Guidance for Industry

Listing of Ingredients in Tobacco Products

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Additional copies are available from:
Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(Tel) 301-796-4800
http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/default.htm

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

November 2009

OMB control number: 0910-0650
Expiration Date: 10/31/2015
See additional PRA statement in Section IV of the guidance.

Table of Contents

I. Introduction

II. Background

III. Discussion

IV. Paperwork Reduction Act of 1995

Contains Nonbinding Recommendations

Guidance for Industry[1]

Listing of Ingredients in Tobacco Products

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.

I. Introduction

This guidance document is intended to assist persons making tobacco product ingredient submissions to FDA. 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;
- When to submit the information; and
- FDA's compliance policies.

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

II. Background

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

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

Section 904(a)(1) of the act requires each tobacco product manufacturer or importer, or agent thereof, to submit 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 by brand and by quantity in each brand and subbrand. For tobacco products on the market as of June 22, 2009, the list of ingredients must be submitted by December 22, 2009. For 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 act also requires submission of information whenever any additive, or the quantity of any additive, is changed.

The failure to provide any information required by sections 904 is a prohibited act under section 301(q)(1)(B) of the act (21 U.S.C. 331(q)(1)(B)). In addition, under section 903(a)(10)(A) of the act, 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.

III. Discussion

FDA has developed an electronic submission tool, eSubmitter, to streamline submission and receipt of the ingredient information required by sections 904(a)(1) and 904(c) of the act. FDA has developed a paper form (FDA Form 3742) as an alternative submission tool, although FDA strongly encourages electronic submission. Both the eSubmitter application and the paper form can be accessed at http://www.fda.gov/tobaccoinfoindustry.

A. What definitions apply?

FDA intends to use the following definitions in implementing the ingredient listing requirements of section 904 of the act:

1. *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 act (21 U.S.C. 387(1)).
2. *Importer:* The term "importer" means the importer of record of a tobacco product into the United States.

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

B. Who submits 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 ingredient information for products they manufacture and, for tobacco products that are imported, the required ingredient information is to be submitted by either the foreign manufacturer or the importer of the product. This includes any regulated tobacco product, whether for sale to consumers or for further manufacturing.

At this time, FDA intends to enforce the ingredient listing requirements with respect to:

- manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use; and
- manufacturers and importers of tobacco (including tobacco leaf blends, reconstituted tobacco, and bulk smokeless tobacco), papers, filters (including filter rods), or pouches, whether such products are for further manufacturing of, or for consumer use as, regulated tobacco products. Products for consumer use include tobacco, papers, and filters sold separately, in kits (such as for roll-your-own tobacco), or as part of accessories.

At this time, FDA does not intend to enforce the ingredient listing requirements in other circumstances.

FDA intends to focus enforcement of the ingredient listing requirements on the manufacturers and importers of cigarettes, smokeless tobacco, and roll-your-own tobacco for consumer use as well as manufacturers and importers of tobacco, filters, papers, or pouches, whether such products are for further manufacturing or for consumer use, because these products comprise the

principal components of most tobacco products sold to consumers. If the agency finds that additional information is needed to protect the public health, the agency may reconsider this compliance policy. We intend to communicate any such compliance policy changes by guidance and/or rulemaking.

For tobacco products that are imported, the required ingredient information is to be submitted by either the foreign manufacturer or the importer. The foreign manufacturer and the importer or importers of an imported product will need to work together to ensure that the 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 information is submitted with the list of ingredients?

1. Manufacturer/Importer Identification

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

- An email address, to facilitate correspondence between you and FDA.
- A Data Universal Numbering System (D-U-N-S®) Number or other unique identifier (codes) for the headquarters of a manufacturer, importer, or agent. The business entity identifier recognized by the FDA Data 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. Dun & Bradstreet assigns and maintains a database of the D-U-N-S® Numbers, which serve as unique identifiers (codes) of business entities. Upon application, each business entity is assigned a distinct site-specific 9-digit D-U-N-S® Number. 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).

2. Product Identification

Under section 904(a)(1) of the act, tobacco product manufacturers/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/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.

Each product for which an ingredient list is submitted is to be clearly and uniquely identified by its brand and subbrand, which includes identifying the type or category of tobacco product (e.g., cigarette, snus). You are to include additional identifiers (e.g., Stock-keeping unit (SKU), catalog numbers or Universal Product Codes (UPCs)) as needed to uniquely identify the brand and subbrand of the product. If you manufacture or import products for further manufacturing and your products are not identified by a brand or subbrand name, you are to uniquely identify your products and include the type or category of product (e.g., paper, filter). You are to do so by using a commercial name and/or any identification numbers necessary to uniquely identify your product.

When you submit an ingredient list by quantity for each of your tobacco products that differs from others in any way (other than packaging differences that do not affect the characteristics of the product), we will consider you to have satisfied the section 904(a)(1) requirements that you list ingredients "by brand and by quantity in each brand and subbrand."

3. Ingredient Identification

Section 904(a)(1) of the 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.

(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 non-proprietary, free, unique, non semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information. For the purposes of the SRS system, substances that form non-covalent 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.C.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.C.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 report 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 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 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 brand and subbrand. FDA cannot publish such a list useful for comparing all brands unless you provide ingredient information using units that are consistent across all products. In addition, the reporting of ingredient quantity is intended to provide the agency with information to assist with implementation of other provisions of the act (e.g., developing tobacco product standards and making substantial equivalence determinations). As such, the quantity needs 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) or per gram of product for a non-portioned tobacco product (e.g., container of loose snuff, reconstituted tobacco).

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 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).

D. How do you submit ingredient information?

The FDA eSubmitter tool is an electronic application designed to streamline the data entry process for ingredient submission. This tool provides an automatic acknowledgement of FDA receipt, and allows users to import large quantities of structured data and attach files (e.g., PDF documents). The FDA eSubmitter tool can also streamline the process for submitting updated ingredient listing information required by section 904(c) of the act.

While electronic submission is not required, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and management. FDA Form 3742, an alternative tool for paper submissions, is available at www.fda.gov/tobaccoinfoindustry.

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

E. When do you submit ingredient information?

For tobacco products that were introduced into interstate commerce before June 22, 2009, section 904(a)(1) of the act requires that a list of all ingredients be submitted by December 22, 2009. Submissions under section 904(a)(1) consist of a listing of all ingredients added as of the date of submission. FDA does not intend to enforce the December 22, 2009, deadline of this subsection provided you submit the ingredient list on or before June 22, 2010.

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, for tobacco products that were not manufactured and distributed before June 22, 2009, you are to submit the product ingredient list at least 90 days prior to delivery for introduction into interstate commerce.

When a manufacturer makes a change to the additives in its tobacco products after June 22, 2009, sections 904(c)(2) and (3) of the act require the manufacturer to report these changes. Specifically, if after June 22, 2009, 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.
- 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 does not intend to enforce the statutory deadlines for ingredient reporting under section 904(c) for additive changes or the initial introduction of products into interstate commerce **occurring between June 22, 2009 and 90 days after your section 904(a)(1) submission**, provided that:

- You submit these report(s) at the time of your section 904(a)(1) submission, and all such submissions are made on or before June 22, 2010; and
- Your report(s) include the date, or planned date, of making the change to the additive or introducing the product into interstate commerce.

We recognize that the forms developed by FDA are new to industry, and so may require additional time to complete accurately. We also recognize that electronic submission, which is strongly encouraged by FDA to improve data quality and consistency, requires several additional steps, such as obtaining an ESG account and becoming familiar with the eSubmitter electronic tool. FDA therefore believes that this additional time for the first submissions of this ingredient information should result in submissions of higher quality information.

F. Will the FDA maintain the confidentiality of the ingredient information I submit?

Information submitted under section 904 of the act may include, but is not limited to, a company's non-public trade secret or confidential commercial information.

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

Section 906(c) of the act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products chapter of the act

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

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

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 3.0 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 10/31/2015).