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FDA Desk Officer Office of Information and Regulatory Affairs Office of Management and Budget (OMB)	202-395-6974 <i>202-395-1005</i>	

REMARKS

The attached comments are submitted on behalf of Lorillard Tobacco Company regarding Docket No. FDA-2009-N-0406, Tobacco Product Establishment Registration and Submission of Certain Health Information.

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SUITE NUMBER: 1061A

Comments of Lorillard Tobacco Company

**Docket No. FDA-2009-N-0406:
Tobacco Product Establishment Registration and
Submission of Certain Health Information**

As one of the tobacco product manufacturers subject to the requirements of the new Sections 904 and 905 of the Food, Drug, and Cosmetic Act (FDCA), as added by the Family Smoking Protection and Tobacco Control Act (FSPTCA), Lorillard Tobacco Company (Lorillard) respectfully submits the following comments regarding the above-captioned notice.

Lorillard supports the expedited creation of a single electronic portal for the submission of information required under FDCA §§ 904(a)(1), 904(a)(4), and 905, as FDA has proposed. This will help manufacturers to prepare their submissions required by FSPTCA and transmit them to the Food and Drug Administration (FDA) in a timely and secure fashion.¹

Lorillard also wishes to comment on FDA's estimates of the reporting burden and frequency of the requirements of FDCA § 904(a)(4). Section 904(a)(4) of the FSPTCA provides that, beginning six months after enactment of the FSPTCA, tobacco product manufacturers must submit to FDA:

[A]ll 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.

¹ Lorillard respectfully submits that this same portal should also be configured to accept reports required by FDCA §§ 904(c)(2) and 904(c)(3), which require tobacco product manufacturers to report to FDA changes in the quantity of tobacco additives, either 90 days in advance of increasing an additive, or within 60 days after decreasing an additive. The information in the section 904(c) reports will contain trade secrets and confidential commercial information similar to the information submitted under section 904(a)(1), and thus should be collected and secured in the same manner.

In its recent notice, FDA estimated the annual reporting burden for this requirement to be only one hour per year per respondent. The same notice provided that the frequency of reporting for this requirement was one time per year.

Presumably, FDA's estimate on the burden this requirement imposes was based on FDA's determination regarding the scope of documents subject to reporting under section 904(a)(4). The text of section 904(a)(4), however, is ambiguous. If construed to require the submission of limited classes of documents, such as final study reports regarding the health effects of tobacco products, FDA's estimate may be reasonable (although even then, most likely underestimated). But if construed more broadly, compliance with this requirement would impose a much more significant burden than indicated by FDA's notice. Accordingly, in order to allow for meaningful comment on FDA's estimate, written guidance from FDA regarding the types of documents that are subject to disclosure under section 904(a)(4) is needed. In this regard, Lorillard believes that a definition of "documents" targeted to final study reports would enhance the quality, utility, and clarity of the information collected by ensuring that FDA receives the most relevant and important documents for the proper performance of its functions. Such a definition would also minimize the burden on regulated companies. Moreover, FDA should also clarify the date by which respondents must submit the information annually.

Lorillard thanks OMB and FDA for providing an opportunity to submit these comments and for considering them in implementing the FSPTCA.

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Abbreviations:

HS: Host send	PL: Polled local	MP: Mailbox print	TU: Terminated by user
HR: Host receive	PR: Polled remote	CP: Completed	TS: Terminated by system
WS: Waiting send	MS: Mailbox save	FA: Fail	RP: Report
			G3: Group 3
			EC: Error Correct