Draft Guidance for Industry

Tobacco Health Document Submission

DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted by January 22, 2010, as described in the notice announcing the availability of the draft guidance in the *Federal Register*. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

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I. Introduction

This guidance document is intended to assist persons submitting to FDA certain documents identified in section 904(a)(4) of the act (referred to in this guidance as "tobacco health documents"). The guidance document explains, among other things:

- The statutory requirement to submit tobacco health documents;
- Definitions;
- Who submits health documents;
- What information is included in the submissions;
- How to submit the information;
- When to submit the information; and
- FDA's compliance policies.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

[1] This guidance has been prepared by the Center for Tobacco Products at the U.S. Food and Drug Administration.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Among its many provisions, the Tobacco Control Act added section 904(a)(4) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 387d(a)(4)), requiring submission of documents related to certain effects of tobacco products.

Section 904(a)(4) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." Information required under section 904(a)(4) must be submitted to FDA beginning December 22, 2009.

The failure to provide any information required by sections 904 is a prohibited act under section 301(q)(1)(B) of the act (21 U.S.C. § 331(q)(1)(B)). In addition, under section 903(a)(10) of the act, tobacco products are deemed misbranded for a "failure or refusal . . . to comply with any requirement prescribed under section 904 . . . ." 21 U.S.C. § 387c(a)(10). Violations relating to section 904(a)(4) are subject to regulatory and enforcement action by FDA, including seizure and injunction.

III. Discussion

A. What definitions apply?

FDA intends to use the following definitions in implementing the health document submission requirements of section 904(a)(4) of the act.

1. *Document:* FDA views Federal Rule of Civil Procedure (FRCP) 34 as providing guidance in this area. Rule 34 defines "documents or electronically stored information," as including "writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations – stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form." FDA interprets the term "document" in 904(a)(4) to include the types of documents or electronically stored information referenced in FRCP Rule 34. The term "document" includes any original or any modified version or draft varying in any way, which is saved or stored separately from other versions and/or distributed to others.
2. *Importer:* The term "importer" means the owner or consignee at the time of entry of a tobacco product into the United States.
3. *Pouch:* The term "pouch" means a permeable pouch, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.

4. *Tobacco Product*: The term "tobacco product" means "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)" (section 201(rr) of the act (21 U.S.C. § 321(rr))). This term does not include an article that is a drug, a device, or a combination product as defined in the act (section 201(rr) of the act (21 U.S.C. § 321(rr))). Thus, the term is not limited to products containing tobacco, but also includes components, parts, and accessories of tobacco products, whether they are sold for further manufacturing or are ready for consumer use. For example, tobacco, papers and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.
5. *Tobacco Product Manufacturer:* The term "tobacco product manufacturer" means "any person, including any repacker or relabeler, who (A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States" (section 900(20) of the act (21 U.S.C. § 387(20)). Thus, the term is not limited to persons who manufacture products containing tobacco, but includes anyone who manufactures any tobacco product as defined above.

B. Who submits tobacco health documents?

The requirements under 904(a)(4) of the act apply to each "tobacco product manufacturer or importer." We interpret this to mean that domestic manufacturers are to submit the required tobacco health documents relating to their current or future tobacco products and, for tobacco products that are or will be imported, the required tobacco health documents are to be submitted by either the foreign manufacturer or the importer of the product.

At this time, FDA intends to enforce the tobacco health document submission requirements with respect to:

- manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use; and

- manufacturers and importers of tobacco, filters, papers, and pouches, whether such products are for further manufacturing of, or for consumer use as, regulated tobacco products. Products for consumer use include tobacco, filters, and papers sold separately, in kits (such as for roll-your-own tobacco), or as part of accessories.

Moreover, FDA intends to enforce section 904(a)(4) of the act with respect to documents in the possession, custody, or control of tobacco product manufacturers only. At this time, FDA does not intend to enforce the tobacco health document submission requirements in other circumstances.

FDA intends to focus enforcement of the tobacco health document submission requirements on the manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use as well as manufacturers and importers of tobacco, filters, papers, or pouches,

whether such products are for further manufacturing or for consumer use, because these comprise the principal components of most tobacco products sold to consumers. Moreover, FDA intends to focus enforcement on documents in the possession, custody, or control of tobacco product manufacturers because research and development documents related to the health, toxicologic, behavioral, and physiologic effects of tobacco products are most likely in the possession and control of tobacco product manufacturers. If the agency finds that additional information is needed to protect the public health, the agency may reconsider these compliance policies. We intend to communicate any such compliance policy changes by guidance or rulemaking.

For tobacco products that are or will be imported, the required health documents are to be submitted by either the foreign manufacturer or the importer. The foreign manufacturer and the importer or importers of an imported product will need to work together to ensure that the health documents are submitted to FDA as required by section 904(a)(4).

C. What is included in the submission of tobacco health documents?

1. Manufacturer/Importer Identification

The name and address of each tobacco product manufacturer/importer, and the name and address of any agent submitting tobacco health documents on its behalf, are to be submitted along with the tobacco health document submission. FDA requests that you also provide additional information to assist us in communicating with you, including:

- The FEI number assigned to you by FDA following establishment reporting or ingredient listing under sections 904 and 905;
- A corporate email address, to facilitate correspondence between you and FDA; and
- A Data Universal Numbering System (D-U-N-S®) Number or other unique identifier (codes) of a business entity. The business entity identifier recognized by the FDA Data Council is the Data Universal Numbering System (D-U-N-S®) Number.[2] Dun & Bradstreet assigns and maintains a database of the D-U-N-S® Numbers, which serve as unique identifiers (codes) of business entities. Upon application, each business entity is assigned a distinct site-specific 9-digit D-U-N-S® Number. The site-specific D-U-N-S® Number for an entity is a useful resource for FDA in identifying the establishment. If the D-U-N-S® Number for a location has not been assigned, a business may obtain one for no cost directly from Dun & Bradstreet (*http://www.dnb.com*). Please note that registrants who wish to obtain a new D-U-N-S® Number should obtain one well in advance of FDA's deadline since the processing time involved in receiving a D-U-N-S® Number may take at least 30 days. Alternatively, you may elect to receive a D-U-N-S® Number within one business day by paying a fee.

2. Health Documents

[2] D-U-N-S® Numbers are proprietary to and controlled by Dun & Bradstreet (D&B).

Under section 904(a)(4) of the act, each tobacco product manufacturer/importer must submit all documents developed after June 22, 2009 "that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives." FDA interprets "current or future tobacco products" to refer to all products commercially distributed at any time after June 22, 2009 and all products in any stage of research or development including experimental products and developmental products intended for introduction into the market. A document is "developed" when it is created or modified in any way. Document duplicates that do not vary in any way from a document you are submitting or have submitted under section 904(a)(4) need not be included in your submission.

In addition to the submission of the documents themselves, you are to identify documents based upon the categories of documents set out in section 904(a)(4) of the act. You should provide sufficient information to make your documents readable and accessible. Finally, you should provide document metadata to structure and provide context for your documents.

a) Document Identification

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). Therefore, you are to organize or label each document according to the following categories:

i) Health, toxicological, behavioral and/or physiologic effects. Each document is to be identified as relevant to at least one of these categories. Documents may address more than one category (e.g. a document relating to the health and behavioral effects of nicotine) and in such circumstances you are to identify the document as relating to all relevant categories.

ii) Current or future tobacco products and/or their ingredients, additives, constituents, smoke constituents or components. Each document is to be identified with the name of at least one current tobacco product, future tobacco product, ingredient, additive, constituent, smoke constituent, or component. Documents may address more than one tobacco product or constituent/ingredient/component (e.g., a document relating to Acme 100 Cigarettes, ammonia, and Acme Filter X), and in such circumstances you are to identify the document as relating to all applicable tobacco products and constituents/ingredients/components. You are to use consistent terminology to identify tobacco products and constituents/ingredients/components across all documents submitted under 904(a)(4). When naming tobacco products and constituents/ingredients/components in document categorization, consider the following:

- You are to identify all marketed tobacco products using a unique commercial name (e.g., brand/subbrand). Any tobacco product in research or development is to be referenced using a unique, consistent identifying name.

- FDA requests that you identify constituents and ingredients using the identification framework described in section III.C.3 of FDA's Final Guidance for Industry: Listing of Ingredients in Tobacco Products, available at www.fda.gov/tobaccoinfoindustry.

- Documents may refer to product or constituent/ingredient classes rather than specific products or constituents/ingredients (e.g., menthol cigarettes or tobacco-specific nitrosamines). In such circumstances, you should identify documents using the product or constituent class.

- In order for FDA to verify that all requirements have been met for a given tobacco product, ingredient, additive, or component, FDA 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.

b) Document Readability and Accessibility

In order to ensure accessibility of your documents and facilitate more fluent and efficient communication between you and FDA regarding your submissions, FDA recommends that you complete the following steps for each of your documents:

- Uniquely number all pages of your submission, a process commonly referred to in the litigation context as Bates numbering;
- Translate all foreign language documents into English;
- Label each document with relevant keywords—FDA recommends that keywords be chosen from the National Library of Medicine's Medical Subject Headings, available at www.nlm.nih.gov/mesh/; and
- Create and submit a glossary or explanation of any abbreviations, jargon or internal (e.g. code) names.

c) Metadata

Metadata is information accompanying a document that provides structure and context for the information contained in the document. Document metadata is routinely submitted with documents produced via discovery in civil litigation. In order to provide context and background for each document, FDA recommends that the following metadata accompany each document:

- Date of creation;
- Document author(s);
- Document recipient(s);
- Document custodian;
- Document title or identification number;
- Beginning and ending Bates numbers;
- If the document references other documents (e.g., an attachment to an email), Bates number ranges for the referenced documents; and

FDA recommends that you submit documents in a digital format that is text searchable. If you scan paper documents for digital production you should use optical character recognition (OCR)

technology to extract searchable text data from the document image. The extracted searchable text should be produced with the document as metadata.

D. How do you submit tobacco health document information?

Although electronic submission is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and management.

The FDA eSubmitter tool is an electronic application designed for preparing certain digital submissions for FDA. This tool provides an automatic acknowledgement of FDA receipt, and allows users to attach large numbers of files (e.g., PDF documents, TIFF files).

Users of the eSubmitter tool first download and install the computer application, enter all data, and then upload the completed submission through the FDA Electronic Submissions Gateway (ESG). The FDA ESG system requires users to apply for a free account before submitting data, a process which can take one to three weeks. FDA therefore urges registrants to apply for ESG accounts well in advance of the statutory deadline for data submission. The eSubmitter tool is available at http://www.fda.gov/ForIndustry/FDAeSubmitter.

If you choose not to use eSubmitter for submission of health documents under section 904(a)(4) of the act, FDA recommends digital production of all documents on a hard drive, CD or DVD, depending on the volume of the submission. These submissions should include digital document images in PDF or TIFF accompanied by a load file containing all metadata and OCR data. In order to assure the accessibility of these documents, FDA requests that you provide the document format, the software used to create the document production and associated load file, and contact information for IT professionals who are able to provide additional technical details about your submission. In order for FDA to access, review, and archive the documents, they cannot be password protected.

If electronic or paper documents submitted under section 904(a)(4) of the act are mailed to FDA instead of packaged with eSubmitter and submitted via the ESG, we request that you include FDA Form 3743 with your submission. The digital media, envelopes, boxes, or volume jackets used for submission should be labeled with the manufacturer/importer name, D&B DUNS number, contact phone number, the statutory provision ("904(a)(4)"), submission date, and series number (e.g., "disc 1 of 2," "box 4 of 4").

All tools and forms for preparing your submission will be available at www.fda.gov/tobaccoinfoindustry.

E. When do you submit tobacco health documents?

Section 904(a)(4) of the act requires submission of tobacco health documents beginning on December 22, 2009. FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for the production of documents in a digital format, which FDA strongly encourages in order to improve the management and accessibility of submitted documents. Therefore, FDA

does not intend to enforce the December 22, 2009, deadline provided you submit by April 30, 2010 all health documents developed between June 23, 2009 and March 31, 2010.

Section 904(a)(4) of the act is an ongoing requirement. In order to allow sufficient time for document collection and preparation, however, FDA will consider you to have fulfilled your requirements under section 904(a)(4) of the act if you submit documents developed after March 31, 2010 according to the following schedule:

Documents Developed Between	**Submit by**
January 1 and March 31	April 30
April 1 and June 30	July 31
July 1 and September 30	October 31
October 1 through December 31	January 31

If you do not have any health documents to report, you are to inform FDA of this by the dates specified above. You may use FDA Form 3743 to notify the agency. If you do not anticipate having any health documents to submit in the future, you may state this in a single 904(a)(4) submission. You remain obligated, however, to produce any documents according to the dates above should you develop documents covered under section 904(a)(4) of the act at a later date.

F. Will the FDA maintain the confidentiality of the health documents I submit?

Information submitted under section 904 of the act may include a company's non-public trade secret or confidential commercial information.

Several laws govern the confidentiality of information submitted under section 904 of the act, including sections 301(j) and 906(c) of the act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and the Freedom of Information Act (FOIA) (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the act and, when relevant, in any proceeding under the tobacco products chapter of the act. Section 301(j) of the act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the act and to Congress in response to an authorized Congressional request.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR Part 20.