

# Lorillard, Inc.

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Draft Guidance on Tobacco Health Document Submission (FDA-2009-D0600)**

Dear Sir or Madam:

As one of the tobacco product manufacturers subject to the requirements of § 904(a)(4) of the Food, Drug, and Cosmetic Act (FDCA), as amended by the Family Smoking Protection and Tobacco Control Act (FSPTCA), Lorillard Tobacco Company (Lorillard) respectfully submits the following comments regarding the Draft Guidance entitled “Tobacco Health Document Submission” (Draft Guidance).

On September 1, 2009, FDA published a Federal Register notice stating that compliance with § 904(a)(4) would impose an average burden of one hour per year for each company required to comply with this provision.<sup>1</sup> Now, just months later, the agency has published a Draft Guidance that is stunningly inconsistent with FDA’s previous notice. FDA’s Draft Guidance calls for an enormous breadth of documents and extensive supplementary information for each document. Respectfully, the approach taken by the Draft Guidance goes far beyond the

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<sup>1</sup> 74 Fed. Reg. 45220. Under the Paperwork Reduction Act, FDA is required to certify that, among other things, the information collected “has practical utility” to the agency, “is not unnecessarily duplicative of information otherwise reasonably accessible to the agency,” and “reduces to the extent practicable and appropriate the burden on persons who shall provide information to or for the agency.” For the reasons explained herein, FDA could not provide such certification with respect to the information requested in the Draft Guidance.

statutory provision enacted by Congress in § 904(a)(4). If followed, the burden imposed by FDA's Draft Guidance would not be one hour per year, but likely hundreds or even thousands of hours for each quarterly submission, while at the same time diminishing the utility of the document submission requirement as compared to a more targeted approach. For the reasons that follow, Lorillard requests that FDA reconsider the approach set forth in its Draft Guidance.

**I. The Draft Guidance is Inconsistent with the Text and Intent of § 904(a)(4)**

It is well established that an agency cannot use a guidance document to establish new, legally-binding obligations. Section 904(a)(4) provides in relevant part:

Each tobacco product manufacturer or importer, or agents thereof, shall submit to [FDA] . . . all documents developed after such date of enactment that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.

The fundamental obligation of § 904(a)(4) is thus unambiguous: manufacturers must submit existing documents that fall within the class that Congress specified. FDA's Draft Guidance, however, goes far beyond this clear requirement. The Draft Guidance appears to take the position that companies not only must submit responsive documents, but must classify, supplement, and explain each document. While at times the Draft Guidance merely recommends actions, in other places the Draft Guidance appears to be setting forth new requirements -- above and beyond what the statute requires -- that FDA suggests must be followed.

The Draft Guidance states that "FDA interprets section 904(a)(4) to mean that *you are to* organize or label documents to correspond to the categories of documents set out in section 904(a)(4)." (emphasis added). Specifically, the Draft Guidance states that manufacturers "are to": (1) label and classify each document as relating to health, toxicological, behavioral, and/or physiologic effects of tobacco products; and (2) identify each document as relating to "the name of at least one current tobacco product, future tobacco product, ingredient, additive, constituent, smoke constituent, or component." The use of the language "you are to," while ambiguous, suggests that FDA may believe these are requirements that must be followed. If this is indeed FDA's intent, such a position would be outside the agency's authority. Nothing in § 904(a)(4) suggests such obligations and FDA cannot create new and additional requirements in a guidance

document. The statutory requirement is to “submit” documents. There is nothing in the statute that requires manufacturers to explain, classify, or categorize any document.

Even were Lorillard to treat those and the other elements of the Draft Guidance as recommendations, the burden that FDA’s approach would place on manufacturers cannot be reconciled with Congress’s intent in enacting § 904(a)(4) or FDA’s public health objectives.

To place the volume of documents and burden imposed by the Draft Guidance in context, prior to FDA’s announcement that § 904(a)(4) would not be enforced until after April 30, 2010, Lorillard was preparing to meet the original December 22, 2009 deadline. Out of an abundance of caution, Lorillard conducted a litigation-style document collection. It took a team of individuals over a six week period to collect, process, review, and prepare nearly *twenty thousand* documents for submission.<sup>2</sup>

Against the background of this massive volume of documents, the Draft Guidance calls for multiple layers of coding to be applied to each and every document. As mentioned above, the Draft Guidance requests that every document be labeled (1) as relating to health, toxicological, behavioral and/or physiologic effects; and (2) with the name of at least one current tobacco product, future tobacco product, ingredient, additive, constituent, smoke constituent, or component.<sup>3</sup> Even standing alone, these two recommendations present an overwhelming challenge.

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<sup>2</sup> In light of this experience, FDA should narrow the definition of “document” in the final guidance. As noted in Lorillard’s previous comments to FDA, “a definition of ‘documents’ targeted to final study reports would enhance the quality, utility, and clarity of the information collected by ensuring FDA receives the most relevant and important documents for the proper performance of its functions.” This would enable FDA to receive a more manageable volume of documents and a production targeted to the most informative documents.

<sup>3</sup> The Draft Guidance also requests that “all identification terminology be as consistent as possible with that used in submissions under sections 904(a)(1), 904(c) and 905 of the act.” Given that the first submissions under §§ 904(a)(1) and 904(c) are not due until June 22, 2010, it would be difficult to code the health documents consistently until the Listing of Ingredients in Tobacco Products is completed under § 904(a)(1).

The categories of health, toxicological, behavioral and/or physiologic effects are overlapping in many—if not all—cases. Nearly every document relating to “toxicological,” “behavioral,” and/or “physiologic” effects also relates to “health” effects. Likewise, “toxicological” effects are often extensions of “physiologic” adaptive effects, and discrimination of one from the other is frequently a matter of subjective, professional judgment or dependent upon experimental circumstances. Toxicological and physiological responses elicited in an experimental system may be similar, and simply manifested at different times or to different degrees. In fact, the overlap is so extensive between these categories that there is no apparent utility in attempting to provide such categorization.

Similarly, labeling each and every document as related to a current product, future product, ingredient, additive, constituent, smoke constituent or component would be incredibly onerous. But, in addition, the Draft Guidance asks for another layer of classification: requesting that each document be labeled with one or more of the 10,871 Medical electronic Subject Headings (MeSH) main terms (with 50,956 MeSH tree headings) in the National Library of Medicine’s Medical Subject Headings. On top of that, FDA requests that respondents create and submit a new document: “a glossary or explanation of any abbreviations, jargon or internal (e.g. code) names.”

These suggested layers of coding and explanation go far beyond normal litigation-style document discovery requirements. Such document identification and production practices would take an enormous time to complete and would impede Lorillard’s ability to submit documents under § 904(a)(4) in a timely manner. This task would literally require a line-by-line review and analysis of thousands of scientific and technical documents to furnish this material. A new department would likely need to be established solely dedicated to § 904(a)(4) compliance. Lorillard would need to recruit and hire new employees highly educated and experienced in the sciences to perform the coding as suggested in the Draft Guidance. Significant time and resources would be required to create, hire and train a completely new department. A new

system would also likely need to be developed to capture or create the suggested information, which may take many months to design and implement (if such a system is feasible at all).<sup>4</sup>

The FSPTCA through its “user fee” provisions, however, provides FDA with adequate funding to implement the FSPTCA, including coding and classifying the submitted information under § 904(a)(4) in ways FDA may find useful for its own purposes.

The text and legislative history of the FSPTCA demonstrate that § 904(a)(4) was never intended to encompass the type of production contemplated by FDA’s Draft Guidance. One of the purposes Congress specified in enacting the FSPTCA was “to ensure that consumers are better informed, to require tobacco products manufactures to disclose research which has not previously been made available.” Lorillard stands ready to comply with that objective by submitting its research to FDA. But the onerous layers of coding and explanation of each document provide no apparent benefit to the public health and cannot be reconciled with congressional intent or the text of the statute. Moreover, while other provisions of the statute expressly require the type of specificity and detail that FDA has called for in its Draft Guidance, § 904(a)(4) does not. For example, § 904(a)(1) specifically requires the submission of a listing of ingredients in tobacco products “by brand and by quantity in each brand and subbrand.” Section 904(a)(4), in contrast, does not require submissions to be made by brand or subbrand. If Congress had intended document submissions under § 904(a)(4) to contain a similar level of granularity, it would have said so. In fact, the legislative history suggests that Congress envisioned that the cost of complying with § 904(a)(4) would be “small.”<sup>5</sup> Clearly, the cost of the production in the manner contemplated by FDA’s Draft Guidance cannot reasonably be characterized as “small.”

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<sup>4</sup> The need to design a new and costly system for providing the requested information is also inconsistent with the statement in the September 1, 2009 notice that “there are no capital costs or operating and maintenance costs associated with this collection of information.”

<sup>5</sup> See Report of Energy and Commerce Committee (Rep. Waxman), Rep. No. 111-58 (111th Cong., 1st Sess.), March 26, 2009 at p.27 (stating in reference to all of the document submission requirements of the FSPTCA that “CBO estimates that the direct cost of complying with these requirements would be small.”).

Furthermore, asking companies to explain and supplement documents is unnecessary in light of the Draft Guidance's recommendation that paper and electronic documents be submitted in a digital format that is text searchable. If followed, this functionality will allow FDA to craft its own targeted searches, thereby enabling it to segregate and obtain those documents that are pertinent to any particular study or review that FDA is undertaking, obviating the need for extensive coding and classification of documents. While a burden is imposed to convert all documents to a text searchable format, Lorillard considers this request to be reasonable. Lorillard also considers FDA's request for limited and identified metadata fields to be submitted (to the extent such information is available) to be reasonable.<sup>6</sup>

## **II. The Draft Guidance Document Should be Amended**

In light of the above, FDA should eliminate parts (a) and (b) from Section III.C.2 of the Draft Guidance. FDA should also amend other provisions of the Draft Guidance.

### ***A. The Schedule for Submission of Documents Should be Modified***

FDA should revisit the suggested submission schedule outlined in Section III.E. The Draft Guidance proposes a quarterly submission of documents. Such a production schedule would require continuous collection and review and, as noted above, likely result in the need for Lorillard to establish a new department dedicated solely to complying with the § 904(a)(4) document submission. An annual system would allow Lorillard to better allocate its resources while still providing the FDA with the documents on a timely basis. An annual submission schedule is also consistent with FDA's September 1, 2009 notice that stated the frequency of the submission would be one time per year.

A one-month period between the end of a reporting cycle and the deadline for submission is not commercially reasonable. Lorillard's experience demonstrates that 60-90 days are

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<sup>6</sup> A point of clarification: metadata, by definition, is only associated with electronically-created documents. For paper documents, metadata does not exist. In addition, as discussed below, the Bates number for "referenced documents" should only apply to attached documents.

required to prepare these submissions, even *without* including the coding and classifying of information that FDA requests in the Draft Guidance.

The first submission will cover June 22, 2009 through March 31, 2010: covering nearly three times the period that Lorillard conducted its document production leading up to December 22, 2009. Thus, it is absolutely necessary that FDA provide significantly more time between the cut-off date of the first document collection and the deadline for submitting these documents to FDA. For these reasons, Lorillard requests that FDA extend the deadline for the first submission of documents for at least an additional 60 days, such that documents developed between June 22, 2009 and March 31, 2010 would be due June 30, 2010 at the earliest.

***B. Clarify That Public Documents Not Developed by the Manufacturer Need Not Be Submitted***

Section 904(a)(4) requires submission of health information documents “developed” after June 22, 2009. It is not clear whether this is intended to cover only documents developed by the manufacturer, or whether every published study, news article or publicly available document not developed by the manufacturer, but relating to the health effects of tobacco products, would need to be submitted by every manufacturer to whom such study or article had been emailed or otherwise transmitted. A significant portion of the overwhelming volume of documents described previously (i.e., documents collected by Lorillard in anticipation of the December 22, 2009 submission) comes from these publicly available sources and were not developed by Lorillard. Inclusion of such documents would be burdensome on Lorillard and, moreover, many such studies are funded and/or conducted by government agencies. FDA has access to such documents through scientific, government, or public databases. Lorillard suggests that FDA can greatly improve the utility and efficiency of submissions by clarifying that published studies, news articles and other documents that are publicly available and not developed by the manufacturer are not within the scope of required submissions.

***C. Bates Numbers for “Referenced Documents” Should Apply Only to Attached Documents***

Section III.C.2(c) recommends that, “if a document references other documents (e.g., an attachment to an email), Bates number ranges for the referenced documents” should be provided.

Lorillard interprets this recommendation to refer solely to documents that are attached to the primary document in some form (either digitally or physically). If a document references an “unattached” document, such as referring to another email or study report, it would be unreasonable and, in some instances, virtually impossible for Lorillard to cross-reference such documents. FDA should amend this recommendation to refer only to “attached” documents.

### **III. Conclusion**

Lorillard is prepared to comply with § 904(a)(4) by submitting responsive documents called for by the statute. However, the document identification provisions contained in the Draft Guidance exceed FDA’s authority under the statute and are so excessively burdensome and impractical that they would hamper our ability to timely submit these documents. Were Lorillard to follow all of the coding and classifying provisions of the Draft Guidance, Lorillard could not meet the April 30, 2010 deadline or subsequent deadlines for submission. Guidance documents are intended to *enhance* compliance, but following the provisions of the Draft Guidance would actually *impede* compliance with § 904(a)(4).

Lorillard respectfully requests that FDA carefully consider these comments as it further develops and refines its guidance regarding § 904(a)(4). Lorillard looks forward to working with FDA to address these important concerns in an effort to provide useful information to FDA.

Sincerely,

A handwritten signature in black ink, appearing to read "Ronald S. Milstein", written in a cursive style.

Ronald S. Milstein