

# Health Document Submission Requirements for Tobacco Products

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## Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to <http://www.regulations.gov>. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with the docket No. FDA-2009-D-0600.

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>. You may send an e-mail request to [smallbiz.tobacco@fda.hhs.gov](mailto:smallbiz.tobacco@fda.hhs.gov) to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

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

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**See additional PRA statement in section IV of the guidance**

\* This is the first revision to the first edition of this guidance, which issued in April 2010. Revisions are noted by date at the end of the guidance.

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# Health Document Submission Requirements for Tobacco Products

## Guidance for Industry<sup>1</sup>

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

### I. INTRODUCTION

This guidance describes FDA's current thinking regarding the submission of health-related documents required by section 904(a)(4) of the Food, Drug, and Cosmetic Act (FD&C Act)(21 U.S.C. 387d(a)(4)). This guidance is intended for manufacturers and importers of cigarettes, cigarette tobacco, roll your own tobacco (RYO), smokeless tobacco and those tobacco products subject to FDA's final rule, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act* (81 FR 28974) (the deeming rule).

This guidance explains, among other things:

- The statutory requirement to submit health documents
- Definitions
- Who should submit health documents
- FDA's compliance policies
- What information to include in health document submissions
- How to make health document submissions
- When to make health document submissions

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

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<sup>1</sup> This guidance was prepared by the Office of Regulations and the Office of Science in the Center for Tobacco Products at FDA.

are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

## II. BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted on June 22, 2009, amends the FD&C Act and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public's health (Pub. L. 111– 31, 123 Stat. 1776). Among other things, the Tobacco Control Act adds section 904(a)(4) to the FD&C Act, requiring each tobacco product manufacturer or importer, or agents thereof, to submit all documents developed after June 22, 2009, that relate to any “health, toxicological, behavioral, or physiological effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives.”<sup>2</sup>

Cigarettes, cigarette tobacco, RYO, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the Act, including section 904, when the Tobacco Control Act went into effect. As for other types of tobacco products, section 901(b) of the FD&C Act (21 U.S.C. 387a(b)) grants FDA authority to deem those products subject to chapter IX of the FD&C Act. Pursuant to that authority, FDA issued a proposed rule seeking to deem all other products that meet the statutory definition of “tobacco product” set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) (except for accessories of those products) (79 FR 23142, April 25, 2014).<sup>3</sup> After review and consideration of comments on the proposed rule, the final rule published on May 10, 2016, (81 FR 28974) (the deeming rule) with the effective date of August 8, 2016. Manufacturers and importers of tobacco products that have been deemed subject to the FD&C Act are now required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents. However, as explained in the preamble to the deeming rule, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents relating to the newly deemed tobacco products (i.e., other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco), so long as a specified set of documents are submitted by February 8, 2017, or in the case of small-scale tobacco product manufacturers (small-scale manufacturers), by August 8, 2017 (81 FR 28974 at 29008-09).

Failure to submit the required health documents has consequences. First, under section 903(a)(10)(A) of the FD&C Act (21 U.S.C. 387c(a)(10)(A)), a tobacco product is deemed misbranded if there is a failure or refusal to comply with any requirement prescribed under section 904. Additionally, the failure or refusal to furnish any information required by section 904 is a prohibited act under section 301(q)(1)(B) of the FD&C Act (21 U.S.C. 331(q)(1)(B)). Violations relating to section 904(a)(4) are subject to regulatory and enforcement action by FDA, including seizure and injunction.

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<sup>2</sup> This guidance uses the term *health documents* to refer to the documents required under section 904(a)(4).

<sup>3</sup> Accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule's deeming provision. Reference the deeming rule for further information about accessories (81 FR 28974).

### III. DISCUSSION

#### A. What Definitions Apply to This Guidance?

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

- **Component or part:** The term *component or part* means any software or assembly of materials intended or reasonably expected:
  - (1) to alter or affect the tobacco product’s performance, composition, constituents, or characteristics; or
  - (2) to be used with or for the human consumption of a tobacco product.Component or part excludes anything that is an accessory of a tobacco product.

FDA notes that *component* and *part* are separate and distinct terms within chapter IX of the FD&C Act. However, for purposes of this guidance, FDA is using the terms *component* and *part* interchangeably and without emphasizing the distinction. FDA may clarify the distinctions between *component* and *part* in the future.

- **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” (Fed. R. Civ. P. 34(a)(1)(A)). FDA understands the term *document* in section 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.

- **Finished tobacco product:** The term *finished tobacco product* means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).
- **Importer:** The term *importer* means any person who imports any tobacco product that is intended for sale or distribution to consumers in the United States.
- **Small-scale tobacco product manufacturer:** The term *small-scale tobacco product manufacturer* means a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of \$5 million or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with.

- ***Tobacco product*** is defined in section 201(rr) of the FD&C Act, which states in relevant part:
  - (1) 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).
  - (2) The term “tobacco product” does not mean an article that is a drug under [section 201(g)(1)], a device under [section 201(h)], or a combination product described in section 503(g) [of the FD&C Act].

Note that this definition includes accessories and components and parts of tobacco products, whether they are made or derived from tobacco and whether they are sold or distributed as finished tobacco products.<sup>4</sup>

- ***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 FD&C 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 Health Documents?**

Section 904(a)(4) provides, in pertinent part:

(a) Requirement—Each tobacco product manufacturer or importer, or agents thereof, shall submit to the Secretary the following information: . . . .

(4) Beginning 6 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act, 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 discussion below provides FDA’s current thinking with respect to the application of section 904(a)(4) to tobacco products deemed subject to FDA authority (those tobacco products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco) and to tobacco products that were immediately covered by FDA’s tobacco product authorities (cigarettes, cigarette tobacco, RYO, and smokeless tobacco).

Section 904(a)(4) requires “[e]ach tobacco product manufacturer or importer” to submit health documents. We interpret this to mean that for products made in the United States, health

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<sup>4</sup> However, accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule’s deeming provision (see note 3). Thus, although they meet the definition of tobacco product, such accessories are not currently subject to regulation under the FD&C Act (including section 904(a)(4)). See section III.C for details on FDA’s compliance policy for tobacco products that are sold or distributed solely for further manufacturing.

documents related to current or future tobacco products are to be submitted by the manufacturer. For products made outside of the United States, health documents for tobacco products that are or will be imported are to be submitted by either the foreign manufacturer or the importer of the product. The foreign manufacturer and the importer or importers of the product should work together to ensure that the health documents are submitted to FDA as required by section 904(a)(4).

### **C. What Is FDA’s Compliance Policy for Regulated Tobacco Products?**

At this time, with respect to all tobacco products — including cigarettes, cigarette tobacco, RYO, and smokeless tobacco, as well as other tobacco products now regulated as a result of the deeming rule — FDA intends to enforce the health document requirements of section 904(a)(1) with respect to finished tobacco products only. FDA does not, at this time, intend to enforce these requirements with respect to products that are sold or distributed solely for further manufacturing.

As defined above, the term *finished tobacco product* means a tobacco product, including all components and parts, sealed in final packaging intended for consumer use (e.g., filters or filter tubes sold separately to consumers or as part of kits).

Components and parts that are sold separately from other tobacco products are also finished tobacco products if they are sold in final packaging intended for consumer use. FDA intends to enforce the health document requirements under section 904(a)(4) with respect to these products. Examples of components and parts that are sold or may be sold as finished tobacco products include pipe tobacco filler, filter tubes, e-cigarette batteries, and e-liquids, whether sold separately to consumers or as part of kits.<sup>5</sup>

Based on our experience with cigarettes, cigarette tobacco, RYO and smokeless tobacco, we are amending our previous compliance policy. Under our previous policy, FDA intended to enforce the health document requirements with respect to manufacturers and importers of tobacco, papers, filters, and pouches whether or not the products were for further manufacturing of, or for consumer use as, regulated tobacco products. However, FDA is announcing a change to that policy because we believe we can obtain the necessary information about tobacco product components and parts through other means, such as premarket applications and health documents for finished tobacco products and through the use of master files, as explained in the Master File guidance.<sup>6</sup>

Additionally, we are aligning our compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco with the products now regulated as a result of the deeming rule to reduce burden on industry. Should FDA find that additional information is needed to protect the public

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<sup>5</sup> As explained in note 3, the Secretary has not deemed accessories of tobacco products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco to be subject to chapter IX of the FD&C Act, and so they are not currently subject to section 904(a)(4).

<sup>6</sup> FDA’s guidance for industry *Tobacco Product Master Files* is available on the Tobacco Products guidance Web site at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

health, the Agency may reconsider this compliance policy. We intend to communicate any such compliance policy changes by guidance or rulemaking. Accordingly, you are to preserve tobacco health documents relating to components and parts for future submission to FDA. Failure to submit tobacco health documents relating to components and parts because of a failure to preserve them will constitute a violation of section 904(a)(4).

**D. What Information and Documents Are Included With the Tobacco Health Documents Submission?**

*1. Manufacturer/Importer Identification*

You should include the following information about the entity making the submission:

- The name and address of the business entity
- Whether the entity is a manufacturer or an importer
- The name, title, and contact information for a point-of-contact, including an address, telephone number, and fax number
- An email address for the point-of-contact, to facilitate communication about your submission
- The FDA facility establishment identifier (FEI) number assigned to your establishment, if any<sup>7</sup>
- The Data Universal Numbering System (D-U-N-S) number assigned to your business entity<sup>8</sup>

If the submission is made by the importer of a foreign product, you should also include the following information about the manufacturer of the imported product:

- The name and address of the business entity
- The name, title, and contact information for a point-of-contact at the manufacturer, including an address, telephone number, and fax number
- An email address for the point-of-contact at the manufacturer
- The FEI number assigned to the manufacturer's establishment by FDA, if any

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<sup>7</sup> In most cases, FDA assigns an FEI number after receiving the establishment's initial registration submission required under section 905 of the FD&C Act (21 U.S.C. 387e).

<sup>8</sup> D-U-N-S is the unique business identifier recognized by the FDA Data Standards Council. D-U-N-S Numbers are proprietary to, and controlled by, Dun & Bradstreet (D&B). If the D-U-N-S number for a location has not been assigned, a business may obtain one for no cost directly from D&B (<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, because it may take 30 days (or longer) to process a new number. Alternatively, you may elect to receive a D-U-N-S number within one business day by paying a fee. If you do not have a D-U-N-S number, include a unique identifier (code) of your business entity.



- The D-U-N-S number assigned to the business entity or, if you do not have a D-U-N-S number, a unique identifier (code) of your business entity

## 2. *Health Documents*

Under section 904(a)(4) of the FD&C Act, 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, are responsive to the health document submission requirement. We discuss FDA's interpretation of the statute and the Agency's compliance policies in the following paragraphs.

FDA interprets "health, toxicological, behavioral, or physiologic" broadly to include, for example, cell-based, tissue-based, animal, or human studies, computational toxicology models, information on addiction, intentions to use, cognition, emotion, motivation, and other behavioral effects at both the population-level (epidemiology) as well as the individual level (such as abuse liability).

For tobacco products subject to the deeming rule, FDA understands "current or future tobacco products" to refer to products commercially distributed on or after August 8, 2016, or products in any stage of research or development at any time after August 8, 2016, including experimental products, and developmental products intended for introduction into the market for consumer use.

For cigarettes, cigarette tobacco, RYO, and smokeless tobacco, FDA understands "current or future tobacco products" to refer to products commercially distributed after June 22, 2009, or products in any stage of research or development at any time after June 22, 2009, including experimental products, and developmental products that were intended for introduction into the market for consumer use.

Section 904(a) applies to "all documents developed" after June 22, 2009, whether the document is developed by you or by any other party. A document is developed when it is created or modified in any way. Thus, a document that was first created before June 22, 2009, but was updated or revised after that date, is responsive to section 904(a)(4).

FDA intends to enforce section 904(a)(4) with respect to documents in the possession, custody, or control of the manufacturer (in the case of domestic products) or either the manufacturer or importer (in the case of imported products), only. For documents relating to 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. Thus, where the importer makes the submission, the importer should work with the manufacturer to ensure that the submission includes documents in the possession, custody, or control of the manufacturer.

Because of the inefficiencies associated with processing and reviewing duplicative documents, substantively identical documents, or publicly available information, FDA does not intend, at this time, to enforce section 904(a)(4) with respect to the following:

- Documents that are exact duplicates of another document that is included in the same or a prior submission under section 904(a)(4)
- Documents that are substantively identical to another document that is included in the same or a prior submission under section 904(a)(4), where any differences are minor and do not affect the meaning or substance of the document (e.g., changes in formatting, spelling, pagination, and letterhead)
- Redacted documents, where an unredacted copy of the same document is included in the same or a prior submission under section 904(a)(4)<sup>9</sup>
- Unaltered or unmarked documents, written in English, that fall into the following categories:
  - Articles published in peer-reviewed journals
  - Published news articles, books, and other documents available to the general public
  - Material Safety Data Sheets (MSDS)
  - HHS correspondence

a. Document Identification

Section 904(a)(4) requires that you submit documents 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 understands section 904(a)(4) to mean that you are to organize and label the documents in your submission to correspond to the categories of documents set out in section 904(a)(4), as follows:

i. Health, toxicological, behavioral, or physiologic effects

Each document is to be identified as to whether the content relates to health, toxicological, behavioral, or physiologic effects. Many documents may relate to more than one of these topics, e.g., a document relating to the health and behavioral effects of nicotine. You are to identify all relevant topics for each document.

ii. Identify tobacco products, constituents, ingredients, components, and additives

Each document is to be identified as to the name of each tobacco product (current and future), ingredient, additive, component, and constituent (including constituents from tobacco product emissions, such as in smoke or aerosol, which some refer to as vapor) to which the document relates. Each marketed tobacco product must be identified as necessary to distinguish it from any other product (e.g., by brand, subbrand, characterizing flavor, size, package type, product quantity). Any tobacco product in research or development should be referenced using a unique,

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<sup>9</sup> See section III.D.2.b regarding redacted documents.

consistent identifying name. Many documents may relate to more than one product, constituent, ingredient, component, and additive. You are to identify *all* relevant tobacco products, constituents (including smoke constituents), ingredients, components, and additives for each document.

### iii. Consistent Terminology

You should use consistent terminology to identify tobacco products, constituents, ingredients, components, and additives across all of the documents in your submission. FDA also recommends the following practices to identify products, constituents, ingredients, components, and additives:

- Identify a constituent or ingredient with a unique, consistent, identifying name that distinguishes it from similar or related materials, according to the framework described in the guidance for industry *Listing of Ingredients in Tobacco Products*.<sup>10</sup>
- If a document relates to a class of constituents, ingredients, components, and additives (e.g., tobacco specific nitrosamines), identify the class to which the document relates.
- If a document relates to more than one current or future tobacco product or an entire class of tobacco products, identify the product category (e.g., ENDS, cigars, waterpipe, pipes, cigarettes, roll-your-own, and smokeless) to which the document applies.

You should use consistent terminology in your submissions under section 904(a)(4) and sections 904(a)(1), 904(c) and 905 in order for FDA to verify that all requirements have been met.

### b. Document Readability and Accessibility

To ensure accessibility of your documents and facilitate more fluent and efficient communication between you and FDA regarding your submissions, FDA recommends that you ensure that your documents meet the following criteria:

- **Unredacted.** Ensure that your documents are not redacted. If you have more than one version of a document, be sure to submit an unredacted version. If there is no unredacted version in your possession, custody or control, you should submit all redacted versions of the document.
- **Page numbered.** Ensure that the pages of each document in your submission are numbered consecutively so that FDA is able to determine that there are no pages missing in a document and that the pages are in proper order. If your documents have Bates numbers, the Bates numbers may serve as page numbers for this purpose.
- **Translated.** Translate all foreign language documents into English.
- **Glossary.** Create and submit a consolidated glossary or explanation of any abbreviations, jargon, or internal names (e.g., code names).

The documents in your submission should be saved in file formats that FDA can readily process,

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<sup>10</sup> FDA's guidance for industry *Listing of Ingredients in Tobacco Products* is available on the Tobacco Products guidance Web site at <http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

read, and archive. These formats include portable document format (PDF), plain text (TXT), comma-separated values (CSV), rich text format (RTF), SAS export (XPT), AVI, TIFF, JPG, GIF, HTML, XML, and similar formats established by the National Archives and Records Administration for preservation of document content and format. You can find more information on file formats in the *FDA eSubmitter User Manual*, available at <http://www.fda.gov/downloads/ForIndustry/FDAeSubmitter/UCM449686.pdf>.

FDA asks that spreadsheets or datasets be submitted both in PDF and in a file type and structured format that allows for meaningful review and analysis of the data such as Excel (XLS), CSV, or (XPT file formats. Where relevant, data submissions should be accompanied by the name and version of software used to create the file, names and definitions of variables, and copies of programs and macros needed to generate your analyses. We request that your submission include any data analyses that stratify scientific results by gender, race/ethnicity, age, health condition, and other similar factors.

FDA recommends that you submit documents in a digital format file that is text selectable and searchable. If you scan paper documents to PDF, you should perform optical character recognition (OCR). If you do not save the document as a PDF file with selectable and searchable text, provide the OCR extracted searchable text as a separate text file. The text file should be named the same as the PDF file and included in the load file.

c. Document Metadata Included in a Load File

Metadata is information, or data, about each document or set of documents. Metadata provides structure and context for the information contained within the document. Whether or not you are using eSubmitter, you should submit the document information and metadata specified below in an index referred to as a “load file.” The load file should be in electronic CSV format and include the information for each document, as below:

- Filename
- Document date
- Document author(s)
- Document recipient(s)
- Document custodian, i.e., the individual with physical control of the document
- Document title, subject, or identification number
- Beginning and ending page numbers, or Bates numbers, if the document is Bates stamped
- Page number or Bates number ranges for other documents physically or digitally attached to the document, e.g., an attachment to an email
- Document type, using one of the following descriptions: Email, Briefing Slides, Publication, Memo, Report, Meeting Minutes, Proposal, Study Design, Teleconference, Lab Notes, Other

- We also request that you identify the presence of the document in the University of California San Francisco Truth Tobacco Documents database<sup>11</sup> as one of the following: present with the Bates number range (begin Bates number to end Bates number), not present, or unknown.
- Whether the content relates to health, toxicological, behavioral, or physiologic effects of tobacco products<sup>12</sup>.
- The name of each tobacco product the document relates to.
- The category or categories of products the document relates to.
- Any specific ingredients, constituents, components, and additives to which the document relates
- Any classes of ingredients, constituents, components, and additives to which the document relates
- The extracted or OCR text for any documents that you submitted in a format that does allow for searching, selecting, or copying text.

#### **E. How Do You Submit Health Document Information?**

Although electronic submission is not required, FDA strongly encourages you to send your submission electronically via eSubmitter, FDA's electronic submission tool. Electronic submission reduces paper and facilitates an efficient (and timely) submission on your end, and efficient processing, review, and archiving of the submission once at FDA. As discussed above, FDA also strongly encourages you to submit the documents in an electronic format that is text searchable and selectable.

You should do the following to ensure that FDA is able to access the information in your electronic submission:

- Identify the document format and any software used to create the document production (and associated load file).
- Provide contact information for your IT professionals who, if needed, can provide technical details about your submission.
- Ensure that no part of the submission is encrypted, password protected, or that any document protection or restriction settings are active. For example, settings should allow for printing, selecting text and graphics, and adding or changing notes and form fields.
- Ensure that any and all files submitted to FDA are computer virus-free. Include a statement confirming that all the media is virus-free, along with a description of the software (name, version, and company) used to check the files for viruses.

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<sup>11</sup> The Truth Tobacco Documents database is online at <https://industrydocuments.library.ucsf.edu/tobacco/>.

<sup>12</sup> If a document relates to more than one of these subjects, you should identify all those subjects that are related to the document.

- Ensure the files are in formats that FDA can readily process, read, and archive, as described in section III.D.2.b (Document Readability and Accessibility).

If you choose to not use eSubmitter, read and follow the instructions for Form FDA 3743. Form FDA 3743 and all tools and forms for preparing your submission are available at:

<http://www.fda.gov/tobaccoproducts/guidancecomplianceregulatoryinformation/manufacturing/default.htm>

### 1. *Submitting Health Documents Electronically Using eSubmitter*

The FDA eSubmitter tool is software provided by FDA for the preparation of electronic submissions. This tool provides an automatic acknowledgement of FDA receipt and allows users to attach large numbers of files, such as PDF documents.

To use eSubmitter, first download the tool from the FDA Web site at <http://www.fda.gov/ForIndustry/FDAeSubmitter> and install it on your computer.<sup>13</sup> Select the “CTP Tobacco Health Document Submission” form within the eSubmitter program and enter information about your submission directly into the software. This includes the information described in III.D.1-2 (What is Included in the Submission of Tobacco Health Documents). You will not need to prepare additional documents with this information, and you will not need to complete Form FDA 3743.

You can then use eSubmitter to enter data, attach files, and upload the completed submission through the CTP Portal or FDA Electronic Submissions Gateway (ESG). You will need to apply for a free account to upload data through either the CTP Portal (<https://ctpportal.fda.gov/ctpportal/login.jsp>) or ESG. Due to the time needed to create new accounts, FDA urges submitters to apply for accounts several weeks in advance of when you intend to submit. The CTP Portal and ESG are both available 24 hours a day, 7 days a week.

### 2. *Submitting Documents When Not Using eSubmitter*

If you choose not to use eSubmitter, you should produce your entire submission on a hard drive, CD, DVD, or USB drive, depending on the overall size of the submission. The disk or drive should include the following:

- The identifying information described in section III.D.1 (Manufacturer/Importer Identification)
- The health documents, submitted as individual files
- A load file containing document-level information and metadata, as described in section III.D.2.c (Document Metadata Included in a Load File)
- FDA Form 3743

Label digital media and any containers, including, e.g., envelopes, boxes, or volume jackets, with the following information:

- The name of the manufacturer or importer making the submission

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<sup>13</sup> The eSubmitter tool requires a computer that runs MS Windows.

- The business entity’s DUNS number
- The name and phone number for a point-of-contact
- The statutory provision, i.e., section 904(a)(4)
- The date of submittal
- A series number (e.g., “disc 1 of 2,” “box 4 of 4”)

Send your electronic media or paper documents to the following address:

Food and Drug Administration  
 Center for Tobacco Products  
 Document Control Center  
 Building 71, Room G335  
 10903 New Hampshire Avenue  
 Silver Spring, MD 20993-0002

Although FDA strongly encourages electronic submission, FDA Form 3743 should be submitted with any paper documents and delivered to the above address.

Submissions delivered to CTP’s Document Control Center by couriers or physical mail will be considered timely if received during delivery hours on or before the due date (see <http://www.fda.gov/tobaccoproducts/aboutctp/contactus/default.htm>); if the due date falls on a weekend or holiday, the delivery must be received on the prior business day. We are unable to accept regulatory submissions by e-mail.

**F. When Do You Submit Tobacco Health Documents?**

FDA recognizes the challenges associated with the collection, review, organization, and production of documents. We also recognize that additional time may be necessary for you to produce documents in a digital format, as FDA strongly encourages you to do. FDA is taking an incremental approach to enforcing this provision with respect to the time frame that documents were developed and the date that documents must be submitted. However, FDA intends to expand these compliance policies in the near future to further pursue the important public health goals of this provision. Accordingly, FDA has adopted the following compliance policies.

*1. Tobacco Products Other Than Cigarette, Cigarette Tobacco, RYO, and Smokeless Tobacco*

FDA adopted a compliance policy to apply to health documents that relate to tobacco products that are subject to the deeming rule. For this group—which includes all regulated tobacco products, except for cigarettes, cigarette tobacco, RYO, and smokeless tobacco—FDA does not intend to enforce section 904(a)(4) until February 8, 2017, or at least 90 days prior to the delivery for introduction into interstate commerce of the tobacco product to which the health document relates, whichever is later. Moreover, although section 904(a)(4) requires ongoing submission of health documents, at this time, FDA does not intend to enforce section 904(a)(4) with respect to documents developed after December 31, 2009. Instead, at this time, FDA

intends to enforce section 904(a)(4) with respect to health documents developed between June 23, 2009, and December 31, 2009.

● ***Small-Scale Manufacturers***

As stated in the preamble to the deeming rule, to address concerns of small-scale manufacturers, and in recognition of FDA’s current enforcement priorities, at this time, FDA does not intend to enforce section 904(a)(4) against small-scale manufacturers until August 8, 2017, or at least 90 days prior to the delivery for introduction into interstate commerce of tobacco products to which the health documents relate, whichever is later. At such time, FDA intends to enforce section 904(a)(4) with respect to documents developed between June 23, 2009, and December 31, 2009.

**FDA’s Compliance Policy for Health Document Submissions  
(for Products Other Than Cigarettes, Cigarette Tobacco, RYO, and Smokeless Tobacco)**

Submit Health Documents that Relate to ...	... and That Were Developed	Compliance Date	Retention Policy
Current or future finished tobacco products	Between June 23, 2009, and December 31, 2009	February 8, 2017 August 8, 2017, for small-scale manufacturers Otherwise, at least 90 days prior to delivery for introduction into interstate commerce	Preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA.

Although FDA does not intend to take enforcement action with respect to the submission of documents developed after December 31, 2009, at this time, FDA does intend to collect health documents developed after December 31, 2009, in the future. At that time, FDA will publish additional guidance specifying the details and timing of subsequent submissions. ***Note that you are to preserve tobacco health documents developed after December 31, 2009, for future submission to FDA.*** Failure to submit tobacco health documents developed after December 31, 2009, because of a failure to preserve them will constitute a violation of section 904(a)(4).

***If you do not have any health documents to report, you should inform FDA of this by February 8, 2017, or August 8, 2017 (small-scale manufacturers).*** You may use FDA Form 3743 or the eSubmitter tool to make this notification. If you do not anticipate having any health documents to submit in the future, you may state this in a single section 904(a)(4) submission. You remain obligated, however, to preserve any documents covered under section 904(a)(4) of the FD&C Act should they be developed at a later date.

2. ***Cigarettes, Cigarette Tobacco, RYO, and Smokeless Tobacco***

Section 904(a)(4) of the FD&C Act requires submission of tobacco health documents beginning on December 22, 2009. Although section 904(a)(4) requires ongoing submission of health documents, at this time, FDA does not intend to enforce section 904(a)(4) with respect to documents developed after December 31, 2009, that relate to cigarettes, cigarette tobacco, RYO, and smokeless tobacco. Manufacturers or importers of cigarettes, cigarette tobacco, RYO, or



smokeless tobacco products must provide all health documents developed between June 23, 2009, and December 31, 2009, at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce.

**FDA's Compliance Policy for Health Document Submissions  
(for Cigarettes, Cigarette Tobacco, RYO, and Smokeless Tobacco)**

Submit Health Documents that Relate to ...	... and That Were Developed	Compliance Date	Retention Policy
Current or future finished tobacco products	Between June 23, 2009, and December 31, 2009	At least 90 days prior to delivery for introduction into interstate commerce	Preserve all health documents including those that relate to products for further manufacturing and including those developed after December 31, 2009, for future submission to FDA.

Although FDA does not intend to take enforcement action with respect to the submission of documents developed after December 31, 2009, currently, FDA does intend to collect health documents developed after December 31, 2009, in the future. At that time, FDA will publish additional guidance specifying the details and timing of subsequent submissions. ***Note that you are to preserve tobacco health documents developed after December 31, 2009, for future submission to FDA.*** Failure to submit tobacco health documents developed after December 31, 2009, because of a failure to preserve them will constitute a violation of section 904(a)(4).

***If you do not have any health documents to report, you should inform FDA of this.*** You may use FDA Form 3743 or the eSubmitter tool to make this notification. If you do not anticipate having any health documents to submit in the future, you may state this in a single section 904(a)(4) submission. You remain obligated, however, to preserve any documents covered under section 904(a)(4) of the FD&C Act should they be developed at a later date.

**G. Will FDA Maintain the Confidentiality of the Health Documents You Submit?**

Information submitted under section 904(a)(4) may include a company's nonpublic trade secret or confidential commercial information. Several laws govern the confidentiality of that information, including section 301(j) and section 906(c) of the FD&C Act, 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) prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904(a)(4), 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 chapter IX of the FD&C Act and, when relevant, in any proceeding under chapter IX of the FD&C Act.

Section 301(j) generally prohibits the release of trade secret information obtained by FDA under section 904(a)(4), among other provisions, outside of the Department of Health and Human Services, except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request.

FDA's general regulations concerning the public availability of FDA records are codified at 21 CFR part 20.

#### **IV. PAPERWORK REDUCTION ACT of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 50 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Food and Drug Administration  
Center for Tobacco Products  
Document Control Center  
Building 71, Room G335  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0654 (expires June 30, 2019).

## DOCUMENT HISTORY

April 2010 — First edition of guidance issued.

November 2016 — *Health Document Submission Requirements* guidance revised to reflect changes in FDA authorities over “deemed” tobacco products. Revisions include minor clarifying and editorial changes to promote consistency throughout our guidances, incorporate “plain language,” and employ grammatically correct phrasing. Specific revisions include the following:

- Section II — Background updated to reflect changes in FDA authorities over “deemed” tobacco products arising from “deeming” rule.
- Section III.A — Definitions of *component or part, finished tobacco product*, and *small-scale tobacco product manufacturer* added, definition of *pouch* removed, definition of *importer* updated.
- Section III.C — Information on FDA’s compliance policy for regulated tobacco products added; compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco amended.
- Section III.D — Former section C retitled and is now section D.
- Section III.D — Information to identify the manufacturer/importer updated.
- Section III.D.1 — Information on Data Universal Numbering System updated.
- Section III.D.2.a — Section reorganized and subsection titles added.
- Section III.D.2.b — “Document Readability and Accessibility” updated.
- Section III.D.2.c — Subsection retitled “Document Metadata Included in a Load File” and updated.
- Section III.E — Former section D is now section E and subsections 1 and 2 added.
- Section III.F — Former section E is now section F and updated to include newly deemed tobacco products.
- Section III.G — Former section F titled revised and is now section G.
- Section IV — PRA section updated