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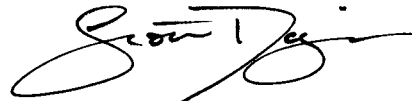
Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

RE: Docket No. FDA-N-2009-0294

To Whom It May Concern:

The attached comments regarding implementation of the Family Smoking Prevention and Tobacco Control Act are submitted on behalf of Lorillard Tobacco Company.

Sincerely,



Scott D. Danzis

**Comments of Lorillard Tobacco Company**

**Implementation of the Family Smoking Prevention and Tobacco Control Act**

These comments are respectfully submitted by Lorillard Tobacco Company (Lorillard) in response to the request for comments on the implementation of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) published by the Food and Drug Administration (FDA) on July 1, 2009.<sup>1</sup>

**I. Introduction**

Founded in 1760, Lorillard is the oldest continuously operating tobacco company in the United States, and it is also the nation's third largest tobacco company. Lorillard is based in Greensboro, North Carolina, where its corporate offices, manufacturing plant, and research and development facility are all located. Lorillard also maintains a leaf warehouse facility in Danville, Virginia. It markets cigarettes under several popular brand names, including Newport, Maverick, Old Gold, Kent, True, and Max. In particular, Lorillard's Newport brand is the second most-purchased cigarette brand in the United States. Lorillard also markets a snus product through a joint venture with Swedish Match. All Lorillard cigarettes are made in Greensboro, North Carolina and sold exclusively in the United States and its territories. Lorillard employs 2,800 workers, and tens of thousands of American jobs, from tobacco farmers to component suppliers to truck drivers, are dependent on the manufacture and sale of Lorillard products alone.

Lorillard has a long standing commitment to preventing youth smoking and has long been a leading proponent of voluntary measures toward that aim. In 1999, Lorillard launched a Youth Smoking Prevention Program and has invested more than \$80 million in this venture to date. The company is also a leading sponsor of the "We Card" program, one of the most widely accepted retail training and education programs to help retailers prevent underage

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<sup>1</sup> 74 Fed. Reg. 31457 (July 1, 2009).

tobacco sales. We believe that these and other efforts of the industry, government and public health community have been extremely successful in driving the rate of youth smoking to their lowest recorded levels.

Lorillard is also committed to compliance with the FSPTCA and other state and federal regulatory requirements. In order for Lorillard and other manufacturers to comply with the new requirements of the FSPTCA, it is critical that FDA provide clear and timely regulations and guidance on various aspects of the new law. In pursuit of this goal, Lorillard wishes to work collaboratively with FDA to identify and resolve areas of ambiguity, and to help FDA exercise its discretionary authority consistent with Congress's intent.

These comments are intended as a first step in a collaborative relationship with FDA. The comments begin by describing the overlapping framework of state, federal, and judicial oversight that apply to tobacco products, of which the FSPTCA now is a part. In light of that framework, the comments then offer a number of principles that can assist FDA in implementing its new authority in a manner that is consistent with this framework and Congress's directives in enacting the FSPTCA. Lorillard looks forward to working with the agency to implement the new law and intends to establish a positive working relationship with agency officials.

## **II. The Context of Tobacco Product Regulation**

The FSPTCA requires FDA to establish a new Center for Tobacco Products, promulgate new regulations and guidance documents over the next several years, and monitor the manufacture and marketing of tobacco products throughout the United States. As FDA begins its work on these enormous tasks, it is important for the agency to be cognizant of the entire landscape of tobacco product regulation. Tobacco products are widely regulated and controlled, with an overlapping system of state regulation, federal regulation, and judicial oversight, including a comprehensive agreement entered into between the states' attorneys general and certain tobacco manufacturers.

A. Existing Federal Regulation

Numerous sources of federal regulation for tobacco products existed prior to the enactment of the FSPTCA and will continue to regulate the sale and marketing of tobacco products into the future. Foremost among these are the Federal Cigarette Labeling and Advertising Act (“FCLAA”)<sup>2</sup> and the Comprehensive Smokeless Tobacco Health Education Act (“CSTHEA”),<sup>3</sup> which together require that all tobacco products bear government-mandated health warnings on packaging and advertising, and forbid advertising tobacco products on television or radio. The FSPTCA retains these statutes, with amendments to make the mandated warnings even more prominent in the near future. Federal law also regulates shipments of tobacco products in interstate commerce,<sup>4</sup> taxes tobacco products,<sup>5</sup> requires certain information to appear on product labels and packaging,<sup>6</sup> and requires states to prohibit the sale of tobacco products to minors as a condition of receiving certain federal funds.<sup>7</sup>

B. State Regulation

State and local governments across the nation also regulate the distribution and use of tobacco products. These laws include regulations limiting where and how tobacco products may be sold and who may sell tobacco products. States and localities have a variety of laws aimed at enforcing the ban on tobacco purchases by minors. State and local bans on

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<sup>2</sup> 15 U.S.C. § 1331 *et seq.*

<sup>3</sup> 15 U.S.C. § 4401 *et seq.*

<sup>4</sup> 15 U.S.C. § 375 *et seq.* (the Jenkins Act) and 18 U.S.C. § 2341 *et seq.* (the Contraband Cigarette Trafficking Act).

<sup>5</sup> Chapter 52 of the Internal Revenue Code (26 U.S.C. § 5701 *et seq.*), recently amended to greatly increase the rate of tax by Pub. L. 111-3 (Children’s Health Insurance Program Reauthorization Act of 2009).

<sup>6</sup> 26 U.S.C. § 5723; 27 C.F.R. Part 45, Subpart E (TTB regulations requiring, among other things, secure containers for tobacco products marked with the name and location of the manufacturer and standardized designations of the products contained, and forbidding the inclusion of indecent images or sweepstakes chances).

<sup>7</sup> 42 U.S.C. § 300x-26.

smoking in public places and private workplaces (including restaurants and bars) are becoming common throughout the country. States and localities also impose significant excise taxes on the sale of tobacco products, with New York City levying the highest rate on cigarettes for a combined state and city tax of \$4.25 per pack. The result is the total tax imposed on cigarettes is more than, and sometimes several times more than, the pre-tax cost of the product.

C. Judicial Oversight

Overlaying these federal and state laws are two major sources of regulation arising out of the judicial system: the Master Settlement Agreement (MSA), and the remedies ordered by Judge Gladys Kessler in the case of *United States v. Philip Morris*.<sup>8</sup> Unlike statutory regulations, the MSA and Judge Kessler's remedies do not apply to every tobacco product manufacturer or importer equally—they only apply to specific parties, including Lorillard and the other major domestic manufacturers. Yet these non-statutory sources of regulation impose very significant constraints on the marketing of tobacco products, reaching far beyond the requirements of FCLAA, CSTHEA, and state laws.

In the Master Settlement Agreement (MSA), Lorillard was one of four Original Participating Manufacturers that voluntarily entered into a permanent, binding agreement with the States that extensively limits Lorillard's marketing practices, the central goal being the reduction of youth smoking. Under the MSA, Lorillard and other participating manufacturers may not, among other things:

- Direct the advertising, promotion or marketing toward any person under 18 or to take any action to initiate, maintain or increase the incident of youth smoking;
- Use cartoons in packaging or advertising;
- Sponsor concerts, athletic events, athletic teams, or events in which minors are participants or a significant percentage of the audience;

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<sup>8</sup> 449 F. Supp. 2d 1 (D.D.C. 2006).

- Sponsor more than one other event each year in the name of the corporation, or *any* events in the name of a tobacco product;
- Advertise on billboards, signs in arenas, stadiums, shopping malls and video game arcades, or other large signs viewable by the general public;
- Pay for product placement in movies or theater productions;
- Sell or distribute apparel or other merchandise bearing the brand name of a tobacco product;
- Provide free samples anywhere except in adult-only facilities;
- Provide non-tobacco gifts in exchange for credits, proofs-of-purchase or coupons to anyone who has not furnished sufficient proof that they are of legal age to purchase tobacco products; and
- Take any other action, directly or indirectly, to target youth with the advertising, marketing or promotion of tobacco products.

In the more than ten years since this agreement went into effect, Lorillard has responsibly worked with the States' Attorneys General to honor both the letter and spirit of the agreement. During this time, youth smoking has continuously declined and currently stands at historic lows.

In addition, Lorillard and the other major domestic tobacco product manufacturers are parties to *United States v. Philip Morris*. In August 2006, Judge Gladys Kessler of the U.S. District Court for the District of Columbia ordered Lorillard and the other tobacco manufacturers to take the following actions:

- Stop using any descriptors indicating lower tar delivery, including "low tar," "light," "mild," and "medium;"
- Disseminate "corrective statements" to be approved by the court, including statements regarding the addictiveness and adverse health effects of smoking and the adverse health effects of second-hand tobacco smoke, through newspapers, television, print advertisements, package "onserts," retail displays, and corporate websites;
- Extend document disclosure requirements of the MSA, which were due to expire soon, by an additional 15 years, and expand access to the documents; and

- Regularly provide detailed marketing data to the U.S. Department of Justice (in addition to the Federal Trade Commission, to which this information is already supplied).

Appeals over this decision, which has already been modified in minor respects by the Court of Appeals, are still pending. The enactment of the FSPTCA calls into question the continuing justification for some of these “prospective” remedies, particularly where there is substantial overlap between Judge Kessler’s order and the new requirements of the FSPTCA. Furthermore, some of the remedies in Judge Kessler’s order would likely conflict with the new requirements of the FSPTCA. For example, compliance with the order to affix corrective statements on its cigarette packages could conceal, and therefore conflict with, the new warning requirements of the FSPTCA. Lorillard hopes that FDA will work closely with the Department of Justice, the federal courts, and the tobacco industry to harmonize the final resolution of this litigation with the new statutory requirements.

Without a thorough understanding of all of these sources of regulation, including the MSA and *United States v. Philip Morris*, FDA may inadvertently implement the FSPTCA in a manner that contradicts these ongoing sources of regulation for the tobacco industry. Contradictory regulation could ultimately undermine Congress’s purpose in enacting the FSPTCA and fail to achieve a cohesive federal regulatory scheme designed to prevent youth smoking and reduce health risks for adults who choose to use tobacco products. Rather, if FDA resolves ambiguities and implements broad authorities in the FSPTCA to make the regulatory requirements consistent with ongoing federal and state regulation, the MSA, and the ultimate resolution of *United States v. Philip Morris*, it will advance the goal of creating an intelligible nationwide system of regulation and enhance the ability of tobacco manufacturers such as Lorillard to faithfully comply with all aspects of the law.

### **III. General Principles for Implementation of the FSPTCA**

In light of the above context, Lorillard proposes the following principles that may guide FDA in fulfilling Congress’s intent for the FSPTCA.

A. The FSPTCA Should Not be Used to Deprive Adults of Meaningful Choices

As the legislative history and findings of the FSPTCA make clear, Congress made an express choice to preserve the legality and availability of tobacco products. In enacting the new law, Congress did not direct or authorize FDA to implement the law in a way that would deprive adults of meaningful choices—including the choice to use tobacco products.

Section 3 of the FSPTCA specifies the purpose of this law. In addition to granting FDA the authority to regulate tobacco products, this section includes the following purposes:

- “to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;”
- “to strengthen legislation against illicit trade in tobacco products;” and
- “to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry’s efforts to develop, introduce, and promote less harmful tobacco products.”

It is clearly not the intent of the FSPTCA to ban adults from using the tobacco products of their choice. Section 906(d) of the Food, Drug, and Cosmetic Act (FDCA), as added by the FSPTCA, specifies that FDA may not require a prescription from a medical practitioner for purchase, and § 907(d)(3) prohibits FDA from banning all cigarettes or other categories of tobacco products. FDCA § 907(b)(2) also requires FDA, in setting tobacco product standards, to consider countervailing effects of regulations, “such as the creation of a significant demand for contraband or other tobacco products that do not meet the requirements of this chapter.” Thus, Congress has directed FDA to refrain from any regulations that would deprive American adults of their ability to purchase the tobacco products of their choice from a legal and regulated source.

As Congress recognized, banning the sale of all cigarettes—or a significant product segment, such as menthol cigarettes—would not advance the public health but would result in a significant increase in illicit cigarette trade. Already, smuggled and counterfeit cigarettes present serious problems for manufacturers, consumers, State and Federal treasuries, and national security. For manufacturers, these illicit products compete on an uneven playing

field, and the counterfeit cigarettes cause serious harm to the value of legitimate brand names. For consumers, illicit and unregulated tobacco products present risks of unknown and increased health risks. Illicit tobacco products cause States and the Federal government to lose billions of dollars in tax revenue each year, according to congressional reports and published newspaper accounts. And smuggling and counterfeiting may be carried out by organized crime groups that frequently use their illicit profits to finance terrorist activities at home and abroad.<sup>9</sup>

Lorillard strongly supports regulations that will reduce counterfeiting and smuggling, such as practical measures authorized under Section 920 of the FDCA. At the same time, regulations that deprive adult consumers of their ability to purchase preferred tobacco products from legal and regulated sources will drive more adults to purchase similar products illicitly over the Internet and/or from foreign, unregulated and untaxed sources.<sup>10</sup> There are better alternatives to advance the purpose of promoting cessation, such as greater education and funding of cessation programs, which will not enlarge the myriad harms of contraband tobacco product trade.

B. FDA's Regulatory Decisions Must be Based on the Best-Available Science

The hallmark of FDA regulation long as been the agency's commitment to science-based decisions that reflect the best available data rather than political pressures. Under the Data Quality Act, FDA has issued guidelines to ensure the quality, objectivity, utility, and integrity of the information that the agency uses and generates. Lorillard urges the agency to amend these guidelines to acknowledge their applicability to tobacco products and to reflect the existence of the Center for Tobacco Products.

Without data quality safeguards, tobacco product regulation could be susceptible to the influence of politics and public pressure. The tobacco industry has been much maligned

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<sup>9</sup> See, e.g., S. Rep. No. 110-153 (2007).

<sup>10</sup> Already, foreign manufacturers of clove cigarettes are offering to sell their products to U.S. customers over the Internet now that the statutory ban on clove cigarettes has gone into effect.

over the years, and many interest groups will undoubtedly seek to convince FDA to wield its authority in ways that are not supported by hard science. As FDA has demonstrated in other product areas, strict standards for data quality insulate FDA from inappropriate influences while allowing interested parties and the general public to fully participate in the deliberative process through venues such as public hearings or opportunities for comment. Were FDA to depart from its well established principles of scientific integrity, it would undermine the agency's credibility in other areas of its jurisdiction.

To ensure that science, not public opinion, remains the cornerstone of FDA's actions, FDA should ensure that key officials and staff do not come to the new Center with entrenched opinions. Rather, FDA officials should be readily able to treat the data with objectivity and provide honest, fact-driven assessments. Similarly, the voting members of the Tobacco Products Scientific Advisory Committee should be scientists who are independent and balanced, and who have a reputation and a history of providing objective assessments of the available scientific data. Over the years, and across many industries, scientists have been hired to present data in the light most favorable to one side or another in boardrooms, press rooms, courtrooms, and beyond. The Advisory Committee should not be a forum for scientists who are on any "side" of the issue.

The first task of the Tobacco Products Scientific Advisory Committee is to consider the impact of menthol in cigarettes. Lorillard believes that, if the Advisory Committee applies objective data quality standards, they will agree that the weight of the scientific evidence does not support the conclusion that menthol cigarettes increase the known risks from smoking, and that the weight of the scientific evidence indicates that smokers of menthol and non-menthol cigarettes have the same rate of success in quitting smoking.

C. Maintaining a Competitive Marketplace

1. *Allowing for meaningful communication with consumers*

The FSPTCA gives FDA unprecedented power to limit communication between tobacco companies and consumers, including draconian restrictions on the advertising and

promotion of tobacco products. If exercised in a manner that limits meaningful communication by manufacturers to their consumers about their tobacco products, FDA would stifle competition and could effectively “freeze” the tobacco market in its present-day state or create a marketplace that favors larger manufacturers that already have entrenched market power. Though FDA has broad powers that *could* be exercised in this way, *should* the FDA act in this way, the impact on the tobacco market would undermine the purposes of the FSPTCA and, ultimately, harm the economy.

In order for adult consumers to make informed choices about tobacco, and in order for them to select among the various types and brands of tobacco products, manufacturers need to have the ability to communicate with their customers in meaningful ways. Lorillard believes that many of the statutory provisions of the FSPTCA prevent such communications in a manner that is not only unfair but unconstitutional, violating the protections of the First Amendment. For this reason, Lorillard has recently joined with other tobacco companies in a lawsuit seeking to enjoin FDA from enforcing the provisions of the FSPTCA that it believes to be unconstitutional. The purpose of the suit is not antagonistic or to undermine FDA’s authority to regulate tobacco products, but to protect the fundamental right to meaningfully communicate information about our products and to obtain the court’s clarification of the rights and responsibilities of both tobacco manufacturers and FDA under the FSPTCA in light of the First Amendment.

*2. Facilitating the development of new products*

In addition, FDA should ensure that it implements the FSPTCA in a way that allows new tobacco products to be developed and introduced to the market. The tobacco industry is not static—every year, manufacturers invest in research and development and introduce new alternatives to the market. This should be encouraged—vigorous competition, including new product offerings, serves to improve the quality and variety of tobacco products available to consumers.

However, the standards and regulatory pathways to introduce new products to the market are fraught with uncertainties. There are at least three separate pathways to introduce

new products following enactment of the FSPTCA: a substantially equivalent product under Section 905(j), a “new tobacco product” under Section 910, or a “reduced risk tobacco product” under Section 911. All of these pathways are uncertain and ambiguous. For example, even if a new product is essentially the same as products that have been on the market for decades, the manufacturer must still submit a 905(j) report demonstrating, to FDA’s satisfaction, that the product is “substantially similar” to a predicate product. If the new product has different “characteristics,” the company may have to develop clinical data demonstrating that the product does not raise different questions of public health.<sup>11</sup> Similarly, an application for both a new tobacco product and a reduced risk tobacco product under Section 911 requires the development of a substantial amount of data and information, the scope and content of which is currently ambiguous. Moreover, in deciding whether to approve a new or modified risk product, FDA is required to assess the relative risks of the product, taking account such things as the “likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the [new] tobacco product” and the “likelihood that persons who do not use tobacco products will switch to the [new] tobacco product.”<sup>12</sup> All of these standards are new and uncertain. If these provisions are interpreted in a way that makes it virtually impossible for new products to be approved, manufacturers will likely cease investing in new products.

Accordingly, Lorillard encourages FDA to implement the regulatory standards and pathways in such a way that does not slow the progress of new and potentially beneficial products to the marketplace. Furthermore, Lorillard encourages FDA to provide guidance on these pathways to market as soon as reasonably possible.

D. Practical Aspects of Tobacco Product Manufacturing

In crafting the FSPTCA, Congress established a number of safeguards to prevent the new law from causing undue burden and harm to tobacco farmers, tobacco product manufacturers, and the national economy. Most importantly, FDA is required to set effective

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<sup>11</sup> FDCA § 910(a)(3)(ii).

<sup>12</sup> FDCA § 911(g)(4). Similar standards apply to new tobacco products under § 910(c)(4).

dates for any tobacco product standards “so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade [and] shall consider information submitted ... by interested parties, including manufacturers and tobacco growers, regarding the technical achievability of compliance with the standard.”<sup>13</sup> Though FDA has not yet proposed any tobacco product standards, it is critical that FDA understand how tobacco products are manufactured and the consequences—as well as achievability—of tobacco product standards that may be issued in the future.

It is critically important for FDA to understand that, unlike in the drug or device manufacturing process, it will be impossible for tobacco manufacturers to ensure uniformity in output by utilizing precisely the same ingredients in every production cycle. Tobacco product manufacturing is much more akin to food processing than pharmaceutical production. First and foremost, this is an industry with an agricultural basis. As with any agricultural crop, natural variations occur in the tobacco leaf, which make it impossible for companies to manufacture consistent final products from the crop without making constant minor adjustments to the formula. These adjustments involve grade substitutions of domestic tobacco, foreign tobacco, reconstituted leaf,<sup>14</sup> and other tobacco in order to maintain product quality standards. Regardless of such adjustments, there will always be some variation within a range when measuring constituents of tobacco products. This produces challenges for complying with certain reporting and labeling requirements, but these challenges could be ameliorated by appropriate FDA guidance.

The tobacco industry’s manufacturing cycle proceeds on a simultaneously long-term and fast-paced scale. After tobacco leaves are harvested and cured, they are aged for up to three years prior to processing in order to enhance their flavor. Numerous other ingredients must

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<sup>13</sup> FDCA § 907(d)(2).

<sup>14</sup> Reconstituted leaf consists of a combination of tobacco stems and fine particles of tobacco collected and recycled from any stage of tobacco processing, manufactured into paper-like sheets. Reconstituted leaf presents particular challenges because it contains varying proportions of foreign and domestic tobacco that may contain trace tobacco additives.

be acquired, stored, and added to the tobacco in order to produce final products. During the final stage of manufacturing, a rapid and automated process comes into play, resulting in the production of tens of thousands of individual cigarettes by the minute, millions by the day, and billions by the year. On the printing and packaging side of production, companies generally pre-print promotional materials, boxes, and cartons months in advance of use. The time-intensive input and rapid-fire output necessitates substantial lead time in order to implement new standards under the FSPTCA without serious disruption to national and international trade.

These comments present only a brief sample of the exigencies of the cigarette manufacturing process that will necessarily shape FDA's regulatory processes. Lorillard wishes to engage in an open dialogue to help FDA become familiar with the production process and workings of the marketplace to enable implementation of realistic and reasonable requirements that will effectuate compliance without inflicting needless inefficiencies and commercial disruption for manufacturers, wholesalers and retailers.

E. Clear and Timely Guidance is Needed for Tobacco Manufacturers to Comply with the Law

Lorillard is committed to exercising the utmost care and effort to fully comply with the FSPTCA. However, certain ambiguities in the law make compliance difficult or require Lorillard to hazard guesses as to FDA's future interpretation of the law, absent FDA guidance on these ambiguous provisions before their effective dates. The matters described below represent only a small subset of the areas of ambiguity that require FDA's attention. We have highlighted issues that have either (or both) a rapidly approaching deadline for compliance or significant ambiguities in the statutory requirement.

Lorillard also emphasizes that it is critical for FDA to be even-handed in applying the statute and in prioritizing the areas for developing guidance. While small tobacco manufacturers are already given certain benefits under the statute,<sup>15</sup> the agency should not

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<sup>15</sup> See, e.g., FDCA §§ 901(f), 906(3)(B)(v), 915(d).

implement the law in a way that creates two sets of rules or prioritize the need for guidance for small manufacturers above guidance applicable to all manufacturers. Congress clearly did not intend for there to be two sets of rules or for one class of manufacturers to be materially advantaged over another.

*1. Section 904(a) Disclosures*

By December 22, 2009—less than 3 months from now—tobacco product manufacturers are required to report the ingredients in their products to FDA, and to begin reporting any documents developed after June 22, 2009 that relate to the health effects of tobacco products. Though the FSPTCA does not require FDA to issue regulations implementing this section, the statutory text is not detailed enough to provide sufficient guidance for Lorillard to submit the information required under FDCA § 904(a) with confidence that the form, content, and timing of such submissions will meet with FDA’s approval.

In this regard, we note that, in the notice recently published by FDA establishing an electronic portal for submission of establishment registrations and other data, the agency estimated the time needed to comply with the Section 904(a)(4) reporting requirement as one hour per year.<sup>16</sup> This estimate was presumably based on FDA’s interpretation of the types of documents captured by this section. The same notice stated that the frequency of reporting for this requirement was one time per year. To clarify this provision, FDA should provide guidance on the types of documents that should be submitted pursuant to § 904(a)(4) and a date for submission of these documents. Lorillard has also submitted comments to OMB on this issue pursuant FDA’s Notice, dated September 1, 2009.

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<sup>16</sup> See Agency Emergency Processing Under Office of Management and Budget Review; Tobacco Product Establishment Registration and Submission of Certain Health Information, 74 Fed. Reg. 45219 (Sept. 1, 2009) (estimating “Annual Frequency per Response” as “1” for § 904(a)(4) disclosures).

2. *Section 903(a)(8) "Brief Statement" Requirement*

Section 903(a)(8) of the FDCA, as added by the FSPTCA, states that a tobacco product is misbranded unless its advertisements and other descriptive printed matter issued with respect to that product bear "a brief statement of the uses of the tobacco product and relevant warnings, precautions, side effects, and contraindications." This requirement becomes effective on June 22, 2010, but Lorillard needs immediate guidance on the meaning of this requirement since design, production and logistics schedules must be established well in advance in order to comply with this requirement.

Without guidance, it is not apparent what language would fulfill the "brief statement" requirement for tobacco products. Although brief safety statements serve to inform patients of the unique risks of a particular product in the context of drugs and devices, these requirements and principles do not translate to tobacco products. Unlike drugs and devices, the risks of tobacco products are already well-known to the public and are essentially the same across all brands within the same class of tobacco products. The FSPTCA expanded the list of warning statements to be placed on all labels, labeling and advertising.<sup>17</sup> The list of required statements now includes nine statements for cigarettes and four statements for smokeless tobacco that, unlike other regulated products, specifically address the "relevant warnings, precautions, side effects, and contraindications" as intended by FDCA Section 903(a)(8), raising the issue whether any additional statement is relevant or necessary. Indeed, it is clear that Congress does not want any representations made that might suggest one tobacco product is less risky than another, absent an extensive review by FDA verifying the truth of such claims. Lorillard believes that FDA can best ensure that "brief statements" do not create any impression of varying risk by issuing guidance as to uniform text (including whether the new warning statements sufficiently satisfy this obligation) that may be used to fulfill the "brief statement" requirement for each type of tobacco product.

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<sup>17</sup> FSPTCA Title II, § 201 and 204, amending section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. § 1333) and amending Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. § 4402), respectively.

### *3. Packaging and Label Requirements*

The FSPTCA includes a number of new requirements for the packaging and labels of tobacco products. These changes will require substantial changes to the design of the packaging for Lorillard's products. Many of these requirements are written in general language, but could be implemented by FDA in the form of specific requirements for the size, placement, or design of label statements. But implementing changes to the packaging design require substantial lead-time. Even seemingly minor packaging changes require time-consuming changes to the design, layout, and printing process for packaging, not to mention the disruption in the marketplace caused by the transition from the old pack designs. For this reason, it is critical for FDA to provide timely and specific guidance well in advance of any effective date. At minimum, FDA should provide guidance on label or packaging requirements at least one year prior to the effective date for the change.

As an example, Section 903(a)(4) requires that a product's label bear, to the exclusion of any proprietary name "its established name prominently printed in type as required by [FDA] by regulation."<sup>18</sup> The statute provides no guidance on where this name should appear, how large it must be to qualify as "prominent," or other details about the requirement. And while the statute calls for regulations on this issue, there is no deadline for FDA issuing such regulations. Despite the lack of deadline for regulations, the statute assigns an effective date for this requirement of one year following enactment of the law.<sup>19</sup> Accordingly, by June 2010, Lorillard is required to add a "prominent" established name to the label of all its products, regardless of whether FDA has provided guidance. In order to comply, Lorillard must coordinate efforts among several departments and outside design firms, printers and suppliers to produce the new packaging before it can manufacture and ship to its customers product with the new labels. Because of this lead time to comply with required labeling changes and the likely

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<sup>18</sup> FDCA § 903(a)(4).

<sup>19</sup> FSPTCA § 103(q)(5).

delays caused by other manufacturers working with many of the same firms and printers, Lorillard is forced to proceed with designing new labels and packaging immediately.

This is just one example of the packaging and label requirements that will be implemented over the next few years. In order to permit companies to comply with these requirements, FDA must issue timely and clear guidance or regulations on these provisions (similar to what the agency has done with food or OTC drug labeling).

#### *4. Internet Communications*

Section 897.32 of FDA's 1996 Final Rule included a provision requiring the use of black text on a white background for tobacco product labeling and advertising, except for advertisements in adult-only settings and publications that the manufacturer, retailer, or distributor demonstrates is an "adult publication."<sup>20</sup> An adult publication is a newspaper, magazine, periodical, or other publication whose readers younger than 18 years of age constitute less than 15 percent of the total readership and less than 2 million persons.

This provision was written prior to internet communications and websites becoming commonplace, and its application to such media is not clear. FDA should provide guidance on the application of Section 897.32 to internet communications, including company and product websites. For example, company websites that provide general information about a company and used to comply with Security and Exchange Commission requirements or used by public companies to communicate to shareholders or the media and that do not expressly promote the use of any specific product, should not be considered product labeling or advertising and should not be limited to a black-on-white format. Similarly, many tobacco companies—including Lorillard—employ sophisticated age verification software that limits access to product-specific websites. Given that this technology is highly effective at limiting access to adults only, this should qualify as an adult-only publication and, as a result, colors and imagery should be permitted. FDA should provide prompt guidance on these issues.

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<sup>20</sup> 21 C.F.R. § 897.32.

5. *Section 905(j)(3) Substantial Equivalence Exemption*

As noted above, the naturally-occurring variations in tobacco leaf frequently necessitate minor formula adjustments to maintain consistent quality for cigarettes. In addition, changes to tobacco products may be necessitated by state law or other legal requirements. But if interpreted expansively, FDCA § 910(a)(1)(B) could be interpreted to mean that every time any tobacco manufacturer makes any change to a tobacco product—no matter how routine or inconsequential—the product becomes a “new tobacco product,” necessitating the submission of a new product application. Were this interpretation to be adopted, manufacturers would need to submit, and FDA would need to review, a “substantial equivalence” application every time a product is adjusted in minor ways. Conducting an intensive review of this sort for every minor change would require an unnecessary expenditure of government resources. Moreover, this would be inconsistent with other provisions of the statute—including § 904(c)(2)–(3), which provide separate notification procedures for adjustments to additives.

To clarify this situation, FDA should promptly issue regulations under FDCA § 905(j)(3). Under § 905(j)(3), FDA may define certain types of changes to tobacco products as “minor modifications,” allowing an applicant to simply report to FDA that each of the changes are exempted “minor modifications,” and then the FDA will not be required to conduct an individualized review of the modified product. The statute provides that FDA must issue such regulations not later than 15 months after enactment (as adjusted by Section 6 of the statute); but given the circumstances described above, FDA should issue the “minor modification” regulations authorized by FDCA § 905(j)(3) as soon as possible.

F. Trade Secrets Should Be Carefully Guarded From Public Disclosure

As tobacco companies comply with the various information disclosure requirements and product data submissions established by the FSPTCA, FDA will gain access to data such as product formulas, methods of manufacture, ingredient blends, and various proprietary information that would result in serious competitive harm to a company were such data to become public. As is the case in FDA’s other regulated industries, trade secrets and other

confidential commercial information are of critical importance in the manufacture and development of tobacco products.

Product formulas are particularly important for tobacco companies, and form the most valuable asset that tobacco companies possess in the competitive marketplace. The confidentiality of these formulas is assiduously protected, and only a few individuals in the company know the formulas. Any leaks of this information could cause severe damage to the value of tobacco product brands, also resulting in losses to the U.S. economy and increasing the potential for illicit international trade in counterfeit cigarettes. This concern equally applies to tobacco company suppliers whose trade secrets must also be protected.

FDCA § 906(c) provides that tobacco-related information disclosed to FDA that is exempt from disclosure under FOIA “shall be considered confidential and shall not be disclosed.” FDA routinely handles extensive amounts of trade secrets and confidential commercial data for other regulated industries, such as the highly-competitive pharmaceutical industry. Lorillard hopes that FDA will apply the same commitment to guard sensitive data regarding tobacco products, regardless of any political pressures that may be brought to bear to the contrary.

#### **IV. Conclusion**

Lorillard believes that adoption of the principles described above will enable FDA to implement the FSPTCA in a way that is goal-oriented, effective, and not unduly burdensome for either the industry or the agency. Lorillard thanks FDA for this opportunity to provide comments on this new legislation. The company looks forward to cooperating with the agency as it begins implementing this new regulatory regime and will be glad to offer assistance and input in any way possible.