify the predicate product, the report is no less deficient and should be rejected under section 1105.10(a)(7).

Second, the agency should use this rule as an opportunity to determine, as a matter of law, that a non-flavored predicate product cannot be used as a point of comparison for a flavored new product. The agency should add this to the list of RTA criteria for SE reports and requests for SE exemption. The agency has already issued NSE orders for new menthol cigarettes that had identified a non-flavored predicate product. Because of the mountain of evidence that flavored products contribute to youth initiation into tobacco use, the FDA should refuse to accept any SE report or SE exemption request that attempts to establish that a flavored product is substantially equivalent to a non-flavored product or that such a change is only a minor modification. Adding this to the RTA criteria enables the FDA to remove such applications from the scientific queue without re-evaluating all of the scientific evidence related to flavors and simply determine that the addition of a characterizing flavor to a new product raises different questions of public health and is not a minor modification.

Finally, the agency should add non-responder status to the RTA criteria. Several Provisional SE report submitters have failed to stay in contact with the agency. Some have had no contact after initially submitting a report. Because there is likely a very high degree of overlap between deficient applications and non-responders, removing these deficient applications from the scientific queue could reduce the backlog of pending applications. Even if an application submitted by a non-responder is complete and would receive marketing authorization, it is unlikely that the report submitter will be marketing the new product. Scientific review of applications by non-responders is a waste of agency resources.

### **III. Conclusion**

We reiterate our strong support of this commonsense regulation. The FDA has been buried under deficient marketing applications for far too long. This rule is a modest but important step to eliminate those applications which do not warrant expending agency resources to review their scientific merits. However, to maximize the public health benefit, the agency must expand the criteria that it utilizes to refuse to accept an application. The FDA’s list is a good start but we encourage the agency to expand that list to increase the number of applications that the FDA can dispose of. We also strongly encourage the agency to clarify that the criteria established in this rule can and will be applied to currently pending Provisional SE reports that were filed before March 22, 2011. These reports represent the most immediate public health threat and there is reason to believe that many of these reports are deficient in the ways that this rule outlines. This rule must empower the agency to reject these deficient reports and remove the non-compliant

products from the marketplace. In addition, we strongly encourage the FDA to clarify that the criteria established in this rule can and will be applied to the newly-regulated products subject to the deeming rule. The implementation of this rule will also see a temporary provisional period for marketing applications and this should not be a barrier to dispensing with deficient applications.

We appreciate the opportunity to provide these comments to maximize the public health benefits of this rule.

Respectfully,



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