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February 3, 2014

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

Re: Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, Exemptions From Substantial Equivalence Requirements (Docket No. FDA–2013–N–1588)

Dear Sir or Madam:

Lorillard Tobacco Company ("Lorillard") appreciates the opportunity to comment on the above-referenced docket and Federal Register notice published December 19, 2013 on the proposed collection of information concerning exemptions from substantial equivalence ("SE") requests.[1] Lorillard is the third largest manufacturer of cigarettes in the United States. Newport, Lorillard's flagship menthol-flavored premium cigarette brand, is the top selling menthol and second largest selling cigarette in the U.S. In addition to Newport, the Lorillard product line has four additional brand families marketed under the Kent, True, Maverick, and Old Gold brand names.

In our comments, Lorillard explains why Food and Drug Administration ("FDA") has significantly underestimated the amount of time necessary to file exemption requests. As a partial remedy, providing additional information on the requirements for exemption requests, such as through guidance documents, webinars and insights into agency reasoning on exemption requests it has refused to file, would greatly aid filers and likely reduce the overall time burden. Lorillard also requests that FDA reevaluate its policies on exemption requests to allow manufacturers to more easily make product changes that could potentially benefit the public health.

I. FDA Grossly Underestimates the Amount of Time Necessary to File an Exemption Request

FDA estimates an average burden of 12 hours to prepare a tobacco product exemption from SE request, 3 hours to prepare additional information requested by the agency, 12 hours to prepare an environmental assessment and 3 hours to prepare a report under section 905(j)(1)(A)(ii). These numbers are drastically lower than FDA set forth in the proposed rule for exemption

[1] 78 Fed. Reg. 76838 (Dec. 19, 2013).

requests. There, FDA estimated "that it would take a manufacturer 360 hours to prepare an exemption request" and "that it will take 50 hours to prepare" FDA requests for additional data.[2] These estimates were based on "Agency experience and approved information collections for other types of submissions to the FDA."[3] In our comments on the proposed rule, Lorillard stated that "given the burdensome requirements proposed for the rule, the agency's estimate of 360 hours required to prepare and submit an exemption request is likely to fall far short of the actual time required." Now, based on our further experience with preparation of filings to CTP, such as SE reports, Lorillard believes that these numbers significantly underestimate the burden involved in filing an exemption request.

For the initial exemption request, FDA regulations require a tobacco product manufacturer to submit, among other things, "[a] detailed explanation of the purpose for the modification," "[a] detailed description of the modification," "[a] detailed explanation of why the modification is a minor modification," "[a] detailed explanation of why a [section 905(j) report] is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health," and a certification "summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to/use by minors, toxicity, or addictiveness/abuse liability." It takes a significant amount of time to gather necessary data and to craft these required "detailed explanation[s]." Lorillard stands by its original assessment that even 360 hours would likely fall short of the time needed to complete an exemption request. FDA explained that it arrived at its reduced estimate because "the preparation of an exemption request does not require a comparison to a predicate or inclusion of information on multiple characteristics."[4] Even if the exemption request does not require comparison to a predicate, characterizing a predicate product to explain the modification and "why a [905(j)] report . . . is not necessary" is likely to take several hundred man hours to assemble.

Further, Lorillard expects that assembling and submitting responses to any follow up requests from FDA will take much longer than the estimated 3 hours. FDA's follow up requests for SE reports have required drafting complex explanations, gathering extensive data and, in some cases, generating new information. All of this follow-up takes several hundred hours. Even to respond to a request concerning an exemption request that "requires more limited information,"[5] Lorillard anticipates that it will take significantly longer than 3 hours as estimated by the agency.

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[2] 76 Fed. Reg. 737, 742-743 (Jan. 6, 2011).

[3] 76 Fed. Reg. 38961, 38973 (Jul. 5, 2011).

[4] *Id.*

[5] *Id.*

II. FDA Should Clarify the Requirements for Exemption Requests

At this point, it is difficult to accurately assess FDA's estimated reporting burden because the agency has not clearly set forth the information necessary to support an exemption request. Lorillard recommends that FDA provide additional information, such as the agency has communicated information required for SE filings. As discussed below, this could be done by providing guidance documents, hosting webinars and releasing summary information on exemption requests that the agency refused to file.

For SE reports, FDA has provided information about the requirements in several ways. FDA issued both a final guidance document on the requirements for *Demonstrating Substantial Equivalence*[6] and a draft guidance with *Responses to Frequently Asked Questions.*[7] The agency hosted multiple webinars to further explain its review of SE reports and highlight commonly seen deficiencies.[8] FDA's website also contains a "Questions & Answers" page on the SE pathway.[9] In addition, FDA has provided limited information about its SE decisions. For tobacco products receiving a Substantial Equivalence Marketing Order, FDA provides both the FDA Order Letter and a summary of the agency's review. Although FDA does not provide product-specific information about products found to be not substantially equivalent ("NSE"), the agency has released a summary of the NSE determinations with "some of the reasons why the FDA concluded that products" were NSE. By providing this information, manufacturers are able to learn more about the agency's approach in reviewing SE reports, although to this date, on the overall, FDA has not provided sufficient information to manufacturers on its SE review criteria. Even after several SE orders, it is still not clear what FDA expects tobacco product manufacturers to provide to demonstrate that differences between subject and predicate in an SE report do not raise different questions or public health.

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[6] FDA Guidance, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (Jan. 2011), http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf.

[7] FDA Draft Guidance, *Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Sept. 2011), http://www.fda.gov/downloads/TobaccoProducts/ResourcesforYou/ForIndustry/UCM271239.pdf.

[8] FDA Webinar, *Substantial Equivalence - An Update* (Apr. 10, 2013); FDA Webinar, *Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports* (Aug. 21, 2012); FDA Webinar, *Reports on Substantial Equivalence: (One Year Later)* (Apr. 24, 2012), *available at* http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/SubstantialEquivalence/ucm304518.htm.

[9] *See* FDA, Q&A: Substantial Equivalence Tobacco Products, http://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/NewTobaccoProductReviewandEvaluation/SubstantialEquivalence/ucm304517.htm.

By contrast, FDA has provided even less information about the requirements for exemption requests. Although the agency issued a final rule on exemption requests in 2011,[10] it has not provided any other guidance or explanation about the requirements. Also, unlike SE requests, FDA has not issued any information about previously filed exemption requests. FDA's website provides that it has issued 22 Refusal to Accept (RTA) letters for Exemption Requests. FDA, however, provides no actual information on the content of the letters or its reasoning for refusal to accept. It is understandable that the agency cannot release confidential information, but it has not attempted to provide a sanitized summary of its reasoning, as it has done for NSE decisions.

The current lack of information impedes manufacturers in filing complete exemption requests. Lorillard recommends that the agency provide additional information for would-be filers. This could be done through issuing guidance documents with a clear set of criteria for the approval of minor modifications, and providing additional information about previously-filed SE exemption requests.

As we have stated before, it is FDA's responsibility to implement the statute in a reasonable and even handed manner. This requires that FDA announce review standards, *prospectively*, and to adequately explain its policies and decisions to all stakeholders.

III. FDA Should Facilitate A Less Burdensome Approach for Manufacturers to Reduce Additives in Their Products

The minor modification exemption pathway is designed to allow manufacturers to modify tobacco products by adding or deleting tobacco additives or increasing or decreasing the quantity of existing additives.[11] That means this is a clear cut pathway through which manufacturers could be reducing or completely removing additives from their products, a goal seemingly in line with FDA's mission to protect the public health. The agency, however, is hindering manufacturers from effectively utilizing this pathway.

First, FDA has interpreted the exemption request pathway to be a two-step process that is more onerous procedurally than submitting a SE report. As reiterated in FDA's recent notice, the agency states that manufacturers who wish to market a product with a minor modification must (1) submit an exemption request under section 905(j), (2) wait until the request is granted, (3) submit a report under section 905(j)(1)(A)(ii) demonstrating that the report meets the requirements of section 905(j)(3) and then (4) wait for FDA to act on the report.[12] The subsequent report under section 905(j)(1)(A)(ii) is required even though manufacturers must submit essentially the same information as a part of the 905(j)(3) submission.

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[10] 76 Fed. Reg. 38961 (Jul. 5, 2011).

[11] FDCA § 905(j)(3).

[12] *See* 78 Fed. Reg. at 76840.

Second, there are many products currently on the market that cannot utilize this pathway. FDA has a backlog of more than 3,500 provisional SE reports that have been pending at the agency since March of 2011.[13] To date, the agency has not acted on a single provisional SE report. To request a SE exemption, the request must cite "a tobacco product that can be sold under this Act."[14] Under this definition, exemption requests could arguably cite provisional products, since these provisional products can be sold under the Act. As a practical matter, however, it appears that FDA would unlikely grant such an exemption request before acting on the provisional SE application. If the provisional product was amended, it would no longer be the subject of a report submitted "21 months after the date of enactment" of the Act and could not be marketed.[15] This means that any manufacturer who, in good faith, wants to reduce the number of additives in a provisional product is apparently precluded from doing so until FDA reviews its provisional SE report.

FDA should review its current policies and interpretations to allow manufacturers to more easily make changes to their products that could benefit the public health. For example, FDA could allow simultaneous filing of reports under sections 905(j)(3) and 905(j)(1)(A)(ii) to ease the burden on filers. FDA ideally would act expeditiously on the pending provisional reports so that these products could be the subject of exemption requests. In the meantime, FDA could work with manufacturers to allow companies to file exemption requests that cite these products and amend the pending provisional SE report with the proposed minor modification, while at the same time being able to market the provisional with the minor modification until such time that FDA reviews it. The agency could also create a scheme whereby a manufacturer may be provisionally granted an exemption request for reasonable changes to an as-of-yet not reviewed provisional predicate. FDA would then review the exemption request and provisional SE report simultaneously when arriving at the provisional in the queue. Adopting such policies would prevent the agency from being a roadblock to changes that could potentially benefit the public.

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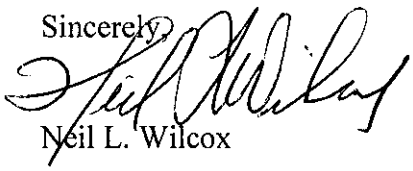
Lorillard appreciates FDA's consideration of our comments. Please contact me if you have any questions or require additional information.

Sincerely,



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[13] *See* FDA, Total Number of Product Submissions Received or Filed in the Month (FY 2011), http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=2011.

[14] FDCA § 905(j)(3)(A)(i).

[15] *Id.* § 910(a)(2)(B).