

August 26, 2014

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

Re: Announce a Policy of Enforcement Discretion With Respect to Premarket Approval Requirements for New Tobacco Products First Introduced Into U.S. Commerce After March 22, 2011 – REOPEN

Dear Sir or Madam:

The Tobacco Control Legal Consortium submits these comments to assist the U.S. Food and Drug Administration (FDA) in reviewing Lorillard’s petition for reconsideration. As will be explained below, the Consortium strongly opposes the action requested in this petition. This comment will discuss the FDA’s authority to approve or deny the sale of new tobacco products as well as actions taken by both the FDA and the tobacco industry since the passage of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). It will also thoroughly outline the reasons that this petition should be denied in addition to discussing the steps that the FDA should take to improve the tobacco product application processes and protect public health.

Founded in 2003, the Tobacco Control Legal Consortium (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. Legal and Factual Background**

With the passage of the Tobacco Control Act, Congress unambiguously delegated to the FDA the authority to approve or deny the sale of new tobacco products before those products can be introduced to the market.<sup>1</sup> This premarket review authority for tobacco products is a first-of-its-kind regulatory power not just for an American administrative agency, but for the entire global tobacco control movement. At the height of a global tobacco epidemic, the success or failure of the FDA to carry out its mission will have repercussions for billions of people throughout the world, for decades to come. For the first five years of its existence, the FDA’s Center for Tobacco Products has struggled to adequately address the tobacco industry’s blatant manipulation of this process and as a result, dangerous products remain on the market despite

their not having been reviewed by the agency. An industry of racketeers<sup>2</sup> has brazenly focused its resources on an unfortunate legal loophole. The FDA's mission is clear and despite the FDA's power to close this loophole, the tobacco industry continues to exploit this process, profiting at the expense of public health. This loophole has and will continue to allow the industry to introduce thousands of new products to the market without the proper level of oversight foreseen by Congress. Rather than close this loophole, Lorillard would have the FDA open another loophole to allow them to introduce new products without the regulatory scrutiny that the Tobacco Control Act mandates.

### **A. The Tobacco Control Act Creates Three Distinct Product Pathways.**

The regulatory scheme envisioned by Congress, established in the Tobacco Control Act, is simple. The Act creates three categories of new products, each with a different set of requirements for a manufacturer to market a new product. The most stringent pathway for new products is the Premarket Tobacco Product Application (PMTA) process. The process was created for products that are the least similar to past products and thus have the greatest potential to do additional harm. The PMTA pathway is intended to be the primary pathway for new tobacco products.<sup>3</sup> A PMTA is to be denied by the FDA if: 1) the product does not appropriately protect public health,<sup>4</sup> considering the product's impact on initiation and cessation;<sup>5</sup> 2) the manufacturing process for the product does not conform to established standards;<sup>6</sup> 3) the product contains false or misleading labeling;<sup>7</sup> or 4) the product does not conform to an FDA established product standard.<sup>8</sup> There is little available information regarding the FDA's review of PMTAs because the tobacco industry submitted the first four PMTAs in August of 2013.<sup>9</sup> The FDA had 180 days to approve or deny these applications,<sup>10</sup> and in February of 2014, the FDA announced that it had refused to file the submissions because they were deficient.<sup>11</sup>

The Tobacco Control Act also establishes a pathway for those products that are "Substantially Equivalent" to products that were marketed in the past. The Substantial Equivalence (SE) pathway, a secondary pathway to bring products to the market, is intended to be used for products that have the same characteristics as past products,<sup>12</sup> or different characteristics that do not raise different questions of public health.<sup>13</sup> This process necessitates the comparison between a past product, called a predicate product, and a new product. To serve as a predicate, a product must be grandfathered and Congress established specific requirements for the certification of such products. Any product commercially marketed (not test marketed), in the United States, on February 15, 2007, can be certified as a "grandfathered" tobacco product,<sup>14</sup> making it eligible to be used as a predicate product on an SE report so long as the product conforms to any product standards established by the FDA. A product that is approved for sale under the SE pathway can also serve as a predicate product even though it is not a "grandfathered" tobacco product.<sup>15</sup>

The final pathway established by the Act creates a narrow exemption from the requirement to submit an SE report. The SE Exemption pathway is intended for a product that is so similar to a predicate product that the difference between the two is considered minor and thus the submission of a full SE report is not necessary to protect public health.<sup>16</sup> The statutory example of a product eligible for this pathway is one where an additive is deleted or added or where the level an existing additive is increased or decreased.<sup>17</sup>

While the intent of the Tobacco Control Act is to give the FDA premarket review authority over all tobacco products, the statute creates a small loophole in this process, presumably to attempt to create a smooth transition between an era when the industry had free reign to make changes to its products without any kind of oversight and an era when even the smallest change to an additive must be cleared by the FDA. This time allowed the FDA to hire and train staff and prepare to fully implement the Tobacco Control Act.

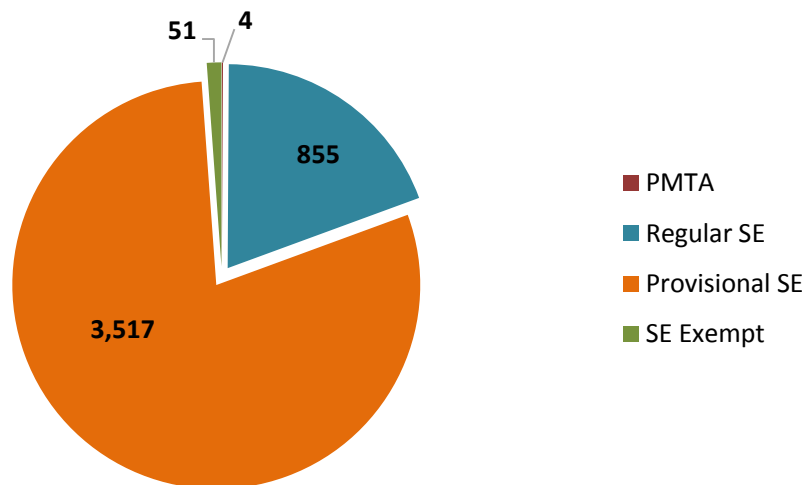
The Tobacco Control Act creates a window in time that allows manufacturers to market a new product through the SE pathway, without premarket review, as long as an SE report has been filed. These SE reports are called “Provisional” SE reports and the products represented by them are allowed to be introduced to the market as long as an SE report was filed on or before March 22, 2011. For these products – and these products only – the products can remain on the market until the FDA denies the SE report. For SE reports submitted starting on March 23, 2011, called “Regular” SE reports, the products cannot be introduced until *after* the FDA has issued an SE order based on the report. In theory, starting on March 23, 2011, no new tobacco product can be introduced into the market without the approval of the FDA regardless of the pathway chosen by the manufacturer.

### B. The Tobacco Industry Has Expended Tremendous Resources to Manipulate the SE Process.

Armed with the knowledge of this loophole, the tobacco industry flooded the FDA with 3,491 SE reports in March of 2011, bringing the total number of Provisional SE reports to 3,517.<sup>18</sup> This represents 79% of the 4,427 submissions that the FDA has received since it was granted authority over tobacco products for all three pathways *combined*.<sup>19</sup> Figure 1 shows a breakdown of tobacco product applications by product pathway including a breakdown of SE reports into Regular and Provisional. This chart attempts to put the tobacco industry’s manipulation into perspective. The volume of Provisional SE reports completely overshadow all other submissions.

**FIGURE 1**

#### Tobacco Product Marketing Applications



It is clear that the tobacco industry has focused its efforts on the parts of the tobacco product application process that will maximize its ability to get new addictive and deadly products on the market with the least amount of scrutiny possible. In the four months that the tobacco industry submitted Provisional SE reports, they inundated the FDA. The vast majority of the reports were submitted immediately before the deadline. Even after this pathway was closed, rather than submit applications under the PMTA pathway, the tobacco industry began submitting Regular SE reports in hopes of finding an easier way to get new products to the market. In the thirty-eight months between March of 2011 and May of 2014, the tobacco industry submitted 935 Regular SE reports. While this is two hundred times more than it has submitted under the PMTA pathway, this is still a fraction of the total that it was able to generate between November of 2010 and March of 2011.

The fact that the industry did not submit a PMTA until August of 2013 alone, is evidence of clear manipulation. Mitch Zeller, Director of the Center for Tobacco Products, has repeatedly stated that the PMTA process was intended to be the primary pathway to bring new products to the market.<sup>20</sup> The amount of evidence and the level of scrutiny required under the PMTA process is appropriate for an industry that has spent decades manipulating its products to deliver the precise amount of nicotine needed to create and sustain addiction.<sup>21</sup> The various tactics used to manipulate the level of nicotine in cigarettes will be outlined below but what must be clear is that the Tobacco Control Act was drafted with the intent to stop this trend. The avoidance of the PMTA process by the tobacco industry racketeers is hardly surprising but nonetheless represents a clear manipulation of the process.

In addition to the avoidance of the PMTA process, there is evidence that the thousands of Provisional SE reports pending before the FDA are actually being used as placeholders that will allow the tobacco industry to continue to introduce new products at will rather than following the proper legal procedures established by the Tobacco Control Act. While the Tobacco Control Act requires that an SE report be filed on or before March 22, 2011, and requires the report to predate the initial marketing of the product by ninety days, there is no deadline for the initial marketing of the corresponding product. Thus, as long as a tobacco company files a Provisional SE report, they are free to market a product – without premarket review – at any point in the future, circumventing the Act's premarket review requirements.

Lorillard has indicated, perhaps unintentionally, in one of its filings to this docket that it believes that “our competitor (P.M. USA) continues to launch product after product having taken advantage of a loophole in the law.”<sup>22</sup> Using a Provisional SE report as a placeholder for a future product is the loophole that Lorillard is referring to. It is very likely that at least some of the more than 3,000 Provisional SE reports are being used as placeholders. If each report represented a product that was introduced ninety days after the report was filed, tobacco retail outlets would have exploded with new tobacco products in late June of 2011. However, there was no expansion of the number of tobacco products available that would correspond with the flood of Provisional SE reports.

There is one example of this tactic with clear documentation. As Lorillard alleges, it seems that Philip Morris USA (PM) is one of the manufacturers that has used Provisional SE reports as placeholders. After filing Provisional SE reports before the March 2011 deadline, PM launched a

new cigarette sub-brand to its Marlboro line of products in 2012 and then expanded the marketing of the product in 2013. In its filings to the U.S. Securities and Exchange Commission, Altria Group, Inc., parent company of PM, explains that the new product, Marlboro NXT, was marketed in twenty-seven states at the end of September 2012.<sup>23</sup> In a subsequent filing, it explains that Marlboro NXT was expanded into an additional twenty-three states in July 2013.<sup>24</sup> Neither filing specifically labels a particular date as the date of initial marketing but clear dates are given for the marketing of the product in all fifty states, with the earliest date being a full year after the ninety day waiting period for the marketing of a product for which a Provisional SE report was filed. Given the sheer volume of Provisional SE reports, it is likely that PM and other manufacturers have used this tactic for other products as well, although it is unclear to what extent.

### **C. The FDA has Not Adequately Remediated the Tobacco Industry's Manipulation of the Tobacco Product Application Process.**

While it may have been difficult to predict the tobacco industry's efforts to flood the FDA with Provisional SE reports while leaving the PMTA process virtually unutilized, now that the damage is done, the FDA has yet to take sweeping action towards a final resolution of this issue. According to the FDA, many of the Provisional SE reports were or are incomplete or deficient in some way. Rather than issue a Not Substantially Equivalent (NSE) order based on these reports or refusing to accept them, the FDA has allowed the tobacco industry to supplement these deficient reports.<sup>25</sup> While the Provisional SE reports languish, the tobacco industry continues to submit new Regular SE reports. The total number of Regular and Provisional SE reports continues to climb, reaching well over 4,000 reports.

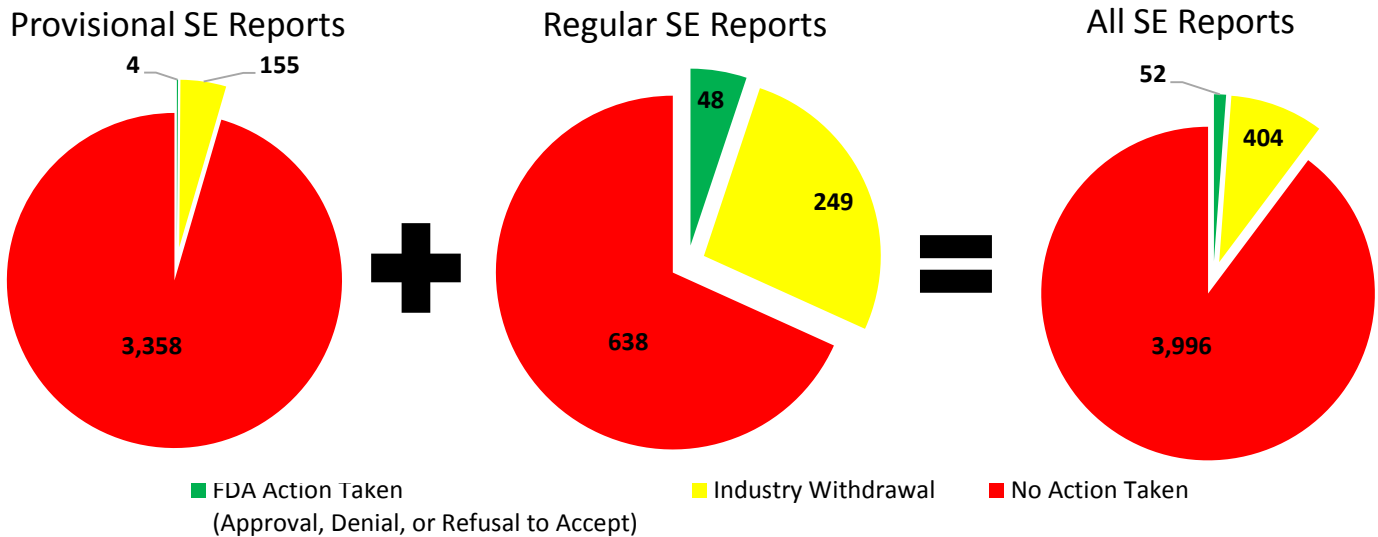
Even with a mountain of untouched Provisional SE reports and a much smaller but growing pile of Regular SE reports, the FDA has focused its efforts on Regular SE reports.<sup>26</sup> Because Regular SE reports represent products that are not yet on the market, delay on these reports poses no threat to public health, only a minor inconvenience to the tobacco industry. However, delay on Provisional SE reports allows the tobacco industry to continue to sell deadly and addictive products that have not been scrutinized by the FDA and also allows the industry to exploit the loophole that allows them to market new products at will.

FDA statements make it clear that there is a deliberate prioritization of Regular over Provisional SE reports. The FDA has stated that the reason for this priority is that regular SE reports represent products that cannot yet be marketed until the FDA has issued an SE order.<sup>27</sup> The FDA has not explained why allowing manufacturers to market new products takes priority over ensuring that harmful products never make it to the market. The FDA has a legal obligation to protect public health; it does not have a legal obligation to expedite the process of allowing the tobacco industry to market new products.

While the FDA continues to publicize its recent actions on a small handful of Regular SE reports, FDA action has not kept pace with incoming reports and at its current rate of action, it seems unlikely that the FDA will be able to prioritize the thousands of Provisional SE reports that have languished for years, representing products that are already in stores or could be introduced at any moment. Figure 2 shows the small fraction of reports that the FDA has acted

on. Among all Regular SE reports, the portion that has received final action is small but when placed in the context of all SE reports, that portion is microscopic.

**FIGURE 2**



The problem of allowing Provisional SE reports to languish while attempting to catch up on Regular SE reports will only be exacerbated if the FDA finalizes its Deeming Regulation as it is proposed. This proposed rule would see an influx of thousands of new Provisional applications from all three new product pathways, likely pushing the review of the current batch of Provisional SE reports much farther into the future.

## **II. Denial of the Petition at Issue is the Only Response that Will Protect Public Health.**

In delegating the authority to regulate tobacco products, Congress entrusted the FDA with the protection of public health.<sup>28</sup> Congress was aware that the tobacco industry has been found by the federal courts to have violated racketeering statutes and that its deceptive practices were likely to continue,<sup>29</sup> and so Congress gave the FDA gatekeeping authority over new tobacco products.<sup>30</sup> The FDA must finally close the gate and properly scrutinize new products. It must not, as Lorillard would have it do, open a new path for the tobacco industry to introduce new products without the proper amount of scrutiny necessary to protect public health.

### **A. Lorillard is Part of a Decades-Long, Ongoing Conspiracy to Deceive the American Public and the Government by Concealing Information about the Deadly and Addictive Properties of Tobacco Products in an Attempt to Addict More Americans and Sell More Tobacco Products.**

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.<sup>31</sup> 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.<sup>32</sup> In this case, the government charged the tobacco industry defendants<sup>33</sup> with violating the Racketeer Influenced and Corrupt Organizations Act.<sup>34</sup> 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 petition. 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 give significant consideration to 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,<sup>35</sup> the addictiveness of and the ability to manipulate nicotine,<sup>36</sup> the lack of any health benefit from light and low tar cigarettes,<sup>37</sup> and the hazard of secondhand smoke.<sup>38</sup> Judge Kessler also details the industry's efforts to ensure that none of its research would be seen by courts or the general public.<sup>39</sup> The tobacco industry has also been found to deliberately market its products to youth for decades,<sup>40</sup> and has been found to destroy and suppress damaging information.<sup>41</sup> 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.<sup>42</sup>

Lorillard's petition represents yet another example of the tobacco industry attempting to manipulate the regulatory system in order to avoid a level of scrutiny that could benefit public health. Instead, the industry's only focus is on selling new tobacco products that will inevitably lead to addiction, disease, and death. All regulatory actions that are suggested and supported by the tobacco industry should be subject to the agency's highest level of scrutiny. The tobacco industry has proved time and again that it has no interest in public health. Its only interest is in selling deadly tobacco products to make money and this puts its goals at odds with the FDA and the public health community. Granting this petition would have disastrous effects on public health and the FDA must use its authority to prevent this sort of catastrophe.

### **1. Lorillard Participated in the Industry-Wide Conspiracy to Manipulate Nicotine Levels While Publicly Denying Its Ability To Do So.**

As is noted above, one of the main goals of premarket review is to stop the tobacco industry's manipulation of nicotine. The entire industry participated in this manipulation and Lorillard is no exception. Judge Kessler's 2006 opinion details the actions of each defendant with regard to manipulating nicotine levels and the lies told to hide the truth.

Given the importance of nicotine to the ultimate financial health of Defendants [including Lorillard], they have undertaken extensive research into how nicotine operates within the human body and how the physical and chemical design parameters of cigarettes influence the delivery of nicotine to smokers. Using the knowledge produced by that research, Defendants have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction. At the same time, Defendants have concealed much of

their nicotine-related research, and have continuously and vigorously denied their efforts to control nicotine levels and delivery.<sup>43</sup>

....

Like the other manufacturers, Lorillard's search for the best way to ensure effective and adequate nicotine delivery evolved through the years, but always had the same goal – determine the amount of nicotine delivery necessary to sustain addiction and produce cigarettes that ensure such delivery. A February 13, 1980 internal memorandum from Richard E. Smith described how Lorillard undertook an internal project to "[d]etermine the minimum level of nicotine that will allow continued smoking." Company scientists hypothesized that there was a nicotine threshold below which "smokers will quit, or return to higher T&N brands."<sup>44</sup>

As early as 1969, Lorillard was actively pursuing a method to more directly control the nicotine content of its cigarettes,<sup>45</sup> and by 1971 it had the capability to analyze and measure the nicotine content of competing brands.<sup>46</sup> Lorillard surmised that the highest selling brands had an optimal ratio of smoke nicotine to tar.<sup>47</sup> Throughout the 1970s, Lorillard focused its efforts on determining how other cigarette manufacturers were artificially raising the nicotine levels of "low tar" cigarettes while decreasing tar.<sup>48</sup> In 1976, Lorillard created an extensive research plan which it dubbed the Nicotine Augmentation Project (NAP), that was designed to "develop a flavorful cigarette delivering lower tar while at the same time delivering a level of nicotine higher than could be obtained normally by conventional cigarette consumption."<sup>49</sup> Among the many methods of increasing nicotine that Lorillard's NAP studied were the addition of nicotine to the cigarette tobacco, adding ammonia to create more free nicotine, using air to dilute cigarette smoke, decreasing the acidity of smoke and developing filters that would filter out tar and allow nicotine to pass through.<sup>50</sup> By 1977, Lorillard had concluded that spraying additional nicotine onto reconstituted tobacco was a potential solution to the problem as it did in fact deliver additional nicotine.<sup>51</sup> NAP also concluded that air dilution in the cellulose acetate filter was also an acceptable method to raise the nicotine to tar ratio and increase smoke pH.<sup>52</sup> Lorillard extensively studied various methods to chemically treat cigarette filters to modify particle size and polarity to increase the amount of nicotine that could pass through the filter.<sup>53</sup> Lorillard also experimented with blending different types of tobacco to optimize the tar to nicotine ratio of its products and periodically monitored the nicotine content of cigarettes in the retail environment to determine the shelf life of the added nicotine.<sup>54</sup>

Throughout all of this research, it was clear that the intent of increasing the nicotine content of cigarettes was to maintain addiction in the consumer for the purpose of selling more cigarettes regardless of the deadly consequences. In fact, in 1976, Lorillard rejected the idea of creating a product with 50% less nicotine because it "could not deliver the smoking satisfaction to sustain consumer purchase."<sup>55</sup> Lorillard's internal memos thoroughly document its efforts to increase nicotine and sell more cigarettes.<sup>56</sup>

Lorillard attempted to protect its public image by deliberately and repeatedly making false public statements about its ability to manipulate the level of nicotine in its products. In 1994 representatives from the largest American tobacco companies testified in a series of hearings



before the House of Representatives Subcommittee on Health and the Environment. Representatives from Lorillard knowingly provided false statements to the subcommittee.

On March 25, 1994, Alexander W. Spears, Vice Chairman and Chief Operating Officer of Lorillard, testified at the Waxman Hearings that "[w]e do not set levels of nicotine for particular brands of cigarettes." Spears further stated that "[n]icotine follows the tar level," that the correlation between the two "is essentially perfect," which "shows that there is no manipulation of nicotine." In a 1981 study, the Chemical and Physical Criteria for Tobacco Leaf of Modern Day Cigarettes, Spears had previously stated explicitly that "low-tar" cigarettes used special blends of tobacco to keep the level of nicotine up while tar is reduced: "[T]he lowest tar segment [of product categories] is composed of cigarettes utilizing a tobacco blend which is significantly higher in nicotine." Spears did not inform Congress of his earlier statement.

....

In response to questioning by the panel concerning data he submitted at the March 25, 1994 hearing, Spears again contended in testimony on April 14, 1994, that the level of nicotine found in cigarette products is a function of the level of tar in those products. Spears testified that "the statement that nicotine follows tar" was true from the 1950s to 1990 and that he "stick[s] with that statement and [he] believe[s] it is accurate."

....

On April 14, 1994, Andrew H. Tisch, Chairman and CEO of Lorillard Tobacco Company, testified at the Waxman Hearings that "the level of nicotine in the products manufactured and sold by Lorillard is solely determined by the tobacco that we buy and the blending of different tobaccos used in our manufacturing. . . . Nicotine levels follow tar levels and are not raised or reduced for particular brands." Tisch also testified that "Lorillard does not take any steps to assure a minimum level of nicotine in our products. Lorillard does not add nicotine to cigarette tobacco for the purpose of manipulating or spiking the amount of nicotine received by the smoker."<sup>57</sup>

Lorillard has proved itself to be untrustworthy generally, and specifically, with respect to its ability to manipulate the nicotine content of its products. This ability and the opportunity to do so with no oversight has had disastrous consequences for public health. In its analysis of this petition, the FDA must put Lorillard's current request in the context of its past behavior. The tobacco industry racketeers cannot be trusted and this petition is another attempt to manipulate the regulatory process and avoid stringent regulation. The industry cannot be allowed to return to the way in which it did business before the Tobacco Control Act was passed. Premarket review is an important tool to stop product manipulation.

**2. The Intent of Delegating the Premarket Review of Tobacco Products to the FDA is to Prevent the Tobacco Industry from Freely Making Changes to its Products that Allow for the Calculation and Manipulation of Nicotine and Other Additives that Maximize Attractiveness and Addiction.**

One of the most important factors in the tobacco industry's success at creating and sustaining addiction to tobacco products is their ability to manipulate the level of nicotine in their products. Congress recognized this as one of the most important reasons for federal action in tobacco product regulation.

The current lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and incidence of disease. Flavors and product modification not only make the products more appealing to youth, but often result in exposure to additional carcinogens and other toxic constituents. The manipulation of nicotine and other chemical levels increases addictiveness and harm.<sup>58</sup>

In addition to this recognition by Congress during the debate of the Tobacco Control Act, the findings and verdict in the *U.S. v. Philip Morris* were officially adopted in the findings of the Tobacco Control Act.<sup>59</sup> Congress fully recognized the public health threat posed by the continued ability of the tobacco industry to freely introduce new products and modify existing products and thus, Congress gave the FDA the authority to oversee even the most minute change to the additives of a particular product. The intention of the law is clear and the reasoning is sound. Even after the passage of the Act, we are still learning about the effects of the tobacco industry's deceitful manipulation of its products. The U.S. Surgeon General has reported that as the prevalence of smoking has been decreasing, the risk of developing deadly adenocarcinoma of the lung from cigarette smoking has been increasing since the 1960s and that rise is the direct result of changes to the design and composition of cigarettes.<sup>60</sup> One of the most likely causes of this increase in the risk of adenocarcinoma is the rise of ventilated filters in cigarettes which dilute tobacco smoke allowing a smoker to draw smoke deeper into the lungs.<sup>61</sup> Ventilating filters were developed in order to decrease measured tar levels (while not actually decreasing tar intake for smokers) while retaining the necessary level of nicotine to create and sustain addiction.<sup>62</sup>

The Tobacco Control Act attempts to put a stop to the tobacco industry's ability to make deadly modifications to its products by delegating premarket review authority to the FDA. Even with the small window offered for the industry to submit Provisional SE reports, there was a clear intent to have the FDA ensure that the manipulation of nicotine and other additives and constituents would end, starting on March 23, 2011. Congress envisioned a regulatory scheme where the industry would no longer be left to do as it had for decades. The creation and marketing of new tobacco products would finally have the kind of oversight necessary to stop current trends and eventually reverse decades of manipulation by the tobacco industry that has led to addiction, disease, and death.

### **3. Lorillard Mischaracterizes the Problem with FDA Review of SE Reports and Would Have the FDA Create Another Deadly Loophole Rather than Close the Existing Loophole.**

While there are certainly problems with the current state of FDA review of SE reports, the tobacco industry's inability to market new products at will is not one of them. In its initial petition to the FDA, Lorillard attempts to paint a picture of a system that is inherently unfair to the tobacco industry and also argues that the FDA's slow review of SE reports violates the Tobacco Control Act.

The FDA has stated, correctly, that while there is a 180 day deadline for action on PMTAs,<sup>63</sup> there is no corresponding deadline for FDA action on SE reports.<sup>64</sup> Lorillard argues that this reasoning invalidates a provision in Section 905j that requires a manufacturer to submit a report 90 days before the initial marketing of the product represented by the report. Lorillard reasons that if there is no deadline for action, a manufacturer cannot "calculate a date that is 90 days before it will introduce a product into interstate commerce."<sup>65</sup> This logic does not stand up to scrutiny.

The statute requires the submission of a report "at least 90 days" prior to the marketing of a product.<sup>66</sup> Were it not for the qualifier "at least," Lorillard's assertion may have been true. However, because the statute only sets a floor and not a ceiling for the waiting period for the introduction of a new product, a manufacturer is not required to calculate a date 90 days prior to introduction of a product into interstate commerce. It requires a manufacturer to submit a report and wait for an SE order. Should that order come within the 90 day period after the report's submission, the manufacturer would be required to wait until the 90 day time period had tolled. Lorillard's assertion that this provision is somehow rendered meaningless without a corresponding deadline for the FDA to act on the report is disingenuous. This is clearly not what the statute requires. Lorillard understands full well how this provision operates in practice. The statute requires a manufacturer to submit a complete report. There is no requirement of counting time and any suggestion that this is somehow a barrier to the tobacco industry's continued submission of SE reports is absurd.

Not only is this logic flawed but Lorillard must know it to be untrue. Only two months have passed between March of 2011 and May of 2014 where the FDA received no SE reports.<sup>67</sup> There is clearly no barrier for the tobacco industry to submit new SE reports. Lorillard and the rest of the tobacco industry fully understand the process and Lorillard is merely searching, in vain, for a statutory provision that would create a deadline for FDA action on its pending reports. The truth is that such a provision doesn't exist. If Lorillard truly desires swift action on new products, it is free to submit a PMTA and receive action in 180 days. A product that is eligible for the SE pathway is not excluded from the PMTA pathway; the manufacturer of the new product is merely obligated to submit its scientific analysis in a different form.

Lorillard may resent the fact that the industry must now wait for an SE order before it can begin marketing activities, making certain aspects of its business more difficult and less predictable, but this is the intention of the Tobacco Control Act. The passage of the Act represents a bellwether in tobacco control ushering in a new era in which there is actual oversight of tobacco

products before they can be sold. Whether or not the tobacco industry is willing to accept it, this means the end of business as usual.

Because Lorillard is unable to begin marketing those products for which it has filed a Regular SE report and the FDA has been slow to review those reports, Lorillard asserts that it has been put into an unfair position. Lorillard has also suggested to the FDA that its competitors are merely using Provisional SE reports as placeholders for products that they continue to introduce. Given these arguments, Lorillard asserts that the necessary solution is for the FDA to allow Lorillard to begin marketing the products for which it has a pending Regular SE report. Rather than closing this loophole and protecting public health, putting all tobacco companies in the unfortunate position of having to wait for the FDA to review their reports, Lorillard would have the FDA create a new loophole that would allow Lorillard and the rest of the tobacco industry to introduce products to the market without premarket review, causing irreparable damage to public health. Lorillard's only desire is to sell tobacco products that are addictive and deadly. Make no mistake; Lorillard has no desire to protect public health.

#### **4. Creating a New Loophole Violates the Intent of the Tobacco Control Act.**

Despite the fact that the Tobacco Control Act creates a short window in time to allow for products to be marketed before being scrutinized by the FDA, the Act clearly anticipates the regulatory scheme reaching a point at which all products will be subject to premarket review by the FDA. For the PMTA and SE exemption pathways, the FDA has had premarket review authority since the passage of the Tobacco Control Act. Only for the SE pathway is there any deviation from this intent and the window created for Provisional SE reports represents a short period of time in the entire scheme of FDA tobacco regulation. As was stated above, in practice, this window was only open for about four and a half months. This year marks the fifth anniversary of the passage of the Tobacco Control act and throughout most of that time, the FDA has had premarket review authority over all products.

The structure of the Act also strongly suggests that the allowance of Provisional SE reports was intended to be a transition to full premarket review of all products. Because that window eventually closed and all reports submitted after that closure are subject to premarket review, it is clear that Congress was moving the tobacco product market towards, rather than away from, premarket review. Had the tobacco industry not flooded the FDA with Provisional SE reports, presumably all reports submitted within the window would have received either an SE or NSE order within a reasonable time. From then on, all new reports submitted as well as all submissions to the other product pathways would be subject to premarket review.

Lorillard would essentially have the FDA convert all Regular SE reports into Provisional reports and reverse the direction of regulation of the market, allowing all new products to avoid the premarket review that the Act clearly intends. Lorillard would have the FDA open up a loophole that completely swallows the requirements of the law. Comparing the number of tobacco industry submissions of SE reports to the other two product pathways reveals the intention to circumvent premarket review. If the FDA were to grant this petition, the industry would have no incentive to avail itself of the more rigorous standards embodied in the PMTA process which should be the primary pathway for new products. The intention of the Act is to move all products

towards premarket review and to subject most products to rigorous scientific standards so that eventually, the tobacco industry is forced to introduce products that will do less harm to public health. Granting this petition would violate that intention.

**B. The Protection of Public Health is the Only Guiding Principle that the FDA Can Use in Its Regulation of Tobacco Products.**

Despite implicit and explicit arguments by Lorillard and several tobacco industry commenters to Lorillard's petition, the financial health of the tobacco industry is not, and should not, be a concern of the FDA in examining the merits of this citizen petition. The FDA's only guiding principle in the regulation of tobacco products is the public health standard established by the Tobacco Control Act.

**1. Despite Allegations to the Contrary, Lorillard Is Suffering No Financial Harm as a Result of Slow Progress at the FDA.**

Lorillard's justification for the action requested in its citizen petition is that the current state of FDA review of SE reports has created a situation where the market is "frozen by a *de facto* embargo."<sup>68</sup> This language is echoed by commenters JT International U.S.A., Inc. (JTI), and The Council of Independent Tobacco Manufacturers of America (CITMA). Both organizations state that the FDA has, "essentially kept the market for regulated products frozen."<sup>69</sup> Lorillard, JTI and CITMA all state that this situation will affect "planning activities."<sup>70</sup> In addition all three organizations speculate that the end result will be harm to their businesses.<sup>71</sup> Setting aside the fact that the financial health of the tobacco industry is not the FDA's concern, by any measure, Lorillard's business has been growing since the passage of the Tobacco Control Act. Between June 2009 and August 2014, Lorillard's stock price has climbed from around \$22 per share to over \$60 per share, peaking in July 2014 at \$67.22. The stock also saw a three for one split of its shares in January 2013.<sup>72</sup> During that same time period, Lorillard's dividend per share increased from \$0.33 to \$0.62. An investor who purchased Lorillard stock when the Tobacco Control Act was passed would have seen more than a ten-fold gain in their investment to date.<sup>73</sup> Lorillard has also seen steady growth of its net sales, operating income, net income and gross profit from 2008 through 2013.<sup>74</sup> Using publicly available information, there is no measure of financial health that would indicate that the FDA's slow review of SE reports has been harmful to Lorillard.

**2. The FDA Must Use the Public Health Standard for All of its Tobacco Product Regulatory Decisions.**

Even if Lorillard's allegations of financial harm were true, which they are not, the FDA should not and cannot take this information under consideration when it creates any tobacco product regulatory policy. The one and only consideration that the FDA can use to regulate tobacco products is the health of the public.

The Food, Drug and Cosmetic Act 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 the products without being exposed to unnecessary and unregulated risks. For food, the FDA must ensure that food is safe, wholesome, sanitary, and properly labeled.<sup>75</sup> For drugs, the FDA must ensure that

drugs are safe and effective.<sup>76</sup> Tobacco is different from food and drugs in that it is an inherently deadly product and thus clearly not safe. Cigarette smoking kills over 480,000 Americans each year,<sup>77</sup> and is the single largest cause of preventable death and disease in the U.S.<sup>78</sup> Nor is tobacco effective (other than at killing more than half of its users).<sup>79</sup> Because tobacco is neither safe nor effective, and because it has no health benefits, only risks, federal food and drug standards simply will not work for the regulation of tobacco products.

Thus, Congress had to develop a new standard for FDA regulation of tobacco products, the public health standard.<sup>80</sup> Rather than focusing 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.<sup>81</sup> This comprehensive public health standard can be a very powerful tool for the FDA, permitting the agency to not just mitigate the ongoing damage caused by tobacco use, but also to prevent future harm. The FDA can implement stringent product and manufacturing standards and ensure that new products inflict less harm on the public's health. The FDA is also 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. The public health standard, referenced thirty-three times in the Tobacco Control Act,<sup>82</sup> lists the only considerations the FDA is allowed to weigh in its regulation of tobacco. Even a cursory analysis of Lorillard's citizen petition reveals that taking the action requested would not protect public health; rather it would cause irreparable harm.

### **C. Lorillard has No Interest in Protecting Public Health.**

As was stated above, Lorillard's true goal in submitting this citizen petition is to attempt to preserve its ability to manipulate and introduce new products at will. Lorillard and the rest of the tobacco industry are not being placed in financial jeopardy by the status quo, despite Lorillard's assertions. In addition to these baseless claims, Lorillard has asserted an illusory argument that a lack of FDA action on SE reports is "preventing innovation and competition in that market that could potentially benefit the public health."<sup>83</sup> This statement could not be farther from the truth.

#### **1. Expediting the Approval Process for Regular SE Reports Will Not Protect Public Health.**

The Tobacco Control Act creates three distinct product pathways with varied levels of data required to receive a marketing order from the FDA. Each pathway has a distinct purpose. The PMTA pathway is intended to be the primary pathway for new products and it requires the most rigorous scientific information because the pathway is for products with the greatest potential to cause more harm. Congress recognized that the growth in the market for new and novel tobacco products could potentially offset the gains made in the reduction of cigarette consumption over the past five decades. Because of the implications on initiation, cessation and dual-use of new products with cigarettes, the Act subjects the least conventional products to the most rigorous standards. Thus, the Act references whether the marketing of a product is appropriate for the

protection of public health as the first of many measures to be considered in the process of acting on a PMTA.<sup>84</sup>

With the SE pathway, the Act only allows a finding of substantial equivalence for those products that have the same characteristics as predicate products or different characteristics that do not raise different questions of public health.<sup>85</sup> Clearly, this pathway is for products that are so similar to past products that there is no net effect on public health. The products are either the same as other products or so similar that public health is not jeopardized with their introduction. The SE Exemption pathway is for products that are nearly identical to past products, so much so that they require less information than the SE pathway which causes no net effect to public health.

Because the SE pathway is intended to allow the marketing of new products that do not change the state of public health, and because Lorillard and the rest of the tobacco industry have made virtually no attempt to market products through the PMTA pathway nor to receive certification that any products can be marketed as Modified Risk Tobacco Products,<sup>86</sup> it is disingenuous for Lorillard to assert that the granting of its petition would allow for the sort of innovation that could benefit public health. If that were the true goal, Lorillard would be utilizing other marketing pathways because the SE pathway is not available to innovative products. As was outlined above, the only reason that Lorillard and the tobacco industry are focusing on this pathway is the potential ease with which they can market new products.

## **2. Granting this Petition Will Unnecessarily Jeopardize Public Health.**

As is summarized above, Lorillard's petition essentially asks the FDA to convert all Regular SE reports into Provisional SE reports, allowing the tobacco industry to begin marketing new products without FDA scrutiny. This tactic would allow the tobacco industry to instantly introduce at least 563 products for which the industry has filed Regular SE reports. Those products could be sold until the FDA takes action and issues an NSE order. This lag time would allow the industry to introduce and sell products that do not meet the standards required for SE reports or potentially allow the industry to sell products that it knows will violate the Tobacco Control Act. This action could cause irreparable harm during the interim period in which the products are on the market but have not yet received an NSE order.

In addition, taking the action requested in this petition would allow the industry to introduce additional new products beyond the 563 products represented by current pending Regular SE reports. With such a policy in place, the FDA would likely see another flood of SE reports submitted by the tobacco industry for the purpose of introducing new products without the proper level of scrutiny required by the Tobacco Control Act. The tobacco industry was keen to exploit the loophole in the Act created to allow for the submission of Provisional SE reports. Similarly, the tobacco industry would see this policy as creating a new loophole. If Lorillard's allegations regarding PM's exploitation of the Provisional SE loophole are true, it seems likely that reopening that door would give Lorillard and the rest of the tobacco industry an incentive to catch up and it would also give PM an incentive to stay ahead. Given the industry's long history of putting profits ahead of public health and all else, it is highly likely that new tobacco products would be introduced. Because those tobacco products would not be subject to premarket review,

public health will suffer. The industry's only goal is to create and sustain addiction to its products; addiction that will inevitably lead to disease and death.

This problem will increase exponentially if the FDA finalizes the Deeming Regulation as it is proposed. According to the FDA's proposal, the agency expects to receive 54 PMTAs, 4,208 SE reports, and 1,402 SE Exemption requests in the first two years after the regulation takes effect,<sup>87</sup> and these estimates may be low because the FDA expects that the regulation will result in over 13,000 new products being brought under its authority. In addition to all of these new applications adding to the existing backlog, the FDA has proposed to defer enforcement of premarket review on all new products – regardless of the pathway – for 24 months following the regulation's implementation. The FDA also proposes to establish that 24 month window as a new provisional period that will allow the tobacco industry to continue marketing new products after the window closes until the FDA finally issues an order to remove the products from the market.

There is a unifying thread that runs through all of the consequences: they harm public health. Because it is the FDA's mission to protect public health, it must deny this petition.

### **III. In Addition to the Denial of this Petition, The FDA Should Take Additional Steps to Protect Public Health.**

The Consortium is aware of significant problems, both substantive and procedural, that have been associated with the product application process since the passage of the Tobacco Control Act and will take this opportunity to provide some insight on how those problems should be resolved to best protect public health.

#### **A. The FDA Should Place the Review of Regular SE Reports On Hold and Focus Its Resources on Provisional SE Reports.**

The most important step that the FDA could take right now, to protect public health in its review of SE reports, is to set aside all Regular SE reports and focus all of the resources dedicated to the review of SE reports to the languishing Provisional SE reports. As was stated above, Regular SE reports represent products that are not yet on the market and the delay of the review of those reports creates a minor inconvenience to the tobacco industry; it does not harm public health. Because the products represented by Provisional SE reports can be marketed without FDA action, the inverse is true. Delay on the reports allows deadly and addictive products to remain on the market regardless of whether or not they will eventually be approved for marketing. It is highly likely that at least some of the 3,358 currently pending Provisional SE applications represent products that will eventually receive an NSE order because either the predicate product upon which the report is based is ineligible or the characteristics between the new product and the predicate product *do* raise different questions of public health.

This was certainly the case for the only four Provisional SE reports that the FDA has acted on. None of the four reports submitted even identified a predicate product. The identity of a predicate product is so foundational to an SE application that it is baffling that it took the FDA so long to act on these reports and that the FDA afforded the report submitters so many chances to correct the deficiency. The entire purpose of an SE report is to compare a past product with a



new product and with no past product to offer as comparison, there is essentially nothing to report. After submitting four grossly deficient SE reports on March 21, 2011, the submitter, Jash International, was not contacted by the FDA until March 2013.<sup>88</sup> FDA staff spoke with an agent of Jash on March 15, 2012, March 19, 2013, April 3, 2013, and April 12, 2013. In July of 2013, the FDA sent a preliminary finding to Jash and then followed up with an agent on August 5, 2013 and August 23, 2013. All told, there was no action on the application for nearly a full year at which point the FDA had a half-dozen follow-up conversations with the report submitter regarding a report that should absolutely have been dead-on-arrival. This kind of catastrophic delay on so simple an action will inevitably reduce the public health community's confidence in the FDA's process.

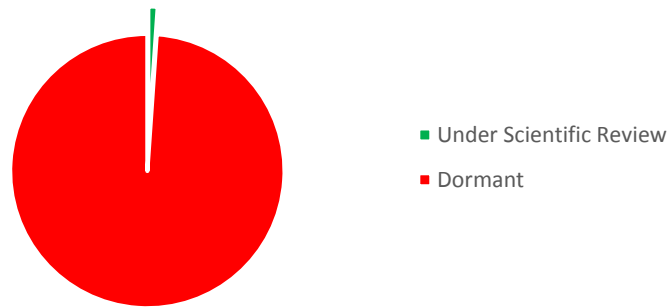
Were it not for the loophole in the Provisional SE process, these products certainly would have never been allowed to be introduced to the market. The omission of the identification of a predicate product would be a laughable deficiency were it not the case that the products were allowed to be legally sold for almost three years. The FDA did not adequately protect the health of the consumers who purchased any one of those four products. A product that will eventually be removed from the market should not be allowed to remain on the market simply because the tobacco industry was clever enough to exploit a loophole. The FDA needs to do its part to fix this problem because every day that such a product is on the market is a day that the health of the public is unnecessarily jeopardized.

In addition, it is clear from information provided by the FDA that it has consciously made Regular, rather than Provisional, SE reports its top priority.<sup>89</sup> The stated reason for this priority is that Regular SE applications represent products that cannot enter the market until the FDA takes action. The FDA has yet to explain why it has determined that allowing manufacturers to market new products is more important than removing potentially harmful products from the market. It is difficult, if not impossible, to reconcile the FDA's prioritization of Regular SE reports with the agency's charge to protect public health. The best way for the FDA to protect public health is to reverse its priorities and focus on Provisional SE reports.

According to data made available by the FDA,<sup>90</sup> not only has there been a mere four NSE orders for Provisional SE reports, the FDA has barely begun its scientific review of these reports. According to the FDA, the scientific review of an SE report is the final step in the review process and it follows the jurisdictional review, completeness review, and the compliance review of an SE report. Figure 3 shows the portion of Provisional SE report that have reached the scientific review stage and those that remain dormant. Thus far, only forty-one Provisional SE reports have reached the scientific review stage and four of those were denied marketing.

**Figure 3**

Provisional SE Reports

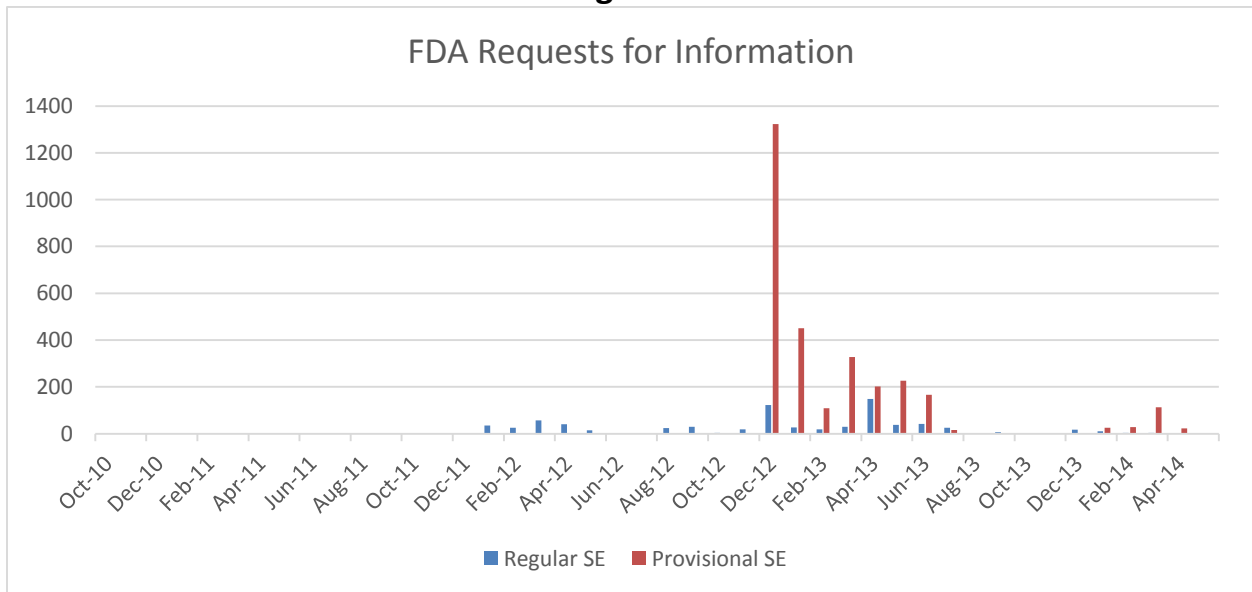


For Regular SE reports, the FDA has initiated scientific review of all 935 that it has received. It is clear that the FDA’s current priority of Regular over Provisional SE reports has resulted in the Provisional SE reports remaining almost completely free of scientific scrutiny. This is unacceptable. The Provisional SE reports represent products that could be in the hands of consumers and the FDA is the only agency tasked with oversight of this process. The FDA is barely devoting its attention to these products and has only undertaken token action on the very lowest of the low-hanging fruit.

This huge divide in resources is also apparent when examining the FDA’s requests for information from SE report submitters. According to the FDA, almost all of the SE reports that it receives are deficient in some way. The FDA has been notifying submitters of deficiencies and allowing them to amend their reports. Figure 4 shows FDA requests for additional information for both Regular and Provisional SE reports.

**Figure 4**

FDA Requests for Information



It is immediately apparent that when the FDA began submitting requests to amend SE reports, it focused on Regular SE reports exclusively for almost an entire year before requesting amendments to Provisional SE reports. Apparently during that period of time, the FDA had not yet begun to examine Provisional SE reports even though they were received first and present an immediate potential threat to public health. This is perplexing given the fact that we now know that some SE reports did not even bother identifying a predicate product which should be a fatal deficiency, at least warranting contacting the report submitter. While the ratio of requests for information per SE report is about the same between Provisional and Regular SE reports, this graph once again highlights the tremendous gulf between the number of Provisional and Regular SE reports that have been submitted, and thus, the number of those reports that are deficient.

The FDA must protect the public from the harms of tobacco and the simplest way to improve the SE report review process to protect public health is to prioritize the review of Provisional over Regular SE reports. This is an elementary step that should be immediately obvious to anyone standing in the agency's shoes.

### **B. The Tobacco Product Application Processes Should Be More Open and Transparent.**

While there have been improvements in the amount and quality of information that the FDA has been willing to share with the public health community, there is still tremendous room for improvement. The Consortium and others in the public health community are continually surprised by the types of information that the FDA does not affirmatively make available forcing those who monitor the tobacco industry and the FDA's regulatory activities to submit requests under the Freedom of Information Act (FOIA). This process is burdensome and wasteful. Furthermore, most requests result in disclosure of heavily redacted documents. Specifically, the Consortium would like to see the FDA release all disclosable information related to all of its SE, PMTA and SE exemption decisions and more up-to-date information on the review process. Only for its first two SE orders did the FDA affirmatively post the original SE reports and information regarding the scientific review and even then, that information was heavily redacted and published only after multiple FOIA requests. There is also little information available with regard to the number of applications that the FDA has received for each of the product pathways and the number of products under each stage of review.<sup>91</sup> The information that is available is updated infrequently and often conflicts with other available information.<sup>92</sup> It should not be this difficult to find accurate, up-to-date information on a process this important and the FDA does itself and the public health community a disservice by not maximizing its transparency.

While we recognize that the tobacco industry has legal rights with respect to the privacy of certain types of information, the FDA has been extremely deferential to the industry in what it is willing to disclose to the public health community. There is no question that an open and transparent process results in better regulation and this is particularly true with regard to the tobacco industry. The FDA would be wise to remember that among the industry's greatest skills is its ability to manipulate and hide information. The public health community cannot rebut false or misleading tobacco industry information without access to that information. The public health community and the FDA share the goal of stringent tobacco regulation and we cannot do our part if the FDA does not adequately share information.

#### IV. Conclusion

The Consortium strongly urges the FDA to deny this petition. Doing so is the only action that will protect public health and uphold the FDA's congressionally mandated mission. In addition, the FDA can improve the SE report review process by prioritizing Provisional reports to close the legal loophole and by making the entire process more open and transparent.

Respectfully,



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<sup>1</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111–31, 123 Stat. 1776, 1794 (2009) (codified at 21 U.S.C. § 387e(j)) [hereinafter Tobacco Control Act]; Tobacco Control Act § 910, 123 Stat. at 1807 (codified at 21 U.S.C. § 387j).

<sup>2</sup> *United States v. Philip Morris USA, Inc.*, 449 F.Supp.2d 1 (D.D.C. 2006). For an overview of industry practices from the findings section of the case, see TOBACCO CONTROL LEGAL CONSORTIUM, THE VERDICT IS IN: FINDINGS FROM THE UNITED STATES V. PHILIP MORRIS (2006) available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-verdict-is-in.pdf>; See also, Desmond Jenson, TOBACCO CONTROL LEGAL CONSORTIUM, RACKETEERS AT THE TABLE: HOW THE TOBACCO INDUSTRY IS SUBVERTING THE PUBLIC HEALTH PURPOSE OF TOBACCO Regulation (2013), available at <http://publichealthlawcenter.org/sites/default/files/resources/tclc-synopsis-racketeers-table-2013.pdf>.

<sup>3</sup> Webinar: 20 Years Later – Returning to FDA to Regulate Tobacco, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm368823.htm> (last visited Aug. 8, 2014).

<sup>4</sup> Tobacco Control Act § 910(c)(2)(A), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(A)).

<sup>5</sup> Tobacco Control Act § 910(c)(4), 123 Stat. at 1810 (codified at 21 U.S.C. § 387j(c)(4)).

<sup>6</sup> Tobacco Control Act § 910(c)(2)(B), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(B)).

<sup>7</sup> Tobacco Control Act § 910(c)(2)(C), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(C)).

<sup>8</sup> Tobacco Control Act § 910(c)(2)(D), 123 Stat. at 1809-1810 (codified at 21 U.S.C. § 387j(c)(2)(D)).

<sup>9</sup> Total Number of Product Submissions Received or Filed in the Month, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all> (last visited Aug. 19, 2014).

<sup>10</sup> Tobacco Control Act § 910(c)(1)(A), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(1)(A)).

<sup>11</sup> Tobacco Product Marketing Orders, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm> (last visited August 25, 2014); U.S. FOOD AND DRUG ADMIN., BRIEF SUMMARY OF “REFUSAL-TO-FILE” DETERMINATIONS (2014), available at <http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM389515.pdf>.

<sup>12</sup> Tobacco Control Act § 910(a)(3)(A)(i), 123 Stat. at 1808 (codified at 21 U.S.C. § 387j(a)(3)(A)(i)).

<sup>13</sup> Tobacco Control Act § 910(a)(3)(A)(ii), 123 Stat. at 1808 (codified at 21 U.S.C. § 387j(a)(3)(A)(ii)).

<sup>14</sup> Tobacco Control Act § 905(j)(1)(A)(i), 123 Stat. at 1792 (codified at 21 U.S.C. § 387e(j)(1)(A)(i)).

<sup>15</sup> Tobacco Control Act § 905(j)(1)(A)(i), 123 Stat. at 1792 (codified at 21 U.S.C. § 387e(j)(1)(A)(i)).

<sup>16</sup> Tobacco Control Act § 905(j)(3), 123 Stat. at 1792 (codified at 21 U.S.C. § 387e(j)(3)).

<sup>17</sup> Tobacco Control Act § 905(j)(3), 123 Stat. at 1792 (codified at 21 U.S.C. § 387e(j)(3)).

<sup>18</sup> Cumulative Number of Substantial Equivalence (SE) Reports Received (1), U.S. FOOD AND DRUG ADMIN., available at <http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-provisional-SE-reports&fy=all> (last visited Aug. 25, 2014).

<sup>19</sup> Through May 30, 2014.

<sup>20</sup> *Webinar: 20 Years Later – Returning to FDA to Regulate Tobacco*, U.S. FOOD AND DRUG ADMIN., <http://www.fda.gov/TobaccoProducts/NewsEvents/ucm368823.htm> (last visited Aug. 25, 2014).

<sup>21</sup> See *supra* note 2 and accompanying text.

<sup>22</sup> Letter from Murray S. Kessler, Chairman, President & CEO, Lorillard, Inc., to Lawrence Deyton, Dir., Ctr. for Tobacco Products, U.S. Food and Drug Admin. (June 26, 2012), available at <http://www.regulations.gov/contentStreamer?objectId=0900006481133c45&disposition=attachment&contentType=pdf>.

<sup>23</sup> Altria Group, Inc., Quarterly Report (Form 10-Q) (Oct. 30, 2012) available at <http://www.sec.gov/Archives/edgar/data/764180/000076418012000030/form10-q.htm> (noting that Philip Morris USA, Inc. was expanding Marlboro NXT into 27 states at the end of September 2012).

<sup>24</sup> Altria Group, Inc., Quarterly Report (Form 10-Q) (July 24, 2013) available at <http://www.sec.gov/Archives/edgar/data/764180/000076418013000064/a2013form10-qq22013.htm> (noting that Philip Morris USA, Inc. had expanded distribution of Marlboro NXT to an additional 23 states).

<sup>25</sup> U.S. FOOD AND DRUG ADMIN., PROGRESS AND EFFECTIVENESS OF THE IMPLEMENTATION OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT (2013), available at <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM371271.pdf>; GOVERNMENT ACCOUNTABILITY OFFICE, REPORT TO THE RANKING MEMBER, SUBCOMMITTEE ON PRIMARY HEALTH AND AGING COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS, U.S. SENATE, NEW TOBACCO PRODUCTS, FDA NEEDS TO SET TIME FRAMES FOR ITS REVIEW PROCESS (2013), available at <http://www.gao.gov/assets/660/657451.pdf>; Corinne G. Husten & Lawrence R. Deyton, *Understanding the Tobacco Control Act: Efforts by the US Food and Drug Administration to make Tobacco-Related Morbidity and Mortality Part of the USA's Past, Not Its Future*, 381 LANCET 1570 (2013); U.S. FOOD AND DRUG ADMIN., REPORTS ON SUBSTANTIAL EQUIVALENCE (905(J) (A)(1)(A) REPORTS: ONE YEAR LATER (2012), available at <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/ForIndustry/Retailer/UCM301597.pdf>; U.S. FOOD AND DRUG ADMIN., REPORTS ON SUBSTANTIAL EQUIVALENCE (905(J) (A)(1)(A) REPORTS: AN UPDATE (2012), available at <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/BreakTheChain/UCM316450.pdf>; U.S. FOOD AND DRUG ADMIN., UPDATE ON REVIEW OF SUBSTANTIAL EQUIVALENCE REPORTS (SE REPORTS) (2012), available at <http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/BreakTheChain/UCM347933.pdf>.

<sup>26</sup> See *supra* note 25 and accompanying text.

<sup>27</sup> See *supra* note 25 and accompanying text.

<sup>28</sup> Tobacco Control Act § 910(c)(2)(A), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(A)).

<sup>29</sup> Tobacco Control Act § 2(47)-(49), 123 Stat. at 1781 (codified at 21 U.S.C. § 387(47)-(49)).

<sup>30</sup> Tobacco Control Act, § 905(j), 123 Stat. at 1974 (codified at 21 U.S.C. § 387e(j)); Tobacco Control Act, § 910, 123 Stat. at 1807 (codified at 21 U.S.C. § 387j).

<sup>31</sup> *Legacy Tobacco Documents Library*, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO, <http://legacy.library.ucsf.edu/> (last visited Aug. 25, 2014).

<sup>32</sup> See *supra* note 2 and accompanying text.

<sup>33</sup> Philip Morris, Inc., now Philip Morris USA, Inc. (a division of Altria), R.J. Reynolds Tobacco Co., now Reynolds American, Brown & Williamson Tobacco Co., now part of Reynolds American, Lorillard Tobacco Company, The Liggett Group, now part of Vector Group Ltd., American Tobacco Co., which merged with Brown & Williamson, now part of Reynolds American, Philip Morris Cos., now Altria, British American Tobacco Investments Ltd., The Council for Tobacco Research U.S.A., Inc., and The Tobacco Institute, Inc.

<sup>34</sup> This decision has led many in the tobacco control community to label the tobacco industry defendants, “racketeers.”

<sup>35</sup> *Philip Morris USA, Inc.*, 449 F.Supp.2d at 146-208.

<sup>36</sup> *Id.* at 208-384.

<sup>37</sup> *Id.* at 430-561.

<sup>38</sup> *Id.* at 694-801.

<sup>39</sup> *Id.* at 801-839.

<sup>40</sup> *Id.* at 561-694.

<sup>41</sup> *Id.* at 801-839.

<sup>42</sup> *Id.* at 35-143.

<sup>43</sup> *Id.* at 308.

<sup>44</sup> *Id.* at 315.

<sup>45</sup> *Id.* at 329.

<sup>46</sup> *Philip Morris USA, Inc.*, 449 F.Supp.2d at 330.

<sup>47</sup> *Id.* at 330.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 331.

<sup>51</sup> *Id.* at 331-332.

<sup>52</sup> *Id.* at 332.

<sup>53</sup> *Id.* at 332-333.

<sup>54</sup> *Id.* at 347-348.

<sup>55</sup> *Id.* at 336-337.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 378.

<sup>58</sup> H.R. Rep. 111-58(i), at 4 (2009), reprinted in 2009 U.S.C.C.A.N. 468, 471.

<sup>59</sup> “In August 2006 a United States district court judge found that the major United States cigarette companies have designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create and sustain addiction while also concealing much of their nicotine-related research. *USA v. Philip Morris, USA, Inc., et al.* (Civil Action No. 99–2496 (GK), August 17, 2006)” Tobacco Control Act § 2(47), 123 Stat. at 1781 (codified at 21 U.S.C. § 387(47)); *see also Id.* at §2(48)-49).

<sup>60</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING – 50 YEARS OF PROGRESS A REPORT OF THE SURGEON GENERAL 186 (2014) [hereinafter SGR 2014]. *available at* <http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf>.

<sup>61</sup> *Id.*

<sup>62</sup> *Philip Morris USA, Inc.*, 449 F.Supp.2d at 430-431.

<sup>63</sup> Tobacco Control Act, § 910(c)(1)(A), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(1)(A));

<sup>64</sup> Tobacco Control Act, § 910(a)(3), 123 Stat. at 1807-1808 (codified at 21 U.S.C. § 387j(a)(3)).

<sup>65</sup> LORILLARD INC., CITIZEN PETITION, (DOCKET NO.FDA-2012-P-0695)(2012) [hereinafter Lorillard Petition], *available at*

<http://www.regulations.gov/contentStreamer?objectId=090000648106dfb2&disposition=attachment&contentType=pdf>.

<sup>66</sup> Tobacco Control Act, § 905(j), 123 Stat. at 1794 (codified at 21 U.S.C. § 387e(j)).

<sup>67</sup> According to the FDA, the fact that a manufacturer has submitted a tobacco product marketing application is protected information and thus the Consortium cannot establish the fact that Lorillard has a pending Regular SE report other than the two mentioned in the initial citizen petition which have since received SE orders. The fact that Lorillard continues to push the FDA to approve the request in the petition strongly suggests that Lorillard has additional pending Regular SE reports that represent products for which it would like to begin marketing.

<sup>68</sup> Lorillard Petition, *supra* note 65, at 5 (Italics in original).

<sup>69</sup> JT INT’L U.S.A., INC., COMMENT IN SUPPORT OF LORILLARD CITIZEN PETITION (DOCKET NO.FDA-2012-P-0695) 3 (2012) [hereinafter JTI Comment], *available at*

<http://www.regulations.gov/contentStreamer?objectId=090000648110789e&disposition=attachment&contentType=pdf>; COUNCIL OF INDEP. TOBACCO MFR.’S OF AMERICA, COMMENT IN SUPPORT OF LORILLARD CITIZEN PETITION (DOCKET NO.FDA-2012-P-0695) 3 (2012) [hereinafter CITMA Comment], *available at* <http://www.regulations.gov/contentStreamer?objectId=09000064810e2907&disposition=attachment&contentType=pdf>.

<sup>70</sup> “This inaction has created a situation in which the tobacco market is essentially frozen by a de facto embargo by FDA on new product introductions. This results in less competition and harms the ability of companies to engage in basic planning activities for the launch of new products.” Lorillard Petition, *supra* note 65 at 5. “[T]his has constrained even basic business planning activities.” JTI Comment, *supra* note 69 at 3. “By failing to take action on SE reports submitted to the agency, FDA has essentially kept the market for regulated tobacco products frozen since March 21, 2011. In so doing, FDA has stifled competition, preserving the colossal market share held by the major U.S. tobacco companies and threatening the continued viability of many small businesses. FDA’s sluggish review of SE reports has prevented CITMA members from making extremely minor changes that no regulator could seriously assert raise different questions of public health (e.g., marketing an exact copy of an existing product under a new brand name). Further, the uncertainty surrounding the SE report review process and the inability to predict whether or when FDA will authorize even the most minor product changes have inhibited CITMA members’ basic business planning activities.” CITMA Comment, *supra* note 69 at 3.

<sup>71</sup> “If FDA needs more time to establish a reasonable and efficient regulatory system, Lorillard and the tobacco industry should not be punished.” Lorillard Petition, *supra* note 65 at 6. “FDA’s inaction is causing significant business hardship for us and all companies in our industry. The proposed policy of enforcement discretion would be an effective solution to alleviate this hardship to industry while allowing FDA to clear its backlog of SE reports for review.” JTI Comment, *supra* note 69 at 1. “By failing to take action on SE reports submitted to the agency, FDA has essentially kept the market for regulated tobacco products frozen since March 21, 2011. In so doing, FDA has stifled competition, preserving the colossal market share held by the major U.S. tobacco companies and threatening the continued viability of many small businesses. FDA’s sluggish review of SE reports has prevented CITMA members from making extremely minor changes that no regulator could seriously assert raise different questions of public health (e.g., marketing an exact copy of an existing product under a new brand name). Further, the uncertainty surrounding the SE report review process and the inability to predict whether or when FDA will authorize even the most minor product changes have inhibited CITMA members’ basic business planning activities.” CITMA Comment, *supra* note 69 at 3. “. . . [T]he requested enforcement discretion policy would lift FDA’s de facto embargo on new or modified products, which has the potential to cause irreparable harm to small businesses.” CITMA Comment, *supra* note 69 at 4.

<sup>72</sup> Press Release, Lorillard Inc., Lorillard Declares 3-for-1 Stock Split (Nov. 13, 2012), *available at* <http://investors.lorillard.com/investor-relations/news/news-details/2012/Lorillard-Declares-3-for-1-Stock-Split/default.aspx>.

<sup>73</sup> Assuming a reinvestment of dividends.

<sup>74</sup> Lorillard Inc., Annual Report (Form 10-K) (Feb. 21, 2014), *available at* <http://lorillardltdc.dc2.q4cdn.com/e5a69ea1-0854-4393-a224-6e6c70fc65c1.pdf?noexit=true>.

<sup>75</sup> 21 U.S.C. § 393(b)(2)(A).

<sup>76</sup> 21 U.S.C. § 393(b)(2)(B).

<sup>77</sup> SGR 2014, *supra* note 60 at 659.

<sup>78</sup> Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses – United States, 2000-2004*, 57 MORBIDITY & MORTALITY WKLY. REP. 1226, 1226-28 (2008), *available at* <http://www.cdc.gov/mmwr/PDF/wk/mm5745.pdf>.

<sup>79</sup> WORLD HEALTH ORG. TECHNICAL REPORT SERIES, THE SCIENTIFIC BASIS OF TOBACCO PRODUCT REGULATION 3 (World Health Org. Press 2007), *available at* [http://www.who.int/tobacco/global\\_interaction/tobreg/who\\_tsr.pdf](http://www.who.int/tobacco/global_interaction/tobreg/who_tsr.pdf).

<sup>80</sup> H.R. REP. NO. 111-58, pt. 1, at 39 (2009), *reprinted in* 2009 U.S.C.C.A.N. 468, 488.

<sup>81</sup> Tobacco Control Act, § 907(a)(3)(B)(1), 123 Stat. at 1800 (codified at 21 U.S.C. § 387g(a)(3)(B)(i)).

<sup>82</sup> 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); § 387g(f)(1); 387h(a)(1); 387i(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).

<sup>83</sup> LORILLARD INC., PETITION FOR RECONSIDERATION (DOCKET NO.FDA-2012-P-0695) 6 (2013), *available at* <http://www.regulations.gov/contentStreamer?objectId=09000064814a275b&disposition=attachment&contentType=pdf>.

<sup>84</sup> Tobacco Control Act § 910(c)(2)(A), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(2)(A)).

<sup>85</sup> Tobacco Control Act § 910(a)(3), 123 Stat. at 1807 (codified at 21 U.S.C. § 387j(a)(3)).

<sup>86</sup> Total Number of Product Submissions Received or Filed in the Month, *supra* note 9.

<sup>87</sup> Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Proposed Rule, 79 Fed. Reg. 23,142, 23,144-23,146 (proposed April 25, 2014) (to be codified at 21 C.F.R. pt. 1100, 1140, and 1143).

<sup>88</sup> Technical Project Lead (TPL) Memorandum Regarding Jash Int’l SE Reports (Feb. 20, 2012), *available at* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/MarketingandAdvertising/UCM386756.pdf>

<sup>89</sup> *See, e.g.*, U.S. FOOD AND DRUG ADMIN., TOBACCO PRODUCTS, WEBINARS, April 10, 2013 *available at* <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/SubstantialEquivalence/ucm304518.htm>; U.S. FOOD AND DRUG ADMIN., TOBACCO PRODUCTS, WEBINARS, April 24, 2012 *available at* <http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/SubstantialEquivalence/ucm304518.htm>; U.S. FOOD AND DRUG ADMIN., TOBACCO PRODUCTS, WEBINARS, August 21, 2012 *available at*

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<http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/SubstantialEquivalence/ucm304518.htm>;

<sup>90</sup> Cumulative number of Substantial Equivalence (SE) Provisional reports received (1), U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-provisional-SE-reports&fy=all> (last visited Aug. 25, 2014).

<sup>91</sup> *Id.*; Cumulative Number of Substantial Equivalence (SE) Reports Received, *supra* note 18; Total Number of Product Submissions Received in a Month, *supra* note 9.

<sup>92</sup> *See supra* note 91 and accompanying text; *Tobacco Product Marketing Orders*, *supra* note 11.