Listing of Ingredients in Tobacco Products

(Revised)*

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 Docket No. [FDA-2009-D-0524].

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/GuidanceComplianceRegulatoryInformation/default.htm. You may send an e-mail request to 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.

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* This is a revision to the first edition of this guidance, which issued in November 2009. Revisions are noted by date at the end of the guidance.

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Guidance for Industry[1]

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 document is intended to assist persons making tobacco product ingredient submissions to FDA. 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, May 10, 2016) (the deeming rule).

The guidance document explains, among other things:

- The statutory requirement to submit a list of all ingredients in tobacco products;
- Definitions;
- Who submits ingredient information;
- What information is included in the submissions;
- How to submit the information;

[1] This guidance was prepared by the Office of Regulations and the Office of Science in the Center for Tobacco Products at FDA.

- 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

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides FDA with the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors (Pub. L. 111–31, 123 Stat. 1776). Among its many provisions, the Tobacco Control Act added section 904 to the FD&C Act (21 U.S.C. 387d), establishing requirements for tobacco product ingredient submissions.

Cigarettes, cigarette tobacco, RYO, and smokeless tobacco were immediately covered by FDA's tobacco product authorities in chapter IX of the FD&C 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 as well. 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).[2] After review and consideration of comments on the proposed rule, the final rule published on May 10, 2016, with the effective date of August 8, 2016. As a result, all products that meet the statutory definition of a tobacco product are subject to the tobacco product authorities in chapter IX of the FD&C Act, including section 904, except those accessories not made subject to FDA's tobacco product authorities by the deeming rule.[3]

Section 904(a)(1) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds,

[2] Accessories of tobacco products subject to the deeming rule are explicitly excluded from the rule's deeming provision.

[3] Examples of currently marketed products that are subject to the deeming rule include: cigars, pipe tobacco, nicotine gel, certain dissolvable nicotine products, and electronic nicotine delivery systems ("ENDS"), including electronic cigarettes (also known as e-cigarettes or e-cigs), e-hookah, e-cigars, vape pens, personal vaporizers (also known as advanced personal vaporizers or APVs), electronic pipes, and nicotine-containing liquids, including the e-liquids used with ENDS products, among other products.

and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand. For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products on the market as of June 22, 2009, the list of ingredients had to be submitted by December 22, 2009.[4] For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. Section 904(c) of the FD&C Act also requires submission of information whenever any additive, or the quantity of any additive, is changed.

As described in the preamble to the deeming rule, for products other than cigarettes, cigarette tobacco, RYO, and smokeless tobacco that are on the market as of August 8, 2016, FDA does not intend to enforce the section 904(a)(1) ingredient listing submission requirement until 6 months after the effective date of the rule for most businesses and 12 months from the effective date for small-scale tobacco product manufacturers (small-scale manufacturers).[5] Under this policy, FDA does not intend to enforce the ingredient list submission requirement until February 8, 2017, for businesses that are not small-scale manufacturers, and August 8, 2017, for small-scale manufacturers (81 FR 28974 at 29008). As for those products that are first marketed after August 8, 2016, manufacturers must provide the ingredient listing information required under section 901(a)(1) at least 90 days before the product is delivered for introduction into interstate commerce, as was required for cigarettes, cigarette tobacco, RYO, and smokeless tobacco first marketed after June 22, 2009 (section 904(c)(1)).

The failure to provide 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)). In addition, 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 was any failure or refusal to comply with any requirement prescribed under section 904. Violations relating to section 904 are subject to regulatory and enforcement action by FDA, including, but not limited to, seizure and injunction.

[4] FDA did not enforce the December 22, 2009 deadline in situations where the ingredient list was submitted on or before June 22, 2010, pursuant to a compliance policy described in the November 2009 edition of this guidance.

[5] For purposes of this compliance policy, FDA considers a *small-scale tobacco product manufacturer* to be 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. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues. In this guidance, we use the shortened term *small-scale manufacturer* to refer to *small-scale tobacco product manufacturer*.

III. DISCUSSION

A. What Definitions Apply to This Guidance?

FDA intends to use the following definitions to implement the ingredient listing requirements of section 904 of the FD&C Act:

- ***Accessory***: The term *accessory* means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following:
  - (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or
  - (2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but
    - (i) Solely controls moisture and/or temperature of a stored tobacco product; or
    - (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

- ***Additive***: The term *additive* means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. (section 900(1) of the FD&C Act (21 U.S.C. 387(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 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.

- ***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.

- ***Pouch***: The term *pouch* means a permeable material, intended to be filled with pre-portioned tobacco product and placed in the oral cavity with the tobacco product.

- ***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****:* 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)." (section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)).

  (2) The term "tobacco product" does not include 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 (21 U.S.C. 353(g))].

  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.[6]

- ***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 Ingredient Information?

The requirements under section 904(a)(1) apply to each "tobacco product manufacturer or importer." We interpret this to mean that domestic manufacturers are to submit the required

[6] However, and as explained above, 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 chapter IX of the FD&C Act (including section 904(a)(1)).

ingredient information for products they manufacture and that either the foreign manufacturer or the importer of the tobacco product is to submit the required ingredient information for imported tobacco products.

For tobacco products that are imported, the foreign manufacturer and the importer or importers of an imported product will need to work together to ensure that the ingredient information is submitted to FDA as required by section 904. If there is a failure or refusal to comply with the ingredient listing requirements, then — among other things — the product is deemed misbranded under section 903(a)(10)(A) and therefore subject to refusal of admission into the United States.

Submissions under section 904(c) are required to be made by the tobacco product manufacturer. An importer of a finished tobacco product for sale or distribution in the United States falls within the definition of a *manufacturer*. An importer that is not a manufacturer required to submit information or reports under section 904(c) may, however, submit the information as an agent on behalf of the manufacturer.

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, smokeless tobacco, as well as other tobacco products now regulated as a result of the deeming rule, FDA intends to enforce the ingredients submission 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 requirements for submission of ingredient information under section 904(a)(1) with respect to such 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.

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 submission of the listing of ingredients requirements with respect to owners and operators engaged in the manufacture of tobacco, papers, filters, and pouches whether or not such products are 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 products components and parts through other means, such as premarket applications for finished tobacco products and through the use of master files, as explained in the guidance *Tobacco Product Master Files*.[7] 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 health, the Agency may reconsider this compliance policy. We intend to communicate any compliance policy changes by guidance or rulemaking.

D. What Information Is Submitted With the List of Ingredients?

1. Manufacturer/Importer Identification

You should include the name and address of each tobacco product manufacturer (and importer, where applicable) with your submission. You should also include the name and address of any agent submitting ingredient information on behalf of a manufacturer or importer. FDA requests that you also provide the following information to assist us in communicating with you:

- Your corporate email address;
- Your Data Universal Numbering System (D-U-N-S) number or other unique identifier;[8]
- The facility establishment identifier (FEI) number assigned to your establishment by FDA.[9]

2. Product Identification

Under section 904(a)(1) of the FD&C Act, tobacco product manufacturers or importers are required to submit ingredient lists for "each tobacco product by brand and by quantity in each brand and subbrand." We interpret this to require that tobacco product manufacturers or

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[7] This guidance is available on the CTP guidance Web page at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.

[8] D-U-N-S numbers are proprietary to, and controlled by, Dun & Bradstreet. 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, 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. The business entity identifier recognized by the FDA Data Standards Council is the D-U-N-S number, and providing the site-specific D-U-N-S number for an entity will help prevent inaccuracies in FDA's database.

[9] You should use the same FEI number for this submission that you have used for prior ingredient listing submissions or establishment registration.

importers submit ingredient lists individually for tobacco products that differ in any way, other than packaging differences that do not affect characteristics of the product. For example, if a soft pack and a hard pack of cigarettes have different moisture contents, shelf lives, or ingredient compositions (including ingredients introduced in packaging but known or reasonably expected to become incorporated into the consumed product), they are considered to be distinct products requiring separate ingredient lists for purposes of section 904(a)(1). Conversely, if the cigarettes sold in different packaging configurations are identical, a single ingredient list should be submitted for the product, noting the different packaging configurations.

For each ingredient list, clearly and uniquely identify the product by brand and subbrand, including the type or category of tobacco product (e.g., cigarette, smokeless tobacco product, cigar, ENDS, waterpipe tobacco product) and subcategory.[10] You are to include additional identifiers (e.g., stock-keeping units (SKUs), Universal Product Codes (UPCs), and catalog numbers) as needed to uniquely identify the brand and subbrand of the product.

3. Ingredient Identification

Section 904(a)(1) of the FD&C Act sets forth the requirements for submission of ingredient information. The statute requires a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product as of the date of submission. Ingredients must be specified for each brand and subbrand of tobacco product.

FDA considers all ingredients added directly by, or at the direction of, the tobacco product manufacturer to be added by the manufacturer. When the manufacturer knows or intends that an ingredient is formed through a chemical reaction during tobacco product manufacturing, FDA considers the resultant material to be an ingredient that is added by the manufacturer. Similarly, when the manufacturer knows or intends that an ingredient added to any type of packaging will become incorporated into the consumed product, that ingredient is considered to be added by the manufacturer to the tobacco product.

Each listed ingredient is to be uniquely identified so as to distinguish it from similar or related materials. The information necessary to uniquely identify an ingredient varies based upon the type of ingredient as discussed below. For single chemical substances and complex purchased ingredients, FDA also requests that you provide additional information, including the expected functions of each ingredient. By asking for the functions of the ingredient, the agency requests that you identify all expected functions of the ingredient in the final product. As examples, an ingredient may function as a humectant, flavor, or chemo-sensory agent that affects perception of mainstream or side-stream smoke.

[10] Lists of categories and subcategories are provided on Form 3742 and the eSubmitter submission template. See section III.E "How Do You Submit Ingredient Information."

a. Single Chemical Substance

Ingredients that are single chemical substances (e.g., sodium chloride, ammonium hydroxide), which may be purchased or prepared in-house and purified, are to be uniquely identified by using a unique scientific name or code, such as the FDA UNII (Unique Ingredient Identifiers) code, Chemical Abstracts Service (CAS) number, or International Union of Pure and Applied Chemistry (IUPAC) name. If you prepare a non-reactive mixture (e.g., a buffer) of single purified chemical substances, you are to report each of the single chemical substances in the mixture individually.

To further identify each single chemical substance, FDA requests that you provide the quality (e.g., percent purity, a published standard) of the ingredient, any internal identification number (e.g., SKU, product code) used within your company to reference the ingredient, and the expected function(s) of each ingredient.

We recommend using the FDA UNII code to uniquely identify single chemical substances. FDA's Substance Registration System (SRS) supports health information technology initiatives by generating unique ingredient identifiers for ingredients in FDA-regulated products. The FDA UNII is a nonproprietary, free, unique, nonsemantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. For the purposes of the SRS system, substances that form noncovalent interactions with other added substances are not new substances or mixtures of substances; they are defined as separate substances.

Many ingredients already have FDA UNIIs. For ingredients that are not already in SRS, you can request an FDA UNII by submitting necessary information to tobacco-UNII@fda.hhs.gov. More information regarding SRS is posted at http://www.fda.gov/forindustry/datastandards/substanceregistrationsystem-uniqueingredientidentifierunii/default.htm.

b. Leaf Tobacco

Leaf tobacco (i.e., whole leaf or parts) that has been prepared solely by mechanical processing that involves no chemical, additive, or substance other than potable water is to be uniquely identified by providing the following information:

- the type (e.g., burley, bright, oriental)
- the variety
- the cure method (e.g., flue, fire, sun, steam, air) and heat source (e.g., propane, wood)
- a description of any recombinant DNA technology used to engineer the tobacco.

We consider the cure method and curing heat source necessary to uniquely identify tobacco-derived materials because these factors change the tobacco composition by altering endogenous constituents (e.g., sugars) and, in some circumstances, adding exogenous constituents (e.g., from partially pyrolyzed organic matter), thus resulting in a distinctly different tobacco material. Similarly, we believe that tobacco derived from recombinant DNA technology (e.g., tobacco

mosaic virus RNA vector) is intrinsically distinct from unmodified tobacco and that a description of the modification and technology used is, therefore, necessary as part of the identification.

FDA requests that you further identify the leaf tobacco with any internal identification number (e.g., SKU, product code) used within your company to reference the ingredient.

Tobacco that has been processed with any chemical, additive, or substance other than potable water is to be reported as described in section III.D.3.c below. Each type of leaf tobacco used in a tobacco product is to be reported as a separate ingredient. For example, if you purchase a tobacco leaf blend or reconstituted tobacco for use in manufacturing a tobacco product, you are to report the blend or reconstituted tobacco as described in section III.D.3.c below. The manufacturer responsible for assembling the blend or reconstituting the tobacco is to submit ingredient lists for its tobacco products and, in doing so, reporting each type of leaf tobacco used in the blend as described in this section.

c. Complex Purchased Ingredients

Ingredients that are not single chemical substances or single types of leaf tobacco are considered complex ingredients to be identified as described in this section. Such ingredients include, for example, chocolate, flavor extracts, tobacco leaf blends, and reconstituted tobacco. Such ingredients also include naturally derived, mechanically processed ingredients (e.g., ground spice, fruit juice). Identifiers such as CAS numbers and FDA UNIIs are not sufficient to uniquely identify most complex ingredients, as they are comprised of multiple substances. This guidance divides the category of complex purchased ingredients into two groups — those that are made to your specifications and those that are not.

Complex ingredients that are made to your specifications (i.e., not available as a commodity but custom prepared for you), including such ingredients purchased via contract or other commercial arrangements, are to be uniquely identified. For this, we believe it is necessary to provide:

- the complete name of the manufacturer;
- the uniquely identifying item name and/or number (e.g., catalog number or UPC) used by the manufacturer; and
- information to uniquely identify each specified ingredient (i.e., each ingredient you specified that the manufacturer use in manufacturing). Each specified ingredient is to be uniquely identified in the same manner as used for other ingredients.

To further identify complex ingredients that are made to your specifications, FDA requests that you provide the quality (e.g., percent purity, a published standard) of each specified ingredient, the expected function(s) of each specified ingredient, any internal identification number (e.g., SKU, product code) used within your company to reference the complex ingredient, and any additional specifications for the complex ingredient (e.g., release specifications, acceptance criteria, a sample certificate of analysis).

Complex ingredients that are not made to your specifications are also to be uniquely identified. For this, we believe it is necessary to provide:

- the complete name of the manufacturer; and
- the uniquely identifying item name and/or number (e.g., catalog number or UPC) used by the manufacturer. The uniquely identifying name and/or number for a complex ingredient that is available for purchase by the general public is one assigned by the seller, not one internally assigned by your company.

To further identify complex ingredients not made to your specifications, FDA requests that you provide the quality (e.g., percent purity, a published standard) of the complex ingredient, the expected function(s) of the complex ingredient, and any internal identification number (e.g., SKU, product code) used within your company to reference the complex ingredient. Many of the complex ingredients purchased for use in tobacco products are proprietary blends. You do not need to list any substance contained in a complex purchased ingredient where the ingredient is not made to your specifications. The manufacturer of the complex ingredient, however, may be subject to ingredient listing reporting requirements, as described in section III.B.

If you use a complex ingredient provided by multiple suppliers interchangeably in a single tobacco product, you are to report all alternative sources in your ingredient listing, including sufficient information to link the ingredients you consider interchangeable.

d. Reaction Products

When the manufacturer knows or intends that an ingredient will be formed through a chemical reaction during tobacco product manufacturing, FDA considers the resultant material to be an ingredient that is added by the tobacco product manufacturer. As such, these reaction products are to be included in the ingredient listing. Reaction products may result from, among other things, reactions that occur during a mixing or processing operation (e.g., casing and drying), during an in-process holding step, or during a storage period. The reaction product(s) may result from a reaction between ingredients in the same part of a product (e.g., reconstituted tobacco) or between ingredients added to different parts of the product (e.g., tobacco, paper) or added at different manufacturing steps. Also, the reaction may occur between added ingredients or between ingredients and chemicals intrinsic to the cured tobacco leaf.

Each reaction product ingredient is to be uniquely identified in the same manner used for single chemical substances. To further identify these reaction products, FDA requests that you state which added ingredients combined to form the reaction product and the expected function(s) of the reaction product ingredient.

4. Part to Which the Ingredient Is Added

Section 904(a)(1) of the FD&C Act requires a listing of ingredients that are added by the manufacturer to the tobacco, paper, filter, or other part. FDA interprets this to mean that

manufacturers/importers are to specify whether an ingredient is added to the tobacco, to the paper, to the filter, or to another part of the tobacco product.

5. Ingredient Quantity

Under section 904(a)(1) of the FD&C Act, you must report ingredients by quantity by brand and subbrand. Under section 904(d) and (e), FDA is required to publish a list of harmful constituents by quantity in each tobacco product by brand and subbrand. FDA intends to rely on consistent reporting from manufacturers and importers to publish this list in a manner that is useful to the public and not misleading to laypersons. Therefore, ingredient information is to be provided using units that are consistent across all products. In addition, the reporting of ingredient quantities is intended to provide the Agency with information to assist with implementation of other provisions of the FD&C Act (e.g., developing tobacco product standards and making substantial equivalence determinations). As such, the quantities need to be reported in consistent units across all products using an absolute measurement that is conserved during chemical reactions. FDA, therefore, interprets the term quantity to mean a unit of mass (i.e., grams with a standard International System of Units prefix as appropriate) of an ingredient contained in a tobacco product.

For all tobacco products, quantity is to be expressed in terms of the unit of use for a portioned tobacco product (e.g., one cigarette, one cigar) or per gram of product for a nonportioned tobacco product (e.g., container of loose snuff, reconstituted tobacco, hookah tobacco, hookah charcoal, e-liquids).

Solvents or other ingredients that are added and subsequently removed during manufacturing are still considered to be added ingredients under section 904(a)(1) of the FD&C Act. As such, the removed ingredient is to be identified and the residual quantity stated (with an appropriate detection limit if the quantity is approximated near zero).

You are to report all ingredient quantities contained in the tobacco product. You may calculate the quantity based on the added amounts and adjusting for known or intended losses and chemical reactions during manufacturing. Alternatively, the quantity contained in the tobacco product may be derived from laboratory testing.

You are to report ingredients as a single quantity whenever possible. FDA understands, however, that in some circumstances manufacturers add ingredients based upon manufacturing specifications to affect product characteristics (e.g., to adjust for total sugars or to achieve a particular pH) resulting in the manufacturer adding varying amounts from batch to batch. If you add a particular ingredient in this way, you are to give the quantity by providing both the range of permitted quantities (e.g., add between 1.01 and 1.05 mg to the product) and the targeted outcome (e.g., in order to achieve a pH of 7.1). Both the range of permitted quantities and the targeted outcome are to be derived from the manufacturing specifications for the addition of the ingredient. Where no quantity range is contained in, or can be derived from, manufacturing specifications, it is to be derived from the actual range of historical quantities added to the product.

Section 904(c) requires the submission of information whenever the quantity of an additive is changed. Almost all ingredients are additives, as that term is defined in section III.A. The quantity before and after the change are reported. A change to the manufacturing specifications for the addition of an additive or to the quantity of an additive as reported constitutes a change triggering the reporting requirements in section 904(c).

E. How Do You Submit Ingredient Information?

FDA strongly encourages you to make your submission electronically. An electronic submission reduces paper and facilitates efficient (and timely) submissions to the Agency and efficient processing, review, and archiving of the submission once at FDA.

The FDA eSubmitter tool (eSubmitter) is software provided by FDA for the preparation of electronic submissions. This tool provides a template form to report ingredient data and 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.[11] Select the "CTP Tobacco Product Ingredient Listing Submissions" within the eSubmitter program and enter information about your ingredient listing directly into the software. You will not need to prepare additional documents with this information, and you will not need to complete form FDA 3742.

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 (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/Manufacturing/ucm515047.htm) 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 FDA eSubmitter tool can also streamline the process for submitting updated ingredient listing information required by section 904(c).

Although FDA strongly encourages electronic submission, FDA Form 3742, an alternative tool for paper submissions, is available at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/Tobacco/default.htm Paper submissions may be mailed to:

[11] The eSubmitter tool requires a computer that runs MS Windows.

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

Submissions delivered to DCC 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 Ingredient Information?

Manufacturers and importers of cigarettes, cigarette tobacco, RYO, and smokeless tobacco products that were introduced into interstate commerce before June 22, 2009, were required by section 904(a)(1) of the FD&C Act to submit a list of all ingredients by December 22, 2009.[12] For cigarettes, cigarette tobacco, RYO, and smokeless tobacco products that were first marketed after June 22, 2009, ingredient lists are due at least 90 days before the product is delivered for introduction into interstate commerce (section 904(c)(1)). Section 904(c) also requires submission of information whenever any additive, or the quantity of any additive, is changed. Submissions under section 904(a)(1) consist of a listing of all ingredients added as of the date of submission.

The preamble to the deeming rule (81 FR 28974) stated that FDA does not intend to enforce the requirement to submit ingredient listing for manufacturers and importers of newly deemed tobacco products that were introduced into interstate commerce on or before August 8, 2016 provided submissions are received by February 8, 2017, or August 8, 2017 for small-scale manufacturers. However, FDA recognizes that some manufacturers of newly deemed products are not familiar with the forms for listing ingredients and, therefore, may need additional time to complete them accurately. In addition, we are aware that some manufacturers may need to prepare and submit multiple lists. Therefore, at this time, for manufacturers and importers of newly deemed tobacco products (21 CFR part 1100) that were introduced into interstate commerce on or before August 8, 2016, FDA does not intend to enforce the requirement to submit ingredient information according to section 904(a)(1) until August 8, 2017. For small-scale manufacturers of newly deemed tobacco products (21 CFR part 1100) that were introduced into interstate commerce on or before August 8, 2016, FDA does not intend to enforce the requirement to submit ingredient information according to section 904(a)(1) until February 8, 2018. FDA believes that this additional time will allow manufacturers to prepare higher quality

[12] FDA did not enforce the December 22, 2009 deadline in situations where the ingredient list was submitted on or before June 22, 2010, pursuant to a compliancy policy described in the November 2009 edition of this guidance..

submissions. However, because we may receive a large number of submissions from certain firms, we encourage manufacturers to begin the process as early as possible.

Tobacco products introduced into interstate commerce after August 8, 2016, are required to submit the ingredient information required by section 904(a)(1) at least 90 days before the product is introduced to interstate commerce.

You are not required to submit ingredient lists for tobacco products that you discontinued and stopped manufacturing before the date of your submission under section 904(a)(1). Such discontinued products, if manufactured and reintroduced into the market, will, however, require the ingredient submission under section 904(c)(1). Under that section, you are to submit the product ingredient list at least 90 days prior to delivery for introduction into interstate commerce. When a tobacco product manufacturer makes a change to the additives in its cigarettes, cigarette tobacco, RYO, and smokeless tobacco products after June 22, 2009, sections 904(c)(2) and (c)(3) require the manufacturer to report these changes. After August 8, 2016, FDA intends to enforce sections 904(c)(2) and (c)(3) for changes in additives to all tobacco products except for accessories of newly deemed products.

Specifically, under sections 904(c)(2) and (c)(3), if a manufacturer:

- eliminates or decreases an existing additive, the change must be reported to FDA within 60 days of making the change;
- adds or increases an additive that FDA has designated in regulations as a tobacco additive that is not a human or animal carcinogen and is not otherwise harmful to health under the intended conditions of use, the change must be reported to FDA within 60 days of making the change; or
- adds a new tobacco additive or increases the quantity of an existing tobacco additive (not designated as described above), the change must be reported to FDA at least 90 days prior to making the change.

FDA COMPLIANCE POLICY FOR INGREDIENT LIST SUBMISSIONS

	FDA Intends to Enforce Ingredient Submissions for These Products	**Date of Introduction or Reintroduction**	**Submission Type**	**Date to Submit**
Cigarettes, cigarette tobacco, RYO, and smokeless tobacco	• Finished tobacco products	Products on the market continuously since June 22, 2009, or earlier.	section 904(a)(1)	FDA did not begin enforcing until June 22, 2010
		Previously marketed products that were discontinued or withdrawn before June 22, 2009, and reintroduced after June 22, 2009.	section 904(c)(1)	90 days prior to delivery for reintroduction into interstate commerce

	FDA Intends to Enforce Ingredient Submissions for These Products	Date of Introduction or Reintroduction	Submission Type	Date to Submit
		Products marketed for the first time after June 22, 2009	section 904(c)(1)	90 days prior to delivery for introduction into interstate commerce
Tobacco products *other than* cigarettes, cigarette tobacco, RYO, and smokeless tobacco	• Finished tobacco products	Products on the market as of August 8, 2016	section 904(a)(1)	•FDA does not intend to enforce until August 8, 2017, for other manufacturers •FDA does not intend to enforce until February 8, 2018, for small scale manufacturers
		Previously marketed products that were discontinued or withdrawn before August 8, 2016, and reintroduced after August 8, 2016	section 904(c)(1)	90 days prior to delivery for reintroduction into interstate commerce
		Products marketed for the first time after August 8, 2016	section 904(c)(1)	90 days prior to delivery for introduction into interstate commerce

G. Will FDA Maintain the Confidentiality of the Ingredient Information You Submit?

Information submitted under section 904 of the FD&C Act may include, but is not limited to, a company's nonpublic trade secret or confidential commercial information.

Several laws govern the confidentiality of ingredient information submitted under section 904 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C 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 FD&C 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 FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C 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 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 contained in 21 CFR part 20.

V. 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 3.75 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 0910-0650 (expires 6/30/2019).

DOCUMENT HISTORY

November 2009 — First edition of guidance issued.

January 2017 — *Listing of Ingredients in Tobacco Products* 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 — Definitions of *accessory*, *component* or *part*, *small-scale tobacco product manufacturer*, and *finished tobacco product* added; definition of *importer* and *pouch* updated.

- Section III.B — Section B "Who Submits Ingredient Listing?" compliance policy for cigarettes, cigarette tobacco, RYO, and smokeless tobacco deleted.

- Section III.C — "FDA's Compliance Policy for Regulated Tobacco Products" added.

- Former section III.C — "What Information Is Submitted With the List of Ingredients?" becomes section III.D.

- Section III.D — Information on Data Universal Numbering System is updated.

- Former section III.D — "How Do You Submit Ingredient Information?" becomes section III.E.

- Section III.E — Information on how to submit ingredient listing information updated.

- Former section III.E — "When Do You Submit Ingredient Listing Information?" becomes section III.F.

- Section III.F — Updated to include submission dates for newly deemed products and provide compliance policy explaining that for tobacco products that were manufactured prior to August 8, 2016, FDA does not intend to enforce the requirement to provide ingredient listing until August 8, 2017, or February 8, 2018, for small-scale manufacturers.

- Former section III.F — "Will the FDA Maintain the Confidentiality of the Ingredient Information You Submit?" becomes section III.G.

- PRA section updated