



# A Look at FDA's New Substantial Equivalence Requirements for Tobacco Products

By William McGrath and Nick Peterson

**B**y the time you read this, the Food and Drug Administration (FDA) will have received hundreds of “substantial equivalence” applications from tobacco manufacturers covering all products on the market as of March 22, 2011, excluding those that were marketed unchanged prior to February 15, 2007. This deluge is part of the new regulatory structure created by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Substantial equivalence, a concept imported into tobacco regulation from FDA’s medical device regime, allows for the introduction of new or modified tobacco products if they meet certain criteria in comparison to products already on the market. In addition to the statute, FDA has issued a final guidance document addressing some of the issues raised by this new regulatory requirement.

However, this guidance document leaves some critical issues unresolved. This article will look at some of these unresolved issues as well as examine points for discussion between FDA and individual tobacco product manufacturers during the review process, where the real fleshing out of substantial equivalence requirements will take place.

## The Substantial Equivalence Statutory and Regulatory Framework

FDA has not issued, and might not issue, more detailed regulations governing the substantial equivalence regime. The requirements are set forth in the language of the statute, as currently interpreted by FDA guidance.



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## The Tobacco Control Act

Prior to marketing a “new tobacco product,” the Tobacco Control Act requires a tobacco product manufacturer to first obtain an order from FDA allowing that product to be introduced. The Tobacco Control Act defines a “new tobacco product” as (i) any product that was “not commercially marketed in the United States as of February 15, 2007” or (ii) 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 tobacco product was commercially marketed in the United States after February 15, 2007.” Tobacco product manufacturers intending to introduce a new tobacco product are required to submit a new tobacco product application (910 report) to FDA prior to the introduction of that product.

For certain types of new tobacco products, a tobacco product manufacturer may submit a report asking FDA to issue an order declaring that the new tobacco product is substantially equivalent to a predicate tobacco product (905(j) report) instead of submitting a 910 report. The Tobacco Control Act defines “substantial equivalence” as when a tobacco product (i) has the same characteristics as the predicate tobacco product or (ii) has different characteristics but does not raise different questions of public health. The term “characteristics” is further defined by the Tobacco Control Act to mean “the materials, ingredients, design, composition, heating source or other features of a tobacco product.”

A tobacco product manufacturer must submit a 905(j) report no later than 90 days prior to introducing the new tobacco product into interstate commerce. However, those products may not be

launched until FDA finds the product to be substantial equivalent to an existing, or predicate, product. For products introduced or changed between February 15, 2007 and March 22, 2011, manufacturers were required to submit a 905(j) report for that product prior to March 23. Those products may remain on the market so long as FDA does not issue an order finding the product is not substantially equivalent.

The Tobacco Control Act provides an exemption from these substantial equivalence requirements for certain minor modifications to tobacco products in the future. This exemption applies to products that meet the definition of substantial equivalence and are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive where FDA has determined that a 905(j) report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health. However, until such regulations are issued, no such exemption exists. FDA is required to issue final regulations implementing this exemption by July 1, 2011.

## The Substantial Equivalence Guidance

On January 5, 2011, FDA released a guidance document interpreting some of the requirements and procedures for demonstrating substantial equivalence for tobacco products (Guidance). The Guidance somewhat limits what products are to be considered “new tobacco products” and who must submit 905(j) reports. Recognizing that tobacco is an agricultural product and not a mechanical one, FDA states that the definition of “new tobacco product” does not include certain changes made to the tobacco blend of a product so long as such changes were made to address the natu-

ral variations of tobacco so that product consistency can be maintained.

FDA also states in the Guidance that it does not intend to require 910 or 905(j) reports for components of regulated tobacco products. Instead, FDA anticipates receiving all relevant information regarding tobacco products with modified or new components in the 905(j) report for the finished tobacco product. The end product manufacturer has the responsibility to ensure that accurate information about the new or modified component is included in the 905(j) report.

As to the content of a 905(j) report, a 905(j) report should include a “side by side quantitative and qualitative comparison of the new tobacco product with the predicate tobacco product with respect to all product characteristics.” FDA states that only a single predicate product should be used for comparison purposes. In addition, if the predicate product to which the new tobacco product is being compared is a product for which FDA issued a substantial equivalence order, the 905(j) report should also include a side by side comparison to the “grandfathered tobacco product.”<sup>1</sup> As mentioned above, the term “characteristics” is broadly defined to include, among other things, ingredients, materials and “other features” of the tobacco product.

In addition to a side by side comparison to all product characteristics, a 905(j) report consists of a cover letter, a summary of the new tobacco product and a summary of any health information related to the new tobacco product, including detailed information regarding any data on adverse health effects.

Additional information is required for new tobacco products that have different characteristics from the predicate product but raise no new questions of public health. In such cases, FDA may request additional data such as consumer percep-

tion studies, clinical data, abuse liability data or toxicology data. This information is not required if the new tobacco product has the “same characteristics” as the predicate product. A new tobacco product has the same characteristics if it is identical to the predicate product except that a minimal number of ingredients or materials have been substituted. In such situations, FDA says that a manufacturer should also include in the 905(j) report data demonstrating the equivalence of the substituted ingredients and/or materials with the original ingredients and/or materials.

Finally, FDA addresses previously submitted 905(j) reports. As mentioned above, the Tobacco Control Act provided a grace period for substantially equivalent products introduced between February 15, 2007 and March 22, 2011. Accordingly, a number of manufacturers submitted 905(j) reports prior to the release of the Guidance. As to these 905(j) reports, FDA states that it will allow those manufacturers who have “acted diligently in preparing their submissions a reasonable amount of time to supplement their initial submissions.”<sup>22</sup>

### What the Guidance Missed

While the Guidance provides basic information regarding the submission of a 905(j) report, a number of issues remain unaddressed or inadequately addressed. These issues make it difficult for tobacco product manufacturers to be in full compliance with the current substantial equivalence requirements and will pose challenges in filing future 905(j) reports.

### How Will Manufacturers Obtain Information About Predicate Tobacco Products?

The bulk of a 905(j) report consists of a detailed comparison between the new to-

bacco product and the predicate tobacco product (and grandfathered tobacco products where applicable). However, there is no current route for tobacco product manufacturers to obtain such detailed information about predicate tobacco products. Much of the information required to be reported for a predicate product is considered confidential commercial information or trade secrets, and as such, submitting manufacturers will likely request that this information not be made public.<sup>3</sup>

In the substantial equivalence regulations for medical devices, this issue of predicate products is resolved through the requirement of a 510(k) summary. The 510(k) summary provides basic information that other manufacturers can use to determine if a particular device can be used as a predicate product.<sup>4</sup> While the Guidance also requires a public summary of the new tobacco product, it limits the scope of that summary to “any health information.” Such a summary will not provide the basic information needed for a manufacturer to evaluate the suitability of any product other than its own as a predicate. Thus, manufacturers that want to find a predicate product for a new tobacco product are effectively limited to those products already in their own portfolios.

This issue is exacerbated because the Guidance requires manufacturers to only use a single tobacco product as a predicate product. This approach differs from the approach FDA uses for medical devices where multiple products can be used as predicates.<sup>5</sup> By restricting manufacturers to a single predicate, FDA is further diminishing the number of predicates available to tobacco product manufacturers. While this may not be too much of an issue for tobacco product manufacturers with large portfolios, it severely hinders the ability of new and

small tobacco manufacturers to file successful 905(j) applications.

Unless FDA creates some mechanism to make information about predicate tobacco products available, or revises the requirements of a 905(j) report to require less detailed information about predicates, manufacturers will be greatly constrained in their ability to locate acceptable predicate tobacco products. This burden will be fall especially hard on new and small tobacco product manufacturers.

### How Will End Product Manufacturers Obtain Information About Components?

The Guidance states that FDA does not intend to enforce the requirements of 910 or 905(j) against the manufacturers of component tobacco products and instead will receive the required component information from the manufacturer of the end product. While FDA’s stance may limit the number of parties that have to submit a 910 or 905(j) report, in practice, many product manufacturers will be unable to adjust components as necessary in the regular course of business.

The main impediment to such a requirement is that end product manufacturers are generally not privy to the specifications of a particular component, which typically includes confidential commercial information and trade secrets. Few component manufacturers may be willing to disclose confidential commercial information and trade secrets to their customers. Additionally, end product manufacturers will have to obtain such information far enough in advance to timely prepare and submit a 905(j) report. If a component manufacturer does not timely provide this information to end product manufacturers, the end product manufacturers

could face significant disruptions to their operations.

In addition, FDA's current interpretation contemplates the filing of 905(j) reports on a brand-by-brand basis even where component changes affect a large swath of end products. One example of such a situation involves reduced ignition propensity cigarette paper. A majority of states have required fire-safe cigarettes in an effort to reduce the number of accidental fires.<sup>6</sup> Accordingly, cigarette manufacturers have incorporated reduced ignition propensity paper into many of their cigarette products. Requiring 905(j) reports for each brand, rather than one 905(j) report covering the component itself, will result in a significant increase in the burden on both the agency and regulated industry, while providing FDA with duplicative and unnecessary information.

FDA's current interpretation will thus result in 905(j) reports being completed by companies without direct access to the product information necessary for a 905(j) report. Further, such an interpretation will drastically increase the number of reports submitted. The current interpretation will unnecessarily drain agency resources and make the filing of 905(j) reports difficult if not impossible for smaller manufacturers.

### How Will Manufacturers Maintain Product Consistency?

By definition, tobacco products contain tobacco, which is an agricultural ingredient subject to great variability. As such, the manufacturing process of tobacco products requires constant minor adjustments to maintain product consistency. The Guidance recognizes the variability in manufacturing by exempting tobacco blending changes from the definition of a "new tobacco prod-

uct." However, tobacco blending changes are not the only manufacturing adjustments made to maintain a product's consistency. As currently interpreted by FDA, any modification to a tobacco product, including minor manufacturing adjustments, would require the submission of a 910 or 905(j) report. Requiring a report, even for the most minor or temporary adjustments, would undermine a manufacturer's ability to control the quality of its products. This problem is compounded because FDA has only released draft regulations regarding the minor modification exemption.<sup>7</sup> Even when FDA releases its final exemption regulations, this exemption may not cover most manufacturing adjustments because the exemption only applies to additives. If FDA continues to maintain an expansive interpretation of "new tobacco products," both manufacturers and FDA may get overwhelmed with the amount of submissions required simply for tobacco manufacturers to maintain product consistency.

### Working with FDA Regarding 905(j) Reports

As mentioned above, the Tobacco Control Act provides a grace period for manufacturers who introduced products between February 15, 2007 and March 22, 2011. FDA has pledged to work closely with manufacturers who have acted in good faith in submitting a 905(j) report during this period. This will provide manufacturers with their first real chance to interact with the agency and understand how FDA works, and provide FDA with a real education as to tobacco products and how they are manufactured. Below are some more general issues that manufacturers may want to focus on during any such discussions with FDA.

### New Tobacco Products with "Same Characteristics"

As a result of the expansive interpretation FDA has adopted for "new tobacco products," a question arises as to how similar certain characteristics must be to be considered as having the "same characteristics" as a predicate product. As previously noted, a manufacturer can show substantial equivalence if the new tobacco product either has the same characteristics as the predicate or the new tobacco product has different characteristics but raises no new questions of public health. FDA states in the Guidance "same characteristics" will be found when "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)."

This strict interpretation of when products have the "same characteristics" may potentially result in bringing the introduction of new processes, brands or brand styles to a halt. For instance, under this interpretation, even if the only modification to a tobacco product involved minor changes in the amount of a material or ingredient, the resulting new tobacco product might not be considered to have the same characteristics. This interpretation does not appear workable for a manufacturer as many such minor changes would not appear to necessitate the additional information required for new tobacco products with different characteristics. A manufacturer and FDA will have to discuss whether it makes sense to require the additional information for certain products that may not meet FDA's precise interpretation.

## 905(j) Reports and Other Required Submissions

In addition to either a 910 or 905(j) report for any new tobacco product, a manufacturer must also submit additive change reports whenever an additive is added, increased, decreased or removed from a tobacco product.<sup>8</sup> A tobacco product manufacturer must also provide FDA a listing of all ingredients, along with other information, prior to the introduction of a new tobacco product.<sup>9</sup> These submissions contain a great deal of information that overlaps with the information provided in a 905(j) report. FDA should work with manufacturers in harmonizing these requirements to avoid unnecessary drain on agency and manufacturer resources.

## FDA Review Times

One issue that should be of particular importance to manufacturers is the length of time FDA will take to review a 905(j) report. Neither the Tobacco Control Act nor the Guidance details how long such a review will take. The Tobacco Control Act provides that FDA has 180 days to review 910 reports, so presumably FDA will take 180 days or less to review 905(j) reports. However, FDA has in the past had difficulty in reviewing drug and device applications within the statutory timeframes. This problem will be further exacerbated in the review of 905(j) reports given that the agency will be building its knowledge base regarding the products. Further, if minor changes to ingredients, additives or components are included, a manufacturer's operations would be significantly impaired if it had to wait 180 days or more for FDA to declare such minor adjustments substantially equivalent. Finally, FDA has not indicated whether its priority will be to devote its resources to the significant number of reports filed in March to the

exclusion of new 905(j) reports, which could seriously damage marketplace competition. Manufacturers should attempt to set a schedule with the agency regarding when a manufacturer can expect to hear back from FDA regarding a particular 905(j) report. Reviews of tobacco products with the same characteristics as a predicate should take much less time than reviews of new tobacco products with different characteristics. Establishing review timelines early can help both FDA and manufacturers better allocate resources.

## HPHC Information

FDA's guidance also contemplates manufacturers reporting information about hazardous and potentially hazardous components (HPHCs) contained in both the new tobacco product and the predicate product. Whether FDA has the authority to do so, and whether manufacturers at this stage have the ability to comply, is uncertain. FDA has not yet finalized a list of HPHCs and is not required to do so until April 2012.<sup>10</sup> Further, once FDA compiles that list of HPHCs, it also has to publish certain testing and reporting regulations by April 2013.<sup>11</sup> These regulations will then govern how tobacco product manufacturers are to test for and report certain constituents, including HPHCs. However, the Tobacco Control Act also provides that no such requirements will be applied to small tobacco product manufacturers until at least two years after the regulations are promulgated, and that such manufacturers will be able to stagger the reporting over four or more years.<sup>12</sup> Accordingly, it seems clear that FDA cannot require tobacco product manufacturers, especially small manufacturers, to test for and report HPHC information at this time as part of a 905(j) report. Manufacturers should address this issue with

FDA, especially if they do not have the ability or resources to test for and report HPHCs at this time.

While the concept of substantial equivalence has long been operative in the medical device realm, for the foreseeable future its application to tobacco products will be a challenge for both the tobacco industry and FDA. FDA's initial attempts at creating substantial equivalence requirements have provided a prospective framework, but critical questions remain. Consistent with FDA's pledge, the agency and manufacturers will need to work together to create an effective, vigorous review process. In so doing, all stakeholders must remember that the purpose and intent of the Tobacco Control Act is to create a comprehensive regulatory system for tobacco products, not to subject regulated industry to death by 1000 cuts. The continued development of the substantial equivalence process will provide a strong signal as to which direction FDA regulation will take. **Δ**

- 1 A grandfathered tobacco product is the product to which the predicate was compared to.
- 2 FDA states that it will determine what constitutes a "reasonable amount of time" on a case by case basis.
- 3 Manufacturers could claim protection for such confidential information under provisions of the Federal Food, Drug and Cosmetic Act, the Trade Secrets Act and the Freedom of Information Act, as well as various FDA regulations.
- 4 21 C.F.R. § 807.92.
- 5 See FDA "How to Find A Predicate Device" available at <http://www.fda.gov/MedicalDevices/Device-RegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm> ("Submitters must compare their 510(k) device to a similar legally marketed U.S. device(s)").
- 6 The Coalition for Fire-Safe Cigarettes provides a listing of states that have enacted fire-safe cigarette laws available at <http://www.firesafecigarettes.org>.
- 7 76 Federal Register 737-744 (January 6, 2011).
- 8 21 U.S.C. § 387d(c)(2), (3).
- 9 21 U.S.C. § 387d(c)(1).
- 10 21 U.S.C. § 387d(e).
- 11 21 U.S.C. § 387o(a).
- 12 21 U.S.C. § 387o(d)(1).