



Ronald S. Milstein
Senior Vice President,
Legal and External Affairs,
General Counsel and Secretary

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(336) 335-7718
Fax (336) 335-7707

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

Re: Draft Guidance for Industry on Listing of Ingredients in Tobacco Products (FDA-2009-D-0524)

To Whom It May Concern:

As one of the tobacco product manufacturers subject to the requirements of the Food, Drug, and Cosmetic Act (FDCA) § 904(a)(1), as added by the Family Smoking Protection and Tobacco Control Act (FSPTCA), Lorillard Tobacco Company (Lorillard) respectfully submits the following comments regarding the Draft Guidance entitled "Listing of Ingredients in Tobacco Products" (Draft Guidance).

Lorillard appreciates FDA's provision of this Draft Guidance, and the opportunity to participate in pilot testing of the eSubmitter program. These have provided a number of important clarifications regarding the mechanics of complying with the requirements of § 904(a)(1). However, certain aspects require further clarification, and some provisions of the Draft Guidance are not consistent with the statutory requirement. Lorillard also requests that FDA extend the deadline for ingredients submission to give manufacturers adequate time to comply with the final guidance.

FDCA § 904(a)(1) requires each tobacco product manufacturer to submit, not later than December 22, 2009, the ingredients in tobacco products "that are, as of such date, added by the

manufacturer.” Lorillard interprets this requirement to mean that ingredient information must be submitted only for such products that are, as of December 22, 2009, currently manufactured by Lorillard, and that Lorillard must only report the quantity of each ingredient that is being added to such products as of such date. However, Section II of the Draft Guidance states that “for tobacco products *on the market* as of *June 22, 2009*, information required under section 904(a)(1) must be submitted by December 22, 2009 . . . and include the ingredients *added as of the date of submission*” (emphasis added). This language is confusing; referring to something occurring both in the past and in the present. If a manufacturer produced a tobacco product after June 22, 2009 but discontinued its production before December 22, 2009, then the manufacturer is no longer “adding” *any* ingredients to such product as of December 22, 2009. The Draft Guidance may have failed to contemplate that a tobacco product may have been on the market on or after June 22, 2009 but that its production was discontinued prior to the December 22, 2009 reporting. Furthermore, there appears to be no statutory basis for reporting ingredients in products that were “on the market” as of June 22, 2009 but no longer manufactured as of December 22, 2009. Lorillard does not believe that the statute supports consideration of what products are “on the market” (i.e. still in the possession of retailers and distributors) as of any given date—the statute refers to ingredients that are being produced and “added by the manufacturer” (i.e. manufactured) as of a particular date. Lorillard requests that the final guidance clarify that ingredients must be reported for any product that is currently manufactured as of December 22, 2009.

The phrase “added by the manufacturer” also indicates that FDCA § 904(a)(1) requires reporting of ingredient quantities according to the *input* specifications of the manufacturer, and not, as the Draft Guidance suggests, ingredients “contained” in the products, “account[ing] for all additions, losses, and chemical reactions.” (Section III.C.5, *see also* Section III.C.3) According to the statute, the constituents that are *output* by the manufacturing process will be reportable under § 904(a)(3), *after* FDA establishes testing methodologies and consistent reporting specifications pursuant to regulations required by § 915. Until FDA issues § 915 regulations, any attempt to measure and report the constituents of end products will likely result in inconsistent reporting methods from different manufacturers. To make the final guidance

consistent with the statute, it should be revised to require manufacturers to report the quantity of ingredients that are “added” to the product, in accordance with the manufacturer’s formula or manufacturing specifications. References to ingredients “contained” or “additions, losses, and chemical reactions” should be removed from the final guidance.

The Draft Guidance provides different reporting methods for “complex materials” depending on whether the complex material is “made to manufacturer specifications” versus “commercially available.” Lorillard requests clarification on this portion of the Draft Guidance (Section III.C.3(c)) in several respects.

1. Definition of “made to specifications”: The Draft Guidance does not provide a definition of “made to specifications.” However, if a complex material is made to a tobacco product manufacturer’s specification, the tobacco product manufacturer is required to provide (a) the material manufacturer’s name, (b) a uniquely identifying name and/or number such as UPC used by the material manufacturer, and (c) information to uniquely identify each specified ingredient. Given this method of reporting complex materials “made to specifications,” Lorillard interprets the term to refer only to complex materials in which some or all of the *ingredients* are specified by the tobacco product manufacturer. Lorillard requests that FDA clarify that “made to specifications” does *not* include specifications of non-ingredient attributes of the material, e.g. dimensions for machinability or specifications related to function, such as porosity of paper. Such materials are not made to meet ingredient specifications and are commercially made available for sale to others by the supplier. Lorillard also requests further guidance regarding the reporting of complex materials in which some but not all ingredients are specified by the manufacturer.
2. Reporting of commercially available complex materials: In Section III.B of the Draft Guidance, FDA states that it intends to enforce ingredient listing requirements only with respect to manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco that are ready for consumer use, and manufacturers and importers of tobacco, filters, papers, and pouches. In other words, the Draft Guidance indicates that FDA does not intend to enforce ingredient listing requirements at this time with respect to

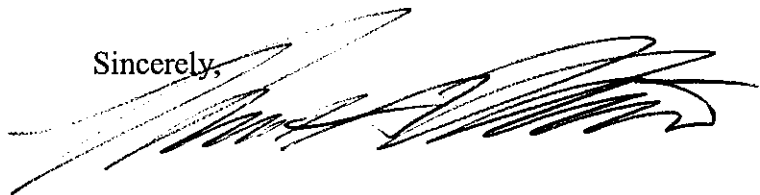
certain categories of suppliers, such as manufacturers of flavoring ingredients, inks and adhesives. Thus, while the cigarette manufacturer will report the identity and manufacturer of a complex material such as a commercially available ink applied to its cigarette paper, the ink supplier presumably will *not* submit a separate report to FDA regarding the individual chemicals and naturally-derived materials that constitute the ink. Lorillard therefore requests confirmation that, under the Guidance, a cigarette manufacturer has no obligation to report the individual chemical entities contained in a commercially available complex material not made to the manufacturer's specifications even where the supplier has no independent duty to file an ingredient report itself. Lorillard also requests clarification that, to the extent that FDA requires reporting of individual ingredients in commercially available complex materials, a tobacco product manufacturer *may* submit information regarding these ingredients on behalf of a supplier, whether or not the supplier has an independent obligation to provide such report, if the tobacco product manufacturer and supplier agree to such an arrangement.

3. Multiple suppliers of the same or functionally equivalent complex material: Tobacco product manufacturers may obtain complex materials from multiple suppliers. To conform to the method specified in the Draft Guidance for reporting complex materials, it appears that the tobacco product manufacturer would need to report the same material obtained from different suppliers under multiple entries in the eSubmitter program. This may create the false impression that such materials are present in larger quantities in the tobacco product (e.g. a material obtained from three suppliers might give the appearance that the product contains 200% more of the material than is actually added to the product). Lorillard requests clarification on how materials from multiple suppliers and the added quantities of those materials should be reported without distorting the quantity of ingredients reported in its products.

Finally, Lorillard notes that reporting ingredients for all of its brands and brand styles in a manner that is consistent with the format of the eSubmitter program is complex and time-consuming. The statutory deadline is just over five weeks away, and many terms and requirements still are not finalized by FDA. Lorillard applauds FDA for recently extending the deadline for FDCA § 905 registration and product listing requirements, giving manufacturers

approximately 120 days to comply after final guidance interpreting this section was issued. Ingredients reporting is even more complex than § 905 requirements, so Lorillard respectfully requests that FDA extend the deadline for enforcement under § 904(a)(1), similar to its extension of the § 905 deadline for registration and product listing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ronald S. Milstein', written over a horizontal line.

Ronald S. Milstein

Senior Vice President and General Counsel