DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

TOBACCO HEALTH DOCUMENT SUBMISSION

Form Approved: OMB No. 0910-0654
Expiration Date: 6/30/2019
(See page 5 for PRA Statement)

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

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 amended the Federal Food, Drug, and Cosmetic Act (the act) by adding a new chapter granting 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.

STATUTORY REQUIREMENTS

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.

DEFINITIONS

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

1. **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 form, 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.

2. **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.

3. **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).

4. **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.

5. **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.

6. **Tobacco product**: The term 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.[1]

7. **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.

[1] However, accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule's deeming provision . 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)). Reference the deeming rule for further information about accessories (81 FR 28974).

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See page 6 for Instructions

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Please type. An item followed by an asterisk (*) denotes a required field.

SECTION I - SUBMITTER IDENTIFICATION

Submitter Type *(Check one)** ☐ Manufacturer ☐ Importer *(Complete Section II)*

Company Name*

Company Headquarters D&B D-U-N-S ® Number	Company Headquarters FDA-assigned Facility Establishment Identifier (FEI) Number

Address*	City*

State, Province or Territory*	Country*	ZIP or Postal Code*

Authorized Representative *(Responsible official authorized to represent the applicant)*

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g.,Sr., Jr., III)*

Professional Suffix *(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name ☐ Check here if same as submitter company name above, and skip to Address.

Address ☐ Check here if same as above, and skip to Section II.	City

State, Province or Territory	Country	ZIP or Postal Code

SECTION II - MANUFACTURER OF IMPORTED PRODUCTS

Required only for importers

Company Name*

Company Headquarters D&B D-U-N-S ® Number	Company Headquarters FDA-assigned Facility Establishment Identifier (FEI) Number

Address*	City*	
State, Province or Territory*	Country*	ZIP or Postal Code*

U.S. Agent *(For foreign firm where Authorized Representative does not reside in the U.S.)*

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Sr., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name ☐ Check here if same as manufacturer company name above, and skip to Address.

Address ☐ Check here if same as above, and skip to Section III.	City	
State, Province or Territory	Country	ZIP or Postal Code

SECTION III - SUBMISSION FORMAT AND CONTENTS

Indicate your submission format (Check all that apply).

☐ **Electronic Documents**

1. ☐ Number of documents _____
2. ☐ Media type *(e.g., CD)* _____
3. ☐ Media quantity *(e.g., # of CDs)* _____
4. ☐ Size of submission *(e.g., MB)* _____
5. ☐ File type *(e.g., PDF)* _____
6. ☐ File software *(e.g., Adobe Acrobat XI)* _____

7. If you are submitting electronic documents, please detail any special instructions for loading or accessing your submission, including contact information for IT professionals who may be able to provide additional technical details about your submission.

☐ **Paper Documents**

1. ☐ Number of documents _____ 2. ☐ Number of volumes _____ 3. ☐ Number of boxes _____

None

☐ I do not have any 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 to submit for this reporting period.

☐ I do not anticipate having documents in the future. If at any time in the future I do have such documents I will immediately notify FDA and begin submitting the documents as required by section 904(a)(4) of the Federal Food, Drug, and Cosmetic Act.

SECTION IV - CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. Electronic media has been scanned and certified to be virus-free. I agree to report changes to this information as required under section 904(c) of the act. **WARNING:** **A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.**	☐ **Agree**
Signature of Authorized Representative or U.S. Agent	Date

Typed Name and Title:

Authorized Representative or U.S. Agent Contact Information

☐ Check here if same as the submitter point of contact information in Section I. If so, you may skip to Company Name.

Prefix *(e.g., Mr., Ms., Dr.)*:

First/Given Name	M.I.	Last Name	Generational Suffix *(e.g., Sr., Jr., III)*

Professional Suffix*(e.g., MD, Ph.D.)*	Position Title	Email Address

Telephone *(Include Country Code if applicable)*	FAX

Company Name ☐ Check here if same as submitter, and skip to Address.

Address ☐ Check here if same as submitter company's, and skip to Section V.	City

State, Province or Territory	Country	ZIP or Postal Code

Submit a separate copy of this page for each document or each set of documents.

SECTION V - DOCUMENT CATEGORIZATION

1. This document or set of documents relates to the following effects *(Check all that apply)*

☐ Health ☐ Behavioral
☐ Toxicological ☐ Physiological

2. This document or set of documents relates to the following: *(Complete Parts A-D, as appropriate. You are to provide a consistent, unique identifying name for each tobacco product, additive, ingredient, constituent or component. You may use continuation sheets if necessary.)*

Part A: Uniquely identified current or future tobacco product(s)

Part B: Category of current or future tobacco products *(e.g., cigarettes)*

Part C: Specific ingredient(s), constituent(s), component(s), or additive(s)

Part D: Class of ingredients, constituents, components, or additives *(e.g., tobacco specific nitrosamines)*

SECTION VI - DOCUMENT READABILITY AND ACCESSIBILITY

1. Glossary or explanation of any abbreviations, jargon or code names *(You may describe below or attach a separate glossary for your entire submission.)*

SECTION VII - DOCUMENT METADATA

1. Document date:
2. Document author(s):
3. Document recipient(s):
4. Document custodian:

5. Document title or identification number	6. Beginning and ending Bates numbers

7. Bates number ranges for other documents physically or digitally attached to the document *(e.g., an attachment to an email)*

8 Document type *(See instructions)*

9. Presence of document in the University of California San Francisco Truth Tobacco Documents database

(Check one) ☐ Present ☐ Not present ☐ Uknown

REFERENCES

Reference for the Tobacco Control Act:
http://www.accessdata.fda.gov/scripts/tobaccocontrol/index.cfm

Reference for *Guidance on Health Document Submission*:
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm

Reference for SRS UNII:
http://www.fda.gov/ForIndustry/DataStandards/ SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII

National Library of Medicine's Medical Subject Headings: http://www.nlm.nih.gov/mesh/

INSTRUCTIONS

General

Provide pages 1 through 3 of this form (Sections I-IV) as a cover sheet for your complete submission. Provide page 4 of this form (Sections V-VII) as a cover sheet for each document.

In order for FDA to access, review, and archive your documents, they cannot be password protected.

If you are submitting paper documents, FDA recommends that all pages are Bates numbered. All regulatory submissions should be hole-punched and bound with metal fasteners. Assure that text is not obscured by hole punching. Ring binders (notebooks) are not recommended as they have been found to open during constant moving. Shipping unbound documents may result in the loss of portions of the submission.

Section I – Submitter Identification

Identify whether the submitter is the manufacturer or the importer.

You are to provide the submitting party's name and address. If you are submitting as an importer, you must complete a separate submission for each manufacturer whose products you import.

If you are submitting on behalf of the manufacturer or importer as an agent, report information for the manufacturer or importer, not your own information.

Section II – Manufacturer Identification

If you are submitting as an importer, you are to identify the manufacturer whose documents you are submitting by completing this section for each submission.

Section III – Submission Format and Contents

Please indicate whether your submission contains electronic or paper documents.

Electronic Documents

Item 1: Indicate the total number of documents you are including in your submission.

Item 2: Specify the type of media you are submitting (e.g., CD, DVD, hard drive).

Item 3: Specify how many pieces of media you are submitting (e.g., 3 CDs).

Item 4: Indicate the total size of your submission.

Item 5: Specify the type of files contained in your submission (e.g., PDF, TIFF).

Item 6: Indicate the type of software used to create your documents (e.g., Adobe Acrobat XI or Summation).

Item 7: Provide any technical details needed for FDA to load or access your documents.

Paper Documents

Item 1: Indicate the total number of documents you are including in your submission.

Item 2: Specify how many volumes of documents you are including in your submission.

Item 3: Specify how many boxes of documents you are including in your submission.

None

If you do not have any health documents to report this period, you are to so inform FDA. If you do not anticipate having any health documents to submit in the future, you may also state this.

Section IV – Confirmation Statement

Please sign and date your submission. If you are submitting as an authorized agent, enter all required identifying information in this section. Check your submission to ensure that you have included a copy of page 4 with each submitted document.

Section V – Document Categorization

Item 1: Select all that apply. You are to select at least one category.

Item 2: Complete Parts A through D, as applicable to the information addressed by your document. You are to use consistent terminology to identify tobacco products and constituents/ingredients/components across all documents submitted under section 904 of the act.

Section VI – Document Readability and Accessibility

Item 1: FDA requests that you provide a glossary or explanation for any abbreviations, jargon or code names used in your documents. You may provide any necessary explanations for this document in the box below, or attach a separate glossary for your entire submission.

Section VII – Document Metadata

Item 1: Specify the document date.

Item 2: List all authors of the document

Item 3: List all recipients of the document

Item 4: Identify the custodian of the document. The custodian is the individual with physical control of the document.

Item 5: Identify the document title or identification number.

Item 6: FDA requests that you uniquely number each page of every document submitted, a practice referred to as Bates numbering. Please provide the beginning and ending Bates numbers for each document.

Item 7: If you are submitting a document with physical or digital attachments (e.g., an email or other memo with attached documents), provide the Bates number range(s) for the attached document(s). Each attached document is to be submitted with a separate completed cover sheet (Sections V-VII of this form).

Item 8: Identify the type of document you are submitting as one of the following: Email, Briefing slides, Publication, Memo, Report, Meeting minutes, Proposal, Study design, Teleconference, Lab Notes, Other.

Item 9: Identify the presence of the document in the University of California San Francisco Truth Tobacco Documents Database as one of the following: present, not present, or unknown.