Guidance for Industry and FDA Staff

Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

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For questions regarding this guidance, contact the Center for Tobacco Products (CTP) at 1-877-CTP-1373.

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

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See additional PRA statement in Section VII of this guidance.

Preface

Public Comment

This guidance document is being implemented immediately without prior public comment under § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline. 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. FDA will review any comments we receive and revise the guidance document when appropriate.

Additional Copies

Additional copies are available from the Internet at http://www.fda.gov/TobaccoProducts. You may also send an e-mail request to annette.marthaler@fda.hhs.gov to receive an electronic copy of the guidance.

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Section 905(j) Reports: Demonstrating Substantial Equivalence for 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 number listed on the title page of this guidance.

I. Introduction

This guidance provides recommendations and information related to the submission and review of reports under section 905(j) of the Federal Food, Drug, and Cosmetic Act (Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31). Section 905(j) authorizes FDA to establish the form for the submission of information related to substantial equivalence (21 USC 387e(j)). In the future, FDA intends to initiate a rulemaking that would establish requirements and standards for substantial equivalence under sections 905(j) and 910 of the Act (the provisions relating to reports intended to demonstrate substantial equivalence). This guidance is intended to assist persons submitting reports under section 905(j) of the Act. It explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence, and provides recommendations on the form and content of section 905(j) reports. This guidance also provides information on FDA's review of 905(j) reports.

The guidance discusses premarket statutory requirements that include certain submissions to be made to FDA no later than March 22, 2011. This guidance document is being

implemented immediately without prior public comment under § 10.115(g)(2) because the agency has determined that prior public participation is not feasible or appropriate, as interested parties need clarity as to FDA's expectations regarding 905(j) reports and sufficient time to prepare submissions in advance of the statutory deadline. You may submit written comments to FDA on this guidance at any time for Agency consideration; in addition, we request that you submit any comments regarding any significant oversight in this guidance within 30 days of the issuance of this guidance (refer to the title page for the issue date).

For 905(j) reports for tobacco products first marketed between February 15, 2007 and March 22, 2011 (many of which are from small manufacturers) that are submitted prior to March 23, 2011, FDA intends to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions, provided these manufacturers submit a 905(j) report by the statutory deadline. FDA intends to determine what constitutes a reasonable period of time on a case by case basis.

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

In general, a tobacco product manufacturer must obtain an order under section 910(c)(1)(A)(i) (order after review of a premarket application) before the manufacturer may introduce a new tobacco product (see definition in Section III below) into interstate commerce (section 910 of the Act; 21 USC 387j). An order under section 910(c)(1)(A)(i) is not required, however, if a manufacturer submits a report under section 905(j) for the new tobacco product and FDA issues an order finding that the tobacco product is (1) substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, and (2) in compliance with the requirements of the Act.[1]

The following sections provide information about FDA's interpretation of the statutory provisions relating to substantial equivalence, as well as recommendations on how to submit a 905(j) report and the information that should be submitted. The guidance also provides information related to FDA's review of the 905(j) report and supporting information.

[1] An order under 910(c)(1)(A)(i) is also not required for a new tobacco product if the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3).

III. Definitions

This section provides the definitions of certain terms used in this guidance.

A. Substantially equivalent or substantial equivalence

Substantially equivalent or substantial equivalence is defined at section 910(a)(3)(A) of the Act. The Act provides:

> In this section and section 905(j), the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—
>
> (i) has the same characteristics as the predicate tobacco product; or
>
> (ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under [section 910 of the Act] because the product does not raise different questions of public health.

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the FDA or that has been determined by a judicial order to be misbranded or adulterated (section 910(a)(3)(C) of the Act).

B. Characteristics

Characteristics, as used in the definition of substantial equivalence, is defined at section 910(a)(3)(B) as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

C. Tobacco Product

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)(1) of the Act. Thus, the term is not limited to products containing tobacco, but also includes components, parts, or 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. This term does not include an article that is a drug, a device, or a combination product as defined in the FD&C Act (section 201(rr)(2) of the FD&C Act (21 USC 321(rr)(2)).

D. New Tobacco Product

A new tobacco product is defined at section 910(a)(1) as "any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." At this time, FDA does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco (e.g., blending changes due to variation in growing conditions) in order to maintain a consistent product. Blending changes that are intended to alter the chemical or perception properties of the new product (e.g., nicotine level, pH, smoothness, harshness, etc.) compared to the predicate should be reported under 910 or 905(j). If you have any questions regarding whether a specific blending change you have made will be subject to the requirements of sections 910 and 905(j), please contact us.

E. Predicate Tobacco Product

A tobacco product manufacturer must show that a new tobacco product is "substantially equivalent, within the meaning of section 910, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 910, is substantially equivalent and that is in compliance with the requirements of this Act." (Section 905(j)(1)(A)(i) of the Act.) The comparison product chosen by the tobacco product manufacturer is referred to by FDA as the predicate tobacco product.

For the purposes of this guidance document, FDA refers to predicate tobacco products that were commercially marketed (other than for test marketing) in the United States as of February 15, 2007 as "grandfathered tobacco products."

For the purposes of 905(j) reports, the new tobacco product is compared to a predicate tobacco product in determining substantial equivalence (section 910(a)(3)(A) of the Act). FDA interprets this to mean that a single predicate tobacco product should be used for comparison purposes, as FDA believes that a meaningful scientific comparison intended to determine whether the characteristics of the products are the same or are different but present no different questions of public health cannot be made between a new tobacco product and multiple predicate products.

IV. General/Administrative Information

A. Who may submit a report under section 905(j)?

As a general matter, before a new tobacco product may be commercially marketed, an application for review must be submitted under section 910, and FDA must issue an order permitting the product to be marketed (section 910(c)(1)(A)(i)). However, section 910 provides that you (a manufacturer of a new tobacco product) are not required to obtain an order under section 910 if you have submitted a report under section 905(j) and FDA has issued an order finding the tobacco product to be substantially equivalent to an appropriate predicate product and in compliance with the requirements of the Act. If FDA is not able to make both of these findings, you must submit an application and receive an order pursuant to section 910 in order to commercially market a new tobacco product. However, manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, who submit a report prior to March 23, 2011, may continue to market the tobacco product unless FDA issues an order that the tobacco product is not substantially equivalent (section 910(a)(2)(B) of the Act).

At this time, however, FDA intends to limit its enforcement of the requirements of Section 910 and 905(j) to finished, regulated tobacco products. These finished, regulated tobacco products include the products named in section 901(b) (i.e. cigarettes, smokeless tobacco and roll-your-own tobacco) and tobacco products deemed by regulation to be regulated under chapter IX, as well as the component parts of regulated tobacco products sold or distributed for consumer use, (e.g., cigarette rolling papers, filters, or filter tubes sold separately to consumers or as part of kits). To avoid the submission of duplicative information, FDA does not at this time intend to enforce the requirements of 910 and 905(j) for components of regulated tobacco products that are sold or distributed solely for further manufacturing into finished tobacco products. We anticipate receiving all relevant information regarding such new tobacco products in the 905(j) reports of the finished regulated tobacco products. It is therefore the finished product manufacturer's responsibility to ensure it has accurate information regarding the components included in its product. The manufacturer must obtain appropriate market authorization for any changes to a tobacco product, including modifications to components. For example, if a finished cigarette manufacturer's filter supplier changed the conformation of its filters, or changed the ingredients in its filters, the finished cigarette manufacturer would be responsible for including this change as part of its submission of its new product application.

B. When should a 905(j) report be submitted?

Section 905(j)(1) of the Act requires that you submit a 905(j) report at least 90 days before introducing or delivering for introduction into interstate commerce for commercial distribution, a tobacco product intended for human use that was not commercially marketed in the United States as of February 15, 2007.

Manufacturers of tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after February 15, 2007, and prior to March 22, 2011, must submit the report no later than March 22, 2011, or your product will be deemed to be both misbranded and adulterated (sections 902(6)(A) and 903(a)(6) of the Act; 21 U.S.C. 387b(6)(A), 387c(a)(6)). If a 905(j) report is submitted prior to March 23, 2011, the tobacco product may continue to be marketed unless and until FDA issues an order that the tobacco product is not substantially equivalent to the predicate tobacco product (section 910(a)(2)(B) of the Act). FDA understands that 905(j) reports for these products are due soon and that some manufacturers may not be able to submit all the data and other information recommended in this guidance by the statutory deadline. For 905(j) reports for this category of products that are submitted prior to March 23, 2011, FDA intends to allow manufacturers who have acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions. FDA intends to determine what constitutes a reasonable period of time on a case by case basis.

New tobacco products first introduced or delivered for introduction into interstate commerce on or after March 22, 2011, and products introduced between February 15, 2007, and March 22, 2011, for which a 905(j) report was not submitted before March 23, 2011, may not be marketed without an order from FDA under either section 910(c)(1)(A)(i) or 910(a)(2)(A) of the Act. If a 905(j) report is submitted for such a product, the product may not be marketed without an order from FDA even if it has been more than 90 days since the 905(j) report was submitted to FDA (section 910(a)(2)(A)).

C. How should the 905(j) report be submitted to FDA?

While electronic submission is not required at this time, FDA is strongly encouraging electronic submission to facilitate efficiency and timeliness of data submission and processing. FDA intends to provide and update information on its website on how manufactures may provide the electronic submission to FDA (e.g., information on media and methods of transmission).

D. How will FDA review the 905(j) report?

FDA will review the 905(j) report and supporting information consistent with the requirements of sections 905(j) and 910 of the Act, i.e., to determine whether the new tobacco product is substantially equivalent to the predicate tobacco product. In addition to determining that the product is substantially equivalent, FDA must also determine that the new tobacco product is in compliance with the requirements of the Act before issuing an order under section 910(a)(2)(A)(i).

If you do not provide FDA with sufficient information to make these determinations, this will affect FDA's review. This may result in delays in review, or a finding that the new

tobacco product is not substantially equivalent to the predicate tobacco product, and/or is not in compliance with the requirements of the Act.

E. How should a request for an exemption under section 905(j)(3) be submitted?

Under Section 910(a)(2)(A)(ii) of the Act, you are not required to obtain a market authorization order if the manufacturer's product is exempted from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3). Section 905(j)(3) of the Act provides that FDA may exempt from the requirements relating to the demonstration that a new tobacco product is substantially equivalent to a predicate product, tobacco products that are modified by adding or deleting a tobacco additive, or by increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that (1) the modification would be a minor modification of a tobacco product that can be sold under the Act; (2) a 905(j) report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and (3) an exemption is otherwise appropriate.

FDA intends to issue a regulation as required under section 905(j)(3)(B) of the Act to implement the exemption provisions in section 905(j)(3)(A) of the Act. If FDA determines an exemption is appropriate, pursuant to the regulation once implemented, you will still have to report to FDA the basis, along with supporting information, for your determination that the tobacco product is modified as described in 905(j)(3), the modifications are to a product that is commercially marketed and in compliance with the requirements of the Act, and all of the modifications are covered by exemptions granted by FDA pursuant to 905(j)(3) (section 905(j)(1)(A)(ii) of the Act).

V. Content/Data to Submit

A 905(j) report must provide sufficient information to enable FDA to determine whether the new tobacco product is (1) substantially equivalent, within the meaning of section 910(a)(3) of the Act, to an appropriate predicate product, and (2) in compliance with the requirements of the Act (section 910(a)(2)(A) of the Act). In addition, a 905(j) report must include information on action taken by you to comply with the requirements under section 907 of the Act that are applicable to the tobacco product (section 905(j)(1)(B) of the Act). In the following sections, FDA provides recommendations on the information it believes a typical 905(j) report may need to include in order to demonstrate substantial equivalence. Manufacturers seeking to demonstrate substantial equivalence may also contact FDA to seek the agency's input on the specific types of information that the agency believes will be necessary to support the manufacturer's 905(j) report. In addition, after reviewing a 905(j) report, FDA may request additional information it determines is needed to make the required findings for a particular tobacco product.

The 905(j) report should provide side-by-side quantitative and qualitative comparisons of the new tobacco product with the predicate tobacco product with respect to all product characteristics. In addition, if the predicate to which the new tobacco product is being compared is a product for which FDA has issued an order of substantial equivalence, FDA recommends that the 905(j) report also include a side-by-side comparison to the grandfathered tobacco product (the tobacco product to which the predicate was compared). If the 905(j) report is for a component, part, or accessory of a tobacco product, FDA requests that you submit information regarding all relevant product characteristics, as identified below, and identify those characteristics that are not relevant to the component, part, or accessory, along with a justification for your determination.

Section 905(j)(1)(A)(i) requires that, in submitting a 905(j) report, you must show that the new tobacco product is substantially equivalent, within the meaning of section 910, to an appropriate predicate product. It is important, therefore, that you submit sufficient information to enable FDA to determine whether the new tobacco product has the same characteristics (defined as the materials, ingredients, design, composition, heating source, or other features of a tobacco product) as the predicate tobacco product, in accordance with 910(a)(3)(A)(i), or has different characteristics but it is not necessary to regulate the product under section 910(c)(1)(A)(i) because it does not raise different questions of public health, as required by 910(a)(3)(A)(ii). FDA understands this to mean that 905(j) reports are to be organized based upon the list of characteristics as set forth in section 910(a)(3). In addition to these characteristics, for products that have different characteristics, FDA may determine that additional information is needed to determine whether the products raise different questions of public health.

A. For All 905(j) Reports

The following items apply to all 905(j) reports, whether for a new tobacco product with the same characteristics as a predicate product under 910(a)(3)(A)(i) or for a new tobacco product with different characteristics, where you believe these different characteristics do not raise different questions of public health under 910(a)(3)(A)(ii).

1. Cover Letter

We strongly recommend that you include a cover letter that describes the data contained in your report, the predicate product to which you claim your tobacco product is substantially equivalent, and whether your new tobacco product has the same characteristics as the predicate tobacco product or different characteristics that do not raise different questions of public health. In addition your cover letter should provide contact information and be signed by a responsible official that either resides in or has a place of business within the United States.

2. Summary Section

We strongly recommend that you include a summary section in your 905(j) report that contains a brief description of the specific similarities and differences between the new tobacco product and the predicate tobacco product and, where applicable, the grandfathered tobacco product, with respect to: design features, ingredients, materials, heating source, composition, and other features, including the presence of harmful and potentially harmful constituents (HPHC). You may also include a brief discussion of the basis for your determination that the new tobacco product is substantially equivalent (SE) to the predicate tobacco product and, where applicable, to the grandfathered tobacco product.

3. Listing of Design Features

You should list design features in a tabular format, and include, but not be limited to, the following information in separate columns (from left to right):

- the component of the tobacco product (e.g., tobacco filler, filter)
- the subcomponent of the tobacco product (e.g., reconstituted tobacco)
- the name of the design feature of the tobacco product (e.g., moisture, pH, ventilation, ventilation hole location, paper porosity, tobacco cut width)
- the unit of measure
- the design feature's specifications in the new tobacco product (with any specification variation, if applicable)
- the design feature's specifications in the predicate tobacco product (with any specification variation, if applicable)
- the design feature's specifications in the grandfathered tobacco product (if applicable) (with any specification variation, if applicable).

4. Listing of Ingredients

You should list ingredients in a tabular format, and include, but not be limited to, the following information in separate columns (from left to right):

- the component of the tobacco product (e.g., tobacco filler, filter)
- the subcomponent, if applicable (e.g., reconstituted tobacco)
- ingredient name
- common name(s)
- Chemical Abstract Services number (for individual chemical ingredients)
- the function of the ingredient
- the unit of measure
- the level used in the new tobacco product (with any specification variation, if applicable)
- the level used in the predicate tobacco product (with any specification variation, if applicable)

- the level used in the grandfathered tobacco product (if applicable) (with any specification variation, if applicable).

Reporting of quantitative levels should follow recommendations in the guidance previously issued related to listing of ingredients under section 904(a)(1) of the Act (http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm191982.htm).

5. Listing of Materials

You should list materials in a tabular format and include, but not be limited to, the following information in separate columns (from left to right):

- the component of the tobacco product referenced (e.g., tobacco filler, filter)
- the subcomponent, if applicable (e.g., reconstituted tobacco)
- the material name
- common names
- material specifications (including units) for the submitted product (with any specification variation, if applicable)
- material specifications (including units) for the predicate tobacco product (with any specification variation, if applicable)
- material specifications (including units) for the grandfathered tobacco product (with any specification variation, if applicable).

6. Description of Heating Source

The 905(j) report should provide a description of the heating source (e.g., burning coal, electric, chemical reaction, carbon tip) used in the consumption of the finished tobacco product. If the heating source of the new tobacco product differs from that of the predicate tobacco product and, if applicable, from the grandfathered tobacco product, this description should be in enough detail to demonstrate that the change in heating source does not raise different questions of public health.

7. Description of Composition

The 905(j) report should include an explanation of how the design, materials, ingredients, and heating source of the product are integrated to produce the final product. If the composition of the new tobacco product differs from that of the predicate and, if applicable, from the grandfathered tobacco product, this description should contain enough detail to demonstrate that the change in composition does not raise different questions of public health.

8. Other Features

a) Listing of Harmful and Potentially Harmful Constituents

For all products, you should report levels of all HPHC in tabular format, with a side-by-side comparison with the predicate tobacco product and, where applicable, to a grandfathered tobacco product. For tobacco products that are smoked (e.g., cigarettes), you should report quantitative levels in smoke using both the International Organization for Standardization (ISO) and Canadian Intense smoking regimens. If an alternative to these regimens is used, you should provide an explanation of why the alternative provides comparable results to the ISO and Canadian Intense regimens.

FDA recommends reporting HPHC information in a tabular format using separate columns, in the order listed below (from left to right), for each of the following:

- the constituent name (the constituents should be listed in **alphabetical order**, top-down in the table)
- common name(s)
- Chemical Abstract Services number
- the unit of measure
- the level measured for the new tobacco product (with 95% confidence intervals)
- the level measured for the predicate tobacco product (with 95% confidence intervals)
- the level measured for the grandfathered tobacco product (if applicable) (with 95% confidence intervals)
- number of replicates
- method of measuring and reference(s).

FDA recommends including separate tables for results generated using the ISO, Canadian Intense, and any other smoking machine regimens.

You should provide documentation showing that the laboratories you used to perform analyses that provide the basis for the results you are submitting are accredited by a nationally or internationally recognized external accreditation organization.

You should provide documentation describing the storage conditions of both the predicate and the new tobacco product.

b) Other

The 905(j) report should address any additional characteristics and their relation to the predicate product.

9. Relationship to Section 910(a)(4) Requirement Regarding Health Information Summary or Statement

Section 910(a)(4)(A) requires that, as part of a 905(j) submission, you include an adequate summary of any health information related to the tobacco product or state that such information will be made available to any person upon request (section 910(a)(4)(A) of the Act). FDA strongly recommends that you include the summary with your 905(j) report. The summary must contain detailed information regarding data concerning adverse health effects and will be made available to the public by FDA within 30 days of the issuance of a determination that the new tobacco product is substantially equivalent to another [predicate] tobacco product (section 910(a)(4)(B) of the Act).

B. Additional Data

In addition to the information requested in Section V.A. above, for 905(j) reports for products with **different characteristics,** but which you do not believe raise different questions of public health under 910(a)(3)(A)(ii), FDA may request additional data needed to make a substantial equivalence determination.

Examples of additional data that may be requested include:

Consumer Perception Studies - data comparing consumer perceptions with respect to the new tobacco product and the predicate that could affect initiation, cessation, frequency of use, patterns of use, smoking behavior, and perceptions of harm or addictiveness.

Clinical data - data comparing the biomarkers of exposure and biomarkers of potential harm and human toxicity of the new tobacco product as compared to the predicate tobacco product and (if applicable) to a grandfathered tobacco product. Your report should include a summary of all studies conducted. In addition, your pivotal studies should be submitted and include: final approved study protocols, statistical analysis plans, any modifications to the study(ies), raw data, analysis platforms, and full reports.

Abuse liability data - data comparing the abuse liability of the new tobacco product to the predicate tobacco product and (if applicable) to a grandfathered tobacco product. Abuse liability can be assessed by a battery of studies, such as animal models of conditioned place preference, drug discrimination and self-administration, and human behavioral pharmacology studies that assess self-administration and subjective effects of the new tobacco product.

Toxicology data - data comparing the toxicity of the new tobacco product to the predicate tobacco product and (if applicable) to a grandfathered tobacco

product. Comparisons between the new tobacco product and the predicate tobacco product can be assessed by a battery of studies, including nonclinical studies such as *in vitro* and *in vivo* mutagenicity and clastogenicity studies, general toxicology studies that include hematological, clinical chemistry, and histopathological endpoints, toxicology studies designed to specifically address cardiac, respiratory, and reproductive/developmental toxicity and studies to assess the carcinogenic potential.

C. Additional Considerations

- Where you believe that all the characteristics of the new tobacco product are identical to those of the predicate tobacco product, except that a minimal number of ingredients, or materials have been substituted (substitution may include the same ingredient or material but from a different source), the 905(j) report should include, in addition to the information described in Section V(A) above, documentation demonstrating that the substituted ingredient(s) or material(s) meets the required specifications for the replaced ingredient(s) or material(s).

Data should be submitted demonstrating equivalence of the substituted ingredient(s) and/or material(s) with the original ingredient(s) and/or material(s).

- Where the characteristics of the new tobacco product are different from those of the predicate tobacco product, FDA recommends that the report include a separate listing of side-by-side quantitative and qualitative comparisons with the predicate tobacco product (and the grandfathered tobacco product, where applicable) of product characteristics that minimally differ between the submitted product and the predicate tobacco product. This listing should include the data described in Section V(B) and should include the raw data, analysis platform, and complete study reports for any differences between the products.

VI. Confidentiality

Information submitted under section 905(j) 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 substantial equivalence information submitted under section 905(j) 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.

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

VII. 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 360 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 0910-0673 (expires 07/31/2014).