

# Rules and Regulations

Federal Register

Vol. 76, No. 128

Tuesday, July 5, 2011

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 16 and 1107

[Docket No. FDA-2010-N-0646]

RIN 0910-AG39

#### Tobacco Products, Exemptions From Substantial Equivalence Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this final rule to establish procedures for requesting an exemption from the substantial equivalence requirements of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The final rule describes the process and statutory criteria for requesting an exemption and explains how FDA reviews requests for exemptions. This regulation satisfies the requirement in the Tobacco Control Act that FDA issue regulations implementing the exemption provision.

**DATES:** This rule is effective August 4, 2011.

**FOR FURTHER INFORMATION CONTACT:** Annette Marthaler, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850-3229, 877-287-1373, [annette.marthaler@fda.hhs.gov](mailto:annette.marthaler@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

In the *Federal Register* of January 6, 2011 (76 FR 737), FDA issued a notice of proposed rulemaking (NPRM) to establish a procedure for requesting an exemption from the substantial equivalence requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) applicable to tobacco

products. This final rule establishes procedures for requesting an exemption under section 905(j)(3) of the FD&C Act (21 U.S.C. 387e(j)(3)). Among the procedures included in this final rule is the requirement that a request for an exemption and all information supporting the request be submitted in an electronic format. The final rule also addresses FDA's review of an exemption request and establishes procedures for rescinding an exemption. The final rule adds these requirements at § 1107.1 (21 CFR 1107.1).

The FD&C Act requires manufacturers to obtain an order under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) before they may introduce a new tobacco product into interstate commerce unless either: (1) FDA has issued an order finding the new tobacco product to be substantially equivalent to an appropriate predicate tobacco product and in compliance with the requirements of the FD&C Act or (2) the tobacco product is exempt from the requirements related to substantial equivalence under a regulation issued under section 905(j)(3) of the FD&C Act (see also section 910(a)(2)(A); 21 U.S.C. 387j(a)(2)(A)). This final rule is issued under section 905(j)(3)(B) of the FD&C Act, which requires that FDA issue regulations to implement the provision on exemptions from the substantial equivalence requirements of the Tobacco Control Act by July 1, 2011. (21 U.S.C. 387e(j)(3)(B); section 6 of the Tobacco Control Act). Section 905(j)(3)(A) of the FD&C Act provides that FDA may exempt from the requirements relating to the demonstration of substantial equivalence, 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 FD&C Act; (2) a substantial equivalence report 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.

##### II. Overview of the Final Rule

We considered all of the comments to the NPRM and the information submitted with the comments. After

considering the comments and to clarify the information to be submitted in an exemption request, we have changed proposed § 1107.1(b) to state that an exemption request must identify the tobacco product(s) that is the subject of the exemption request and, as required by part 25 (21 CFR part 25), include an environmental assessment. On our own initiative, we also made minor edits to the introductory language in proposed § 1107.1(b) to more clearly state that all submissions need to be legible and in the English language. As discussed in the NPRM, FDA will provide information on its Web site on submitting an exemption request in an electronic format that FDA can review, process, and archive (e.g., information on electronic media and methods of transmission) (<http://www.fda.gov/TobaccoProducts/default.htm>).

In response to comments expressing concern regarding the potential burden of requesting an exemption and after reconsidering the burden estimates, we have revised the burden estimates to more accurately reflect what we believe the burden will be for requesting an exemption. This is discussed in further detail in sections VII and VIII of this document.

##### III. Comments on the Proposed Rule

We received 13 comments on the NPRM. Comments were received from individuals, a trade association, and tobacco product manufacturers. To make it easier to identify comments and our responses, the word "Comment," in parentheses, will appear before each comment, and the word "Response," in parentheses, will appear before each response. We have combined similar comments under one comment. In addition, several sets of comments included comments on the "Guidance for Industry and FDA Staff—Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products" (76 FR 789, January 6, 2011); those comments will be considered as part of FDA's review of that document.

###### A. General Comments

(Comment 1) Several comments generally objected to the rulemaking, stating, for example, that there "should not be an exemption for the product" and suggesting instead that tobacco products be removed from the market. We received one comment that expressed concern about using the term

“approval” with respect to tobacco products because it implies that FDA sanctioned the product.

(Response) The issuance of a rule implementing the substantial equivalence exemption provision of the FD&C Act is explicitly required by section 905(j)(3)(B) of the FD&C Act. The statute requires FDA to implement the exemptions provision through rulemaking. This regulation fulfills that directive by establishing the procedures manufacturers must follow in order to request an exemption from the substantial equivalence provisions of the law. Neither the proposed nor final rule uses the term “approval.”

(Comment 2) One comment stated that we failed to satisfy our statutory obligation to implement the FD&C Act and its provision authorizing exemptions from the statute’s substantial equivalence requirements. This comment continued by stating that the proposed rule was not a meaningful attempt to comply with the statutory directive “to issue regulations to implement” the exemption provision and that, at most, the proposed rule “would act as a placeholder to allow FDA to defer indefinitely its responsibilities under section 905(j)(3)(B).” The comment stated that the proposed rule failed to give the exemption provision either meaningful substantive content or a viable procedural pathway. The comment also stated that this “dereliction” was concerning given the amount of time that has passed since the Tobacco Control Act was enacted.

(Response) We disagree with these comments. The statute requires FDA to implement the exemptions provision through rulemaking. This regulation fulfills that directive by establishing the procedures manufacturers must follow in order to request an exemption from the substantial equivalence provisions of the law. The rule provides a premarket pathway that will facilitate granting exemptions for tobacco products with minor modifications to additives that meet the statutory criteria. Many of the comments provided us with detailed information about the wide range of modifications made to tobacco product additives; these comments support the need for an exemption regulation that will accommodate various minor modifications to additives that meet the exemption criteria.

(Comment 3) One comment suggested that the rulemaking does not further the objectives of the Tobacco Control Act and will require the unnecessary expenditure of FDA and industry resources on submissions that have no

bearing on the goals sought to be achieved by the Tobacco Control Act.

(Response) We disagree. The exemption pathway is a significant part of the regulatory scheme Congress enacted to achieve the goals of the Tobacco Control Act. The FD&C Act, as amended by the Tobacco Control Act, requires that new tobacco products undergo some type of premarket review by the FDA. This premarket review may be through a premarket application (section 910(b) of the FD&C Act; 21 U.S.C. 387j(b)), a substantial equivalence report (section 905(j); 21 U.S.C. 387e(j)), or a request for an exemption from the substantial equivalence requirements (section 905(j)(3)) (section 910(a)(2); 21 U.S.C. 387j(a)(2)). To ensure appropriate oversight over tobacco products, it is crucial that FDA have information about modifications to additives in tobacco products in order to determine whether the modifications are minor and, accordingly, whether it is appropriate to exempt the tobacco product from the substantial equivalence requirements of the statute (assuming the other required findings can be made).

(Comment 4) Some comments stated that FDA needs to address the meaning of “new tobacco product” before issuing a final exemption regulation. One commenter stated that “simply repeating the language of the statute is insufficient,” noting that the statutory definition of “new tobacco product” includes the term “modification” and, depending on how broadly the term “modification” is interpreted, “potentially thousands of products that Congress intended to grandfather could be swept into the category of ‘new tobacco products’ simply because they have undergone routine, consistency-maintaining adjustments that have no public health significance.” The commenter further stated that the lack of notice regarding the meaning of the terms “new tobacco product” and “modification” raises due process and Administrative Procedure Act concerns because it is “difficult for interested persons to provide meaningful commentary on a proposed exemption from requirements applicable only to ‘new tobacco products’ when FDA has not revealed its understanding of what constitutes a ‘new tobacco product.’”

(Response) The FD&C Act, as amended in 2009 by the Tobacco Control Act, defines “new tobacco product” 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.” The definition expressly states that a new tobacco product includes “any” modification of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007. Therefore, FDA disagrees with the suggestion in the comments that the term “new tobacco product” has not been sufficiently defined.

(Comment 5) Some comments stated that there are categories of routine, consistency-maintaining adjustments that are not intended to alter the chemical or perception properties of the product and that, therefore, should not be treated as modifications for which a premarket application, substantial equivalence report, or exemption request should be required. The comments cited to various provisions of the FD&C Act, such as the good manufacturing practice provisions under section 906(e) of the FD&C Act and the notifications under section 904(c) (21 U.S.C. 387d(c)), as support for their view that these “routine consistency maintaining adjustments” are not “modifications” for which premarket review is required, because these other provisions are intended to ensure that we receive information on these types of adjustments and, consequently, these provisions would otherwise be rendered meaningless. Other comments similarly stated that adjustments made in response to variations in manufacturing, and differences in materials from lot to lot that are necessary to maintain consistent product characteristics, should not be considered modifications. Some comments identified specific adjustments that should not be considered modifications, including specific adjustments to compensate for the inherent variability of tobacco, the need for multiple suppliers for components, and adjustments made at the supplier’s initiative to maintain consistency. The comments stated that if “modification” were interpreted to include these adjustments, “that excessively broad interpretation would result in hundreds of legally marketed products being swept into the statutory and regulatory regime for ‘new tobacco products’ even though they would not have changed in any meaningful way” and that this would impose severe

burdens on both FDA and industry. One comment noted that a dictionary definition of “modification” supported excluding these “adjustments” from the scope of modification.

(Response) As previously discussed, the FD&C Act defines the term “new tobacco product” as specifically including any modification of a tobacco product where the product was commercially marketed after February 15, 2007. The statutory definition is not limited to modifications intended to have a certain effect or that are more than a routine adjustment of the product. While FDA agrees that the FD&C Act’s reporting obligations and other requirements related to tobacco products would apply to tobacco products modified as the commenters suggest, we disagree that these various requirements suggest that these types of modifications would not subject the modified tobacco product to the premarket requirements for new tobacco products. Manufacturers and interested parties should refer to FDA’s Web site for guidance on current enforcement policies related to premarket requirements for tobacco products (<http://www.fda.gov/TobaccoProducts/default.htm>).

(Comment 6) Some comments stated that a broad construction of “modification” in the definition of new tobacco product would allow FDA to eliminate grandfathered products because, for example, consistency-maintaining changes are routinely made to “grandfathered” products to ensure continued consistency of the tobacco product.

(Response) We use the term “grandfathered” to refer to those tobacco products that were commercially marketed in the United States as of February 15, 2007. Under the FD&C Act, a “grandfathered” product is not a “new tobacco product” and is not subject to the statute’s premarket requirements unless the product has been modified after February 15, 2007. The statute provides that if there has been “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 [the] tobacco product where the modified product was commercially marketed in the United States after February 15, 2007” the modified product is considered a “new tobacco product,” and is subject to the premarket requirements. (Section 910(a)(1); 21 U.S.C. 387j(a)(1).) This rule is consistent with that provision.

(Comment 7) Some comments stated that the proposed rule envisions an application and approval process for obtaining exemptions that is “procedurally indistinguishable from the process for obtaining a substantial equivalence order.”

(Response) We disagree with these comments because, as provided in § 1107.1, the information required for a new product in an exemption request is significantly different from the information submitted in a substantial equivalence report. Furthermore, after examining the detailed comments and information submitted to the NPRM, including information on the range of modifications made to tobacco products, we have reconsidered the estimates of the numbers and hours of submissions. We do not expect that an exemption request will be as lengthy or detailed as a 905(j) substantial equivalence report. We believe that the exemption pathway will be an efficient pathway to market when used for tobacco products with minor modifications to additives, where the modifications meet the criteria in section 905(j)(3) of the FD&C Act and where tobacco product manufacturers provide the information required in § 1107.1. Sections VII and VIII of this document provide additional information on the revised burden estimates.

(Comment 8) Several comments suggested that FDA define “minor modification.”

(Response) FDA declines to include in the rule a specific definition of the term “minor” because the meaning of the term may vary depending on the type of tobacco product. To enable FDA to determine whether a particular modification is minor and therefore may be exempted from the substantial equivalence requirements, the manufacturer must submit the information in § 1107.1(b), including information explaining why the modification is minor. Given that this program is just beginning, FDA does not have the experience needed at the present time to provide a useful definition of “minor modifications.” Although FDA is not defining “minor modifications” in this rule, as FDA gains experience in evaluating exemption requests, FDA will consider issuing a rulemaking defining minor modifications.

(Comment 9) Several comments suggested that FDA should use the 510(k) program applicable to medical devices as a model in implementing the substantial equivalence and exemption provisions. For example, the comments suggested that FDA place the burden on manufacturers to make the initial

determination as to whether the modification is minor according to the criteria in section 905(j)(3) of the FD&C Act. The comments continued by suggesting that FDA could issue a guidance with a decision-tree to facilitate the identification of changes that would not generally require FDA premarket review. Other comments suggested that reports regarding changes that do not impact public health should not be required to be reported to FDA, but rather should be documented by the manufacturer in a memorandum to file, similar to the requirements for medical devices cleared through premarket notifications (510(k)s).

(Response) FDA did consider the requirements applicable to medical devices when developing this rule, but concluded those requirements are inconsistent with section 905(j)(3) of the FD&C Act. Section 905(j)(3) specifically requires FDA to make certain findings, including a determination of whether the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, when determining whether to exempt a tobacco product from the requirement to demonstrate substantial equivalence.

#### *B. Comments on Categories of Exemptions*

(Comment 10) Several comments also suggested that FDA revise the proposed rule to create actual categories of minor modifications, or identify specific modifications, that meet the statutory criteria for exemption. The comments suggested that specific categories of changes could be exempted under section 905(j)(3) of the FD&C Act, including changes intended to ensure consistency or minor blend changes (e.g., to ensure that the specifications of a tobacco product are consistently met), changes that do not raise public health concerns (e.g., changes to additives that have been deemed by FDA as not harmful to health or changes reported to FDA under section 904(c)), changes in “commodity” ingredients (e.g., changes in ingredient suppliers or use of interchangeable ingredients obtained from different manufacturers which are within pre-defined specification tolerances for use in the tobacco product), changes in packaging text or graphics where the manufacturer does not know whether, or does not intend that, the ingredient will become incorporated in the consumed product. One comment stated that, once the Agency decides to grant an exemption request for a particular additive, it should establish a categorical exemption for a range of levels of that additive that would then apply to all similar products

(e.g., all cigarettes or all smokeless tobacco products). One comment suggested that the Agency develop a generic catalog of minor modifications that are classed by tobacco product type and manufacturing process upon which small manufacturers could rely in asserting that product modifications are exempt from the substantial equivalence requirements.

(Response) As discussed previously, in developing the proposed rule, we considered various approaches, including whether to include categories of exemptions in this initial rulemaking, but determined that we do not currently have sufficient information to enable us to make the findings required by the statute to support establishing categories of exemptions. However, we believe this information will develop as we review exemption requests and we intend to establish categories of exemptions when we have such information.

We have changed proposed § 1107.1(b) to clarify that a request for an exemption must identify the tobacco product(s) that is/are the subject of the exemption request. Although we are not establishing categories of exemptions at this time, manufacturers may submit one exemption request for multiple tobacco products if the request identifies the specific products and the information submitted under § 1107.1(b) applies to all the specified products. Finally, a manufacturer may submit an exemption request for a tobacco product(s) for a minor modification of an additive if the manufacturer specifies a range with a maximum and minimum as has been typically used for that tobacco product; again, the request must include the information required in § 1107.1(b) in order for us to make the necessary findings.

As discussed in the NPRM, FDA intends to provide technical and other nonfinancial assistance to small tobacco product manufacturers in complying with the premarket requirements of sections 905 and 910 of the FD&C Act, along with other requirements of the FD&C Act. Small tobacco product manufacturers may contact FDA at [smallbiz.tobacco@fda.hhs.gov](mailto:smallbiz.tobacco@fda.hhs.gov) for assistance. Additionally, FDA is considering the best way to provide information about what kinds of modifications have been determined to be minor. One option might be to create a public database of exemption determinations that may help inform manufacturers when preparing exemption requests. We would appreciate feedback from manufacturers about whether they would be concerned about disclosure of exemption determinations and whether disclosing

them would provide useful information. The other option would be for FDA to issue guidance in Question and Answer form which could be updated with new information on a regular basis.

(Comment 11) One comment suggested that the final rule should allow an exemption request to cover multiple products or a category of products and allow for modifications within a certain range. As one example, the comment suggested that, if supported by appropriate toxicological data, an exemption should allow a manufacturer to add a particular ingredient to any of its cigarette products up to a specified level, without requiring the manufacturer to file a substantial equivalence report or a separate exemption request for each product. Some comments urged adoption of a final rule that would establish a process focused on whether the addition of, or an increase in, the amount of an additive would increase the toxicity of the tobacco product. Similarly, other comments suggested that an exemption is appropriate when certain types of minor modifications would not increase the inherent public health risks of the product.

(Response) As discussed previously, a single exemption request may be submitted for multiple tobacco products. Note that manufacturers must identify each tobacco product proposed to be included within the exemption and include the information required by § 1107.1(b) in the request. Also, a manufacturer may submit an exemption request for a tobacco product(s) for a modification of an additive within a specified range. As provided in § 1107.1(c), the Agency's determination on whether to grant an exemption request will be based on whether the criteria in section 905(j)(3) of the FD&C Act are met.

(Comment 12) One comment stated that the language of section 910(a)(2)(A)(ii) of the FD&C Act "contemplates that exemptions from substantial equivalence will be categorical in nature, based on general regulations promulgated ex ante" and the statute does not require an affirmative "order."

(Response) We disagree with the comment suggesting that section 910(a)(2)(A)(ii) requires categorical exemptions; the language the comment refers to states that an order under section 910(c)(1)(A)(i) for a new tobacco product is required unless "the tobacco product is exempt from the requirements of section 905(j) pursuant to a regulation issued under section 905(j)(3)." This rule implements section 905(j)(3)'s exemption provision by

establishing a pathway for manufacturers to seek exemptions from the substantial equivalence requirements of the FD&C Act. An exemption granted through this pathway would be an exemption "pursuant to a regulation issued under section 905(j)(3)." The rule is also consistent with language in section 905(j)(3) of the FD&C Act requiring FDA to make specific determinations, and language in section 905(j)(1)(A)(ii) of the FD&C Act that indicates that FDA must affirmatively "grant" an exemption.

(Comment 13) Some comments requested that the Agency use its general rulemaking authority under section 701(a) of the FD&C Act to broaden the rule to include exemptions for more than just the addition or deletion of a tobacco additive, for example, to exempt minor modifications resulting from a company's change in vendors, blend maintenance adjustments, or adjustments in cigarette ventilation to maintain consistent strength of taste in response to agronomic variations. Similarly, some comments stated that FDA could issue other types of exemptions based on the "where otherwise appropriate" language in section 905(j)(3) of the FD&C Act. For example, the comment suggested we rely on this language to issue industry-wide exemptions for materials and/or components that are mandated by state or Federal law (such as Fire Safe Compliance paper).

(Response) Under section 905(j)(3), FDA may exempt from the requirements relating to the demonstration of substantial equivalence only tobacco products that are modified by adding or deleting a tobacco product additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA makes three specific findings. One of these findings is that the exemption is otherwise appropriate. Thus, under the statutory language, exemptions from substantial equivalence requirements are limited to modifications of additive levels; the "otherwise appropriate" language is not a separate ground for exempting a tobacco product from the substantial equivalence requirements of the statute.

(Comment 14) Some comments suggested that the reduction or elimination of an additive should be categorically exempt from the substantial equivalent requirements. These comments referred to section 904(c)(3), which requires manufacturers to notify FDA within 60 days after entering a product into the market when a manufacturer "eliminates or decreases an existing additive, or adds or increases an additive that has by

regulation been designated by the Secretary as an additive that is not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.” One comment suggested that the final rule should categorically exempt such modifications in recognition of the Congressional determination that additions or increases of “designated” additives do not require premarket review before a manufacturer enters a product into the market. The comment also suggested merging the exemption process with the “designation” process under section 904(c)(3).

(Response) As discussed previously, we do not have sufficient information at this time to establish categorical exemptions, although we intend to establish categorical exemptions as information develops. Thus, comments related to the designation of additives that are not human or animal carcinogens as being one category of modifications that should be exempted are premature and outside the scope of this regulation.

#### *C. Comments on Specific Provisions of the Rule*

(Comment 15) One comment discussed the proposed certification provision and noted that Congress excluded any consideration of behavioral effects from the substantial equivalence evaluation and in the evaluation of exemption requests for minor modifications. Similarly, other comments requested clarification that the rule would not require tobacco manufacturers to conduct behavioral research because the proposed rule might be read as meaning that a manufacturer would need to conduct behavioral research on minors in order to evaluate a product’s appeal to minors. One comment stated that the data and certification requirements pose insurmountable practical problems because the comment did not believe that sufficiently sensitive tools exist to measure addictiveness, appeal to, or use by, minors. The comment stated, however, that toxicity data would likely be needed to evaluate some minor modification exemption requests and that data should be presented in a truthful manner. The comment suggested that if the Agency believes a certification is necessary, a more appropriate requirement would be similar to 21 CFR 807.87(k) (this provision requires that a premarket notification (510(k)) include a statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted are truthful

and accurate and that no material fact has been omitted).

(Response) We did not intend for the proposed rule to imply that behavioral research must be conducted or submitted to support a certification. Rather, the rule requires only that the certification summarize the supporting evidence, which could be a literature review, previous studies, or other information. The certification is intended to provide us with assurance that there is a basis for making the findings required by section 905(j)(3) of the FD&C Act.

#### *D. Comments on FDA’s Implementation of the Rule and Review of Requests*

(Comment 16) Several comments stated that the proposed rule would create an enormously burdensome process, similar to a premarket application, for minor modifications to tobacco products. For example, several comments noted that, if finalized, the rule would require a tobacco product manufacturer to submit three reports to FDA regarding the requested minor modification: The initial minor modification report, a 905(j)(1)(A)(ii) report, and a separate report under section 904(c)(2) or (c)(3) for any change in a tobacco additive. One comment stated that this would create a duplicative process that would exceed the requirements for new tobacco product applications and modified risk tobacco products, and other comments stated that the reporting of certain changes to additives in section 904(c)(2) would be rendered meaningless. Some comments stated that the process established in the proposed rule—requiring submission of an exemption request and, once granted, submission of a report under section 905(j)(1)(A)(ii) of the FD&C Act—is more burdensome and potentially lengthier than submission of a 905(j) substantial equivalence report or a premarket tobacco application.

(Response) These comments refer in part to the requirement that a manufacturer who obtains an exemption is also required to report to FDA under section 905(j)(1)(A)(ii) of the FD&C Act (this requirement is not addressed in this rulemaking). Specifically, section 905(j)(1)(A)(ii) of the FD&C Act requires the applicant to report to FDA at least 90 days prior to introducing or delivering for introduction into interstate commerce the tobacco product that is the subject of the exemption, the basis for the applicant’s determination that “the tobacco product is modified within the meaning of [section 905(j)(3)], the modifications are to a product that is commercially marketed

and in compliance with the requirements of this Act, and all of the modifications are covered by exemptions granted by FDA pursuant to [section 905(j)(3)].” In addition, this submission must describe “action taken by [the applicant] to comply with the requirements under section 907 (21 U.S.C. 387g) that are applicable to the tobacco product” (section 905(j)(1)(B) of the FD&C Act). As noted earlier, the FD&C Act does set up distinct notification and reporting requirements, including those in sections 904(c) and 905(j)(1)(A)(ii), related to additives. In addition, in some cases the statute does require manufacturers to make multiple submissions before they may market a new tobacco product. We expect, however, that the overall exemption pathway to market will be less burdensome than the substantial equivalence or premarket application pathways to market. In addition, as discussed previously, a single exemption request may be submitted for multiple tobacco products, as long as each tobacco product is identified and the information required by § 1107.1(b) is submitted with the request. Also, a manufacturer may submit an exemption request for a modification of an additive within a specified range, which would minimize potential burden and duplication of information. Moreover, a manufacturer may submit the information required by 904(c)(2) in conjunction with the submission of a section 905(j)(1)(A)(ii) report.

(Comment 17) Several comments noted that the proposed process provided no time limit for FDA review of exemption requests and, consequently, a manufacturer may have to wait a long time for FDA to review its request for an exemption for a minor modification to its tobacco product. One comment suggested that FDA should make a decision on an exemption request within 90 days. This comment also suggested that one way to achieve more efficient review would be to allow a manufacturer to provide the notification required under section 905(j)(1)(A)(ii) at the same time FDA reviews the exemption request (submitting the information for an exemption request with the report under 905(j)(1)(A)(ii)); another comment suggested that the manufacturer document the exemption in its files rather than submit the section 905(j)(1)(A)(ii) report. These comments suggested that these approaches would eliminate the inefficiency of requiring an Agency decision on an exemption request before a manufacturer could

submit a 90-day notification under section 905(j)(1)(A)(ii) of the FD&C Act.

(Response) We agree that review of exemption requests should occur in a timely manner, and we do not expect the review process to be lengthy if the request includes the information stated in § 1107.1(b). We do not expect that the information submitted in an exemption request will be as lengthy or detailed as in a 905(j) substantial equivalence report. We understand that concerns regarding the length of time needed to prepare a submission were due in large part to the burden estimates in the NPRM; as discussed previously, however, we have revised our burden estimates. More discussion on the burden estimate can be found at sections VII and VIII of this rulemaking.

We disagree, however, that the report under section 905(j)(1)(A)(ii) of the FD&C Act could be made in conjunction with an exemption request under § 1107.1 or that documenting the information specified in section 905(j)(1)(A)(ii) in the manufacturer's files would be appropriate. Section 905(j) requires that each person who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution a new tobacco product must submit either a report under section 905(j)(1)(A)(i) demonstrating that the new tobacco product is substantially equivalent to an appropriate predicate product, or a report under section 905(j)(1)(A)(ii) stating the basis for their determination that the product is modified within the meaning of section 905(j)(3), the modifications are to a commercially marketed product, and that the modifications are covered by exemptions granted by FDA. Thus, documenting the information in the manufacturer's files would not be appropriate. Furthermore, the information required in a report under section 905(j)(1)(A)(ii) that "all of the modifications are covered by exemptions granted by [FDA]" will not be available until FDA grants the exemption; thus, the report under section 905(j)(1)(A)(ii) may not be submitted simultaneously with the exemption request.

(Comment 18) One comment proposed an alternative rule that would require manufacturers to report to FDA "a baseline list" that would include "maximum use levels" of each additive in each product, the maximum use levels (MULs) of each tobacco type used in that category, and the established ranges for all other design parameters used in products in that category." The comment suggested that FDA could use these reports to create a composite list

of MULs and established design parameter ranges for each product category based on information from grandfathered products and other legally marketed products. The composite list would be published in the Code of Federal Regulations. Manufacturers would be required to submit changes to its baseline list to reflect any new tobacco products the manufacturer has legally introduced into the market. Through an amendment process, tobacco manufacturers could increase MULs or expand design parameter ranges when there is evidence that use levels or design parameters are "generally recognized as appropriate for public health." The comment stated that its proposal would also clarify that adjustments to tobacco products that are not intended to alter the chemical or perception properties of the product are not "modifications" and thus do not make the product a new tobacco product subject to premarket requirements.

(Response) In general, we disagree that this alternative would appropriately implement section 905(j)(3) of the FD&C Act. We note, for example, that a key premise of the alternative is the definition of "modification" which, in the alternative, would be defined, with certain exceptions, as "any change made by a tobacco product manufacturer \* \* \* that is intended to or does alter the chemical or perception properties of the product." This definition is inconsistent with the language of section 910(a) of the FD&C Act, which does not include intent as an element of the definition of "modification."

(Comment 19) Some comments suggested that, because regulations implementing section 905(j)(3) are not yet in place, FDA should exercise enforcement discretion for tobacco products that might use that pathway to market when the regulations are in place. These comments suggested that exemptions from reporting are essential to a workable system and FDA is bound to receive a significant volume of submissions for minor and inconsequential changes to tobacco products before such exemptions are issued.

(Response) This final rule implements the exemption provision pathway to market and renders this comment moot.

(Comment 20) One commenter requested an extension of the comment period.

(Response) FDA declines to extend the comment period in an effort to ensure that the exemption pathway becomes available as required by statute. As indicated in the preamble to the proposed rule, however, FDA

anticipates that there will be further guidance and rulemakings on this topic and will request comment accordingly.

#### IV. Effective Date

For the effective date of this final rule see the **DATES** section of this document.

#### V. Legal Authority

Section 905(j)(3)(A) of the FD&C Act provides that FDA may exempt from the requirements relating to the demonstration of substantial equivalence tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act; a substantial equivalence report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and an exemption is otherwise appropriate. Section 905(j)(3)(B) of the FD&C Act requires that FDA issue regulations to implement the provision on exemptions from the substantial equivalence requirements of the Tobacco Control Act. FDA is issuing this rule as required by section 905(j)(3)(B) of the FD&C Act. Additionally, section 701(a) of the FD&C Act (21 U.S.C. 371) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

#### VI. Environmental Impact

The Agency has determined under § 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VII. Analysis of Impacts

##### A. Introduction

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not an economically significant

regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the exemption pathway put into place by this rule provides an option that potentially reduces costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

#### *B. Public Comments Concerning Impact Analysis*

FDA received several comments covering such topics as the accuracy of FDA’s assessment of social costs and benefits, the accuracy of burden estimates, compliance with requirements such as Executive Order 12866 and the Regulatory Flexibility Act, and the effect of this rule on small businesses.

(Comment 21) One comment stated that bringing a modified product to market under the proposed exemption pathway could cost as much or possibly more than filing a section 905(j) report alone because the Agency estimated that requesting an exemption and filing a section 905(j) report would each require 360 hours. Bringing a product to market under an exemption would require both submissions.

(Response) This comment reflects some misunderstanding of the nature of the reports submitted under 905(j) of the FD&C Act with and without substantial equivalence exemptions. In the absence of an exemption, a report demonstrating substantial equivalence under section 905(j)(1)(A)(i) must be submitted. If an exemption has been requested and granted, a report must still be submitted under section 905(j)(1)(A)(ii), but it will cite the exemption(s) in place of demonstrating substantial equivalence. The 360-hour estimate refers to a section

905(j) report demonstrating substantial equivalence. A report citing an exemption would be far shorter.

(Comment 22) One comment stated that FDA incorrectly concluded that the proposed rule was not significant under Executive Order 12866.

(Response) FDA should have stated that the proposed rule was not economically significant. We have added that statement to the final rule.

(Comment 23) One comment argued that FDA’s conclusion that the proposed rule does not impose social costs is “irrational,” “erroneous,” and “so unreasonable as to be arbitrary and capricious.” The comment further stated that FDA “inappropriately stacks the deck” by using a baseline scenario in which there are no exemptions and that by this reasoning, “it is literally impossible for its exemption rule to impose costs, regardless of how burdensome or byzantine an exemption pathway the rule sets forth.” In light of the statutory mandate to implement exemptions, the no-exemption scenario cannot be treated as the baseline. Finally, the comment argued that FDA had not complied with its obligation to rationally consider the costs of the rule compared with alternative means of implementing exemptions.

(Response) FDA disagrees that the proposed rule would impose social costs. The current regulatory framework requires submission of a substantial equivalence report (or a premarket application) before introducing any new tobacco product, and without rulemaking this framework would continue into the future. Substantial equivalence reports have a substantial burden, preliminarily estimated at 360 hours. Use of this baseline is appropriate and does not “stack the deck.” The Office of Management and Budget’s (OMB’s) Circular A-4 states that the baseline “should be the best assessment of the way the world would look absent the proposed action.” Without this rule, all new tobacco products would be required to submit a premarket application or substantial equivalence report.

We do not argue that under the stated baseline it is literally impossible for this exemption rule to impose costs. We acknowledge the theoretical possibility that uncertainty regarding the kinds of product modifications that may be granted an exemption and the amount of supporting evidence that will be required as the basis for an exemption could impose additional social costs. We think this is extremely unlikely, especially in the long run, because uncertainty will be reduced as manufacturers gain experience with the

regulatory regime. Although the theoretical possibility exists that this rule could increase costs in the short run, we therefore do not anticipate that it will increase costs in the long run.

The comment seems to imply that a regulatory alternative in which certain types of modifications are automatically exempted should be used as the baseline. This suggestion confuses the choice of baseline with an analysis of alternatives. Nevertheless, FDA recognizes that there are regulatory alternatives, such as identifying categories of modifications that are exempt, that could have reduced costs more than this rule will. That is why in the future, when the Agency has sufficient information to do so, FDA may identify categories of modifications that are exempt.

This comment may be reacting to the apparent lack of cost savings under the exemption pathway, or the perceived large cost of both the exemption and substantial equivalence pathways. As discussed elsewhere in this preamble, FDA now believes it significantly overestimated the burden of requesting an exemption. Our current estimate, based on new information, indicates that the exemption pathway will offer cost savings.

(Comment 24) One comment argued that based on the history of FDA’s 510(k) Program, it is clear that the broad interpretation of the section 905(j) reporting mandate embodied in current guidance (“Guidance for Industry and FDA Staff—Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” (76 FR 789, January 6, 2011)) will “impose an incredible and unnecessary administrative burden on the Agency and the tobacco product manufacturing industry.” Many of the submissions will be unnecessary for protection of the public health. FDA estimated that 905(j)(3) reports will cost \$35,000 each, “evidencing the burden on industry of an onerous reporting mandate.”

(Response) FDA acknowledges that tobacco product manufacturers may face new challenges in complying with the various provisions of the Tobacco Control Act. However, this rule will not impose any new obligations on manufacturers. In the absence of this rule, all modifications leading to new tobacco products would require the demonstration of substantial equivalence (if not submission of a premarket application), as discussed previously in this document. This rule provides an alternative pathway to substantial equivalence and premarket applications for marketing new tobacco products and may reduce both industry

costs and the burden on FDA of reviewing submissions.

(Comment 25) A comment argued that the approach taken in FDA's impact analysis is legally deficient because it would allow the Agency to skirt its obligations under the Regulatory Flexibility Act by assuming any regulation issued to implement substantial equivalence exemptions is cost free. The comment further stated that FDA can only avoid the requirements of the Regulatory Flexibility Act by certifying that the rule will not have a significant impact on a substantial number of small businesses and that such a certification must be reasonably supported.

(Response) FDA disagrees that the Agency has skirted any obligations under the Regulatory Flexibility Act. FDA proposed to certify that the rule would not have a significant impact on a substantial number of small entities because compared to the appropriate baseline, the rule would offer an alternative channel that may reduce costs. See the Response to Comment 23 for a discussion of the baseline on this issue.

(Comment 26) A comment argued that the approach taken in FDA's impact analysis is legally deficient because it would allow the Agency to skirt its obligations under Executive Order 12866 by assuming any regulation issued to implement substantial equivalence exemptions is cost free. FDA must rationally compare the costs and benefits of the proposed rule and consider reasonable alternatives. After assessing costs and benefits FDA must proceed "only upon a reasoned determination that the benefits of the intended regulation justify its costs."

(Response) FDA disagrees. For regulatory actions which are not economically significant, Executive Order 12866 requires a statement of potential costs and benefits. FDA has rationally compared the costs and benefits of the proposed rule according to the correct baseline, as explained in the Response to Comment 23. An analysis of regulatory alternatives is only required for economically significant rules.

(Comment 27) A comment argued that the approach taken in FDA's impact analysis is legally deficient because it would allow the Agency to skirt its obligations under the Administrative Procedure Act. "FDA's assumption that the cost of its proposed rule is zero demonstrates that FDA's assessment of social costs is so unreasonable as to be arbitrary and capricious."

(Response) FDA disagrees with the assertion that the Agency's assessment

of social costs is unreasonable, arbitrary, or capricious. See the Response to Comment 23 for a discussion about the baseline for details.

(Comment 28) A comment argued that FDA's impact analysis is unreasonable because after incorrectly concluding that the proposed rule is costless, FDA conducts a cursory impact analysis quantifying the cost of preparing an exemption request.

(Response) FDA concluded that the proposed rule was highly unlikely to impose social costs. We do not conclude or state that preparing and submitting a request for exemption would be without cost. The question of interest in the impact analysis is the cost of marketing a new tobacco product through the exemption pathway compared to the cost of marketing a new tobacco product through the substantial equivalence pathway. FDA provided an estimate of the absolute cost of obtaining an exemption to allow the reader to make additional comparisons.

(Comment 29) A comment argued that FDA's impact analysis is unreasonable and "so misguided as to demonstrate that FDA has no real understanding of the practical consequences of its proposed rule for the industry it is charged with regulating."

(Response) FDA disagrees that the analysis is misguided or that the Agency has no understanding of the industry it is charged with regulating. However, the Agency does acknowledge that because statutory deadlines compelled us to start developing a rule for substantial equivalence exemptions before substantial equivalence reporting requirements went into effect, there was considerable uncertainty surrounding our estimates as well as the process itself. For this reason we repeatedly requested comment throughout the preliminary impact analysis. Because we have gained additional information and experience since publishing the proposed rule, we have revised our estimates as discussed in the paragraphs that follow.

(Comment 30) Multiple comments asserted that FDA's impact analysis is unreasonable and dramatically underestimates the costs and burdens associated with the proposed rule. One comment stated that if FDA takes the position that routine, minor adjustments to maintain consistency trigger the need for an exemption or substantial equivalence report, then FDA's best estimate that 50 exemption requests will be submitted per year is "absurdly low." Multiple comments indicated that there will be at least several hundred exemption requests submitted per year, possibly several thousand. One

comment stated that it is arbitrary to estimate that 50 of 233 new products introduced each year would be the subject of an exemption request; FDA's approach based on counting new products is flawed because manufacturers will have to file potentially hundreds of exemption requests each year for existing tobacco products; and, the estimate that FDA will request additional information for 40 requests per year is also far too low.

(Response) The estimates referred to by this comment are not estimates of the cost of this rule, but estimates of the absolute cost of preparing exemption requests. As described in the preliminary regulatory impact analysis, this rule offers a potentially cost-reducing additional pathway for marketing a subset of new tobacco products.

Based on the original estimate that 233 new products are introduced each year, FDA disagrees that it was arbitrary to choose 50 as our best estimate of how many exemption requests we would receive. Because the statute sets specific criteria for when exemptions may be granted, we can clearly expect that not all new products would be eligible.

Since publication of the proposed rule, FDA has gained additional information from viewing comments and initial substantial equivalence reports and through other activities within the usual scope of operation for FDA's Center for Tobacco Products. We now know more about the range and frequency of modifications that are made to tobacco products. Based on this new information, we have revised upward the number of exemption requests we expect to receive to 500 per year. We now anticipate requesting additional information for 150 of these requests.

(Comment 31) Comments argued that FDA provided "no basis whatsoever," "reasonable or otherwise" for its estimates that it will take 360 hours to prepare an exemption request and 50 hours to respond to a request for additional information. Comments further argued that these estimates are arbitrary and capricious and do not comply with requirements under the Paperwork Reduction Act (the PRA), the Regulatory Flexibility Act, and Executive Order 12866; preparing these submissions will take substantially longer than estimated; and the lack of basis for the burden estimate is clear because the same burden estimate, 360 hours, was used for demonstration of substantial equivalence and requesting a substantial equivalence exemption.

(Response) The estimates referred to by this comment are not estimates of the



cost of this rule, but estimates of the absolute cost of preparing an exemption request. FDA disagrees that these estimates are too low and are completely without basis. The processes FDA is implementing for substantial equivalence reports and substantial equivalence exemptions are completely new, so there is considerable uncertainty around the time that such submissions will take to prepare. The estimates in the proposed rule represented the Agency's best estimates at the time, based on the requirements set out in the rule and other submission processes administered by the Agency. There was no ideal submission process to which to compare a substantial equivalence exemption request. Although comments have asserted that the time it takes to request an exemption was underestimated, no alternative estimates were provided. The fact that the burden estimates were originally the same for demonstrating substantial equivalence and requesting an exemption reflected an effort to be conservative in estimating the cost savings offered by this rule and uncertainty surrounding these burdens.

Since publication of the proposed rule, FDA has gained additional information from reviewing comments and initial substantial equivalence reports and through other activities within the usual scope of operation for FDA's Center for Tobacco Products. We now know more about the range of modifications that are made to tobacco products and are persuaded that we overestimated the time that will be required to prepare and submit an exemption request. Based on the limited information required relative to a substantial equivalence report, we now estimate that an exemption request for a suitable product, meeting the requirements set forth in this rule, could be prepared in 12 hours, and that a response to a request for additional information could be prepared in 3 hours. For more detail see section VIII of this document.

(Comment 32) One comment argued that FDA does not show how costs will be reduced through this rule because the cost of demonstrating substantial equivalence is not estimated.

(Response) As noted by many comments, FDA initially estimated that demonstrating substantial equivalence and requesting an exemption would each take 360 hours, which would imply that on average costs would not actually be reduced by this rule (though costs could certainly be reduced for some subset of potentially eligible new tobacco products). The initial estimate of the time required to prepare a

substantial equivalence report is currently being updated based on initial submissions to the Agency, but we anticipate that the updated estimate will remain substantially higher than our downwardly revised estimate of the cost of preparing an exemption request.

(Comment 33) Comments argued that uncertainty about the circumstances under which FDA would request additional information makes it more difficult for manufacturers to determine whether it will be less costly to request an exemption and that FDA should provide additional information regarding the types of modifications that will be considered for exemption requests. One comment further argued that spending 360 hours on an exemption request that is ultimately denied, and then submitting a substantial equivalence report, wastes resources.

(Response) FDA disagrees that it is prudent to provide additional information at this time regarding the types of modifications that will be considered for an exemption, as explained elsewhere in the preamble. We also note that based on current information, we estimate the burden of submitting an exemption request to be far lower than initially estimated, the cost of responding to a request for additional information will also be lower than initially estimated, and fewer resources will be expended if an exemption request is ultimately denied. Nevertheless, it is up to the individual manufacturer to make a reasoned determination as to whether the likelihood that an exemption is granted justifies the cost of submitting an exemption request. The criteria set forth in the statute and this rule will form the basis for that determination.

(Comment 34) A comment argued that in estimating the time required to prepare an exemption request, FDA has not considered the "massive amount of confusion and uncertainty" that will stem from the lack of clear definition of "minor modification" or clear standards for what modifications would be eligible for exemptions.

(Response) The statute and this rule plainly state that only modifications pertaining to tobacco product additives could be eligible for an exemption. The time we have estimated that it takes to submit an exemption request reflects the reality that we have not set up categories of modifications which are automatically exempt. Instead the manufacturer must provide an explanation as to why the modification should be exempt, following the requirements of this rule.

(Comment 35) A comment asserted that FDA discounts the possibility that overall submission costs could increase as a result of the uncertainty generated by the proposed rule and pointed out that FDA does not estimate the annual number or percentage of exemption requests it expects to deny. The comment argues that because the number of exemption requests will far exceed 50 per year, the number of requests denied due to inadequate information regarding the exemption criteria will be higher than FDA anticipates. The comment further states that "having failed to provide any meaningful guidance on the exemption criteria in the nearly 2 years since the Family Smoking Prevention and Tobacco Control Act was signed into law, FDA cannot blithely assume that the criteria will somehow become clear in time to save manufacturers from incurring major, unnecessary costs in preparing exemption requests that are denied because they are found not to meet criteria that FDA has not divulged." A similar comment argues that the cost savings of this rule are merely theoretical.

(Response) FDA disagrees with the characterization that the Agency discounted the possibility that overall submission costs could increase. This possibility was discussed in the preliminary analysis precisely because the Agency did not feel it should be ignored. FDA maintains the conclusion that in the long run, absolute costs for preparing exemption requests will certainly not exceed the baseline costs for demonstrating substantial equivalence because manufacturers always have the option available of demonstrating substantial equivalence for these products. Manufacturers can limit the number of exemption requests which are ultimately denied by adhering to the criteria for an exemption set forth in the statute and this rule. Only modifications pertaining to additives could possibly be eligible. Although costs could theoretically be generated in the near term, this is unlikely because the cost savings likely to result from a single exemption is high relative to the cost of preparing a single exemption request.

While we agree that the number of exemption requests will be higher than initially estimated, we do not attempt to estimate the number (or proportion) that will ultimately be denied because it depends on the quality and suitability of the submissions. In light of currently available information, the exemption pathway is reasonably expected to offer cost savings.

(Comment 36) Comments argued that due to the high estimated cost of preparing exemption requests, FDA should assist small businesses by setting up categorical exemptions and developing a catalog of minor modifications (by product type and manufacturing process) that are exempt from substantial equivalence requirements.

(Response) Our reasons for not setting up categorical exemptions at this time are discussed elsewhere in the preamble. FDA reiterates that this rule activates an additional pathway for marketing new tobacco products, providing manufacturers with an option that may reduce costs. Therefore this rule imposes no incremental burden from which to provide relief.

However, FDA also acknowledges that setting up categorical exemptions or developing a catalog of minor modifications could offer greater potential cost savings for tobacco product manufacturers, many of which are small, in complying with requirements under the Tobacco Control Act. That is why the Agency may choose to set up categorical exemptions in the future when there is more information about what categories would be appropriate.

(Comment 37) Manufacturers commented that FDA should issue industry-wide exemptions from 905(j) requirements, or 910 requirements if applicable, for modifications that are required to comply with a change in state or Federal law because not exempting such modifications could cause small manufacturers to go out of business and would place an undue burden on small manufacturers.

(Response) FDA disagrees that declining to broaden the scope of the exemption pathway places an undue burden on small manufacturers. FDA reiterates that this rule establishes an additional pathway for marketing new tobacco products, providing manufacturers with an option that may reduce costs. Therefore this rule imposes no incremental burden from which to provide relief. For changes in additives, small manufacturers may request an exemption. The absolute cost of requesting an exemption is expected to be far less than originally estimated, and the potential cost savings relative to demonstrating substantial equivalence far greater. Although broadening the scope of the exemption pathway could offer a larger potential reduction in costs, FDA declines to do so as explained elsewhere in the preamble.

(Comment 38) Manufacturers commented that the estimated 360 hours it would take to prepare an

exemption request would be an unduly burdensome requirement to place on small manufacturers for the addition or deletion of an additive, or a change in the quantity of an additive. The comments stated that small manufacturers do not have in-house scientists or engineers who can spend all their time preparing exemption requests and could be driven out of business by this requirement.

(Response) As discussed previously in this document, FDA has revised downward the estimate of the time it takes to prepare an exemption request. FDA reiterates that because this rule activates an alternative pathway for marketing new tobacco products that may reduce costs, it imposes no incremental burden from which to provide relief. Regardless of whether the preparation of submissions to FDA is done entirely in-house or with the help of contractors, the cost should not increase as a result of this rule. Small manufacturers would have to prepare substantial equivalence reports for all new products (not requiring a premarket application) in the absence of this rule. Small manufacturers may realize some savings by submitting exemption requests for a subset of their new products rather than demonstrating substantial equivalence.

#### C. Baseline

Under the current regulatory framework, tobacco product manufacturers must submit to FDA either a premarket application or a report under section 905(j)(1)(A)(i) demonstrating substantial equivalence to an appropriate predicate product, and FDA must issue the appropriate corresponding order, before a new tobacco product may be introduced or delivered for introduction into interstate commerce. This rulemaking activates a third option, the substantial equivalence exemption pathway for marketing new tobacco products. Compared with the cost associated with the current baseline, this rule may result in cost savings if tobacco manufacturers request, and are granted, substantial equivalence exemptions for some new tobacco products.

#### D. Number of Affected Entities

This final rule may potentially apply to any tobacco product manufacturer or importer whose products are regulated under the Tobacco Control Act. Statistics of U.S. Businesses data indicate that there are 20 domestic cigarette manufacturers and 46 other tobacco product manufacturers (U.S. Census, 2009). Because other tobacco product manufacturers would include

cigar and pipe tobacco manufacturers, not all 46 firms represent manufacturers that are currently regulated under the Tobacco Control Act.<sup>1</sup> An unknown number of importers would be affected.<sup>2</sup> It is possible that not all potentially affected manufacturers and importers will choose to request exemptions.

#### E. Number of Exemption Requests

The number of new products introduced in a given year is the theoretical maximum number that could be introduced under a substantial equivalence exemption. However, some new products may not be substantially equivalent to an appropriate predicate tobacco product and will require premarket authorization under section 910(c), in which case they will certainly not be eligible for an exemption. The remaining products could demonstrate substantial equivalence in a 905(j)(1)(A)(i) report. Under this final rule, a subset of those substantially equivalent products will be eligible for possible introduction into interstate commerce through the substantial equivalence exemption pathway.

FDA considers AC Nielsen scanner data, industry comments, and experience from substantial equivalence reports submitted since passage of the Tobacco Control Act in order to estimate the number of exemptions that may be requested on an annual basis. We assume the average number of new products introduced annually will be approximately the same going forward as in recent years. However, it is also possible that requirements imposed by the Tobacco Control Act will lead manufacturers to introduce new products at a lower rate in the future.

Using AC Nielsen scanner data covering late 2007 to late 2009, FDA counts a Universal Product Code (UPC) as introduced in 2008 if total dollar sales in late 2007 were zero, but total dollar sales in 2008 were greater than zero. With this definition, FDA finds that 628 new cigarette UPCs, 215 new chewing tobacco UPCs, 36 new smoking tobacco UPCs (excluding pipe tobacco), and 36 new cigarette paper UPCs were introduced in 2008. This sums to an estimated 915 new UPCs in 2008.

Unique UPCs are often assigned to different types of packaging for otherwise identical products. In the preliminary regulatory impact analysis,

<sup>1</sup> A possible offsetting factor is that these data only include firms with payroll, and there could be some small tobacco product manufacturers without payroll.

<sup>2</sup> Manufacturers, wholesalers, and retailers could all theoretically import tobacco products. Census data do not distinguish firms that import from firms that do not.

FDA excluded from consideration new UPCs that appeared to be for products that differed from existing products only in packaging. In response to comments stating that our initial approach undercounted new tobacco products because of the extremely minor changes that are often made to existing products, we consider all new UPCs in this final regulatory impact analysis. The number of new UPCs still may not accurately reflect the number of new tobacco products if enough modifications are so minor that they do not trigger a UPC change. FDA does not know the extent to which this may be the case, but based on comments from industry and experience with substantial equivalence reports, relatively minor modifications are more common than originally thought.

As outlined previously, some new products may require premarket authorization under section 910(c), and an unknown proportion of the remaining products would be introduced through the exemption pathway. This rule does not require a one-to-one correspondence between the exemption requests and new products introduced through the exemption pathway. Based on the number and content of substantial equivalence reports FDA has received so far, FDA estimates that in the first years after the procedure is in place, 500 exemption requests will be submitted per year covering 750 new tobacco products. This number has been revised upward substantially from the estimate in the preliminary regulatory impact analysis as FDA has learned from industry comments and from substantial equivalence reports that tobacco product manufacturers make many small modifications to their products which may qualify for an exemption. FDA anticipates requesting additional information to support 150 of those exemption requests. This number is uncertain because it depends on the quality of the initial requests.

#### *F. Benefits and Costs*

The main effect of this final rule would be a potential reduction in the costs of introducing new tobacco products compared with the current baseline. Under the baseline scenario, all new products that do not undergo premarket review under section 910(c) must submit a substantial equivalence report under section 905(j)(1)(A)(i). If an exemption request is submitted and granted, a manufacturer would be able to submit a different 905(j) report in which, under section 905(j)(1)(A)(ii), a discussion of the exemption(s) is used in place of the demonstration of

substantial equivalence. On a per-product basis, when one exemption request covers one new tobacco product, the cost savings attributable to this rule equals the difference between the cost of demonstrating substantial equivalence and the cost of both requesting an exemption and submitting a report under section 905(j)(1)(A)(ii).<sup>3</sup> The savings could be greater in cases in which a single exemption request is used for multiple products.

FDA has concluded that we significantly overestimated the burden of requesting a substantial equivalence exemption as we prepared the proposed rule. The estimate, 360 hours, was based in part on other submission processes the Agency has direct experience with, but there was no ideal existing submission process to which to compare a substantial equivalence exemption request. We did not yet have experience reviewing the substantial equivalence reports this pathway provides an exemption from. Since publication of the proposed rule, we have gained additional information from reviewing comments and initial substantial equivalence reports and through other activities within the usual scope of operation of FDA's Center for Tobacco Products. We now know more about the range of modifications that are made to tobacco products. Based on the limited information required to be submitted relative to a substantial equivalence report, we now estimate that preparing an exemption request will require 12 hours for the requirements of § 1107.1(b)(1) through § 1107.1(b)(8). We also estimate an additional 12 hours will be required to prepare the environmental assessment, for a total of 24 hours. For more detail on the estimate, see section VIII of this document, which explains that an exemption request does not require a comparison to a predicate or inclusion of information on multiple characteristics, but rather requires limited information for the product that is the subject of the exemption request and on the modification of the additive.

Based on the requirements set forth in the codified language, FDA anticipates that preparation of most sections would require technical scientific and engineering expertise. Legal input and review would also play a role. Therefore, in valuing the time cost, FDA uses the weighted average of tobacco manufacturing industry-specific hourly wages for life, physical, and social science occupations (\$30.91), architecture and engineering

<sup>3</sup> An environmental assessment would be required with either pathway.

occupations (\$40.93), and legal occupations (\$71.83) (Ref. U.S. BLS, 2010). FDA assigns these occupational categories weights of 40 percent, 40 percent, and 20 percent. The resulting composite wage is \$43.10. FDA then doubles this amount to \$86.20 to account for benefits and overhead. Multiplying this wage by the burden estimates above yields a cost per exemption request of \$1,034 for the requirements of § 1107.1(b)(1) through § 1107.1(b)(8) and an additional \$1,034 for the environmental assessment, or a total of \$2,069. FDA anticipates that when it asks a manufacturer to provide additional information in support of an exemption request, it will take an average of 3 hours to prepare the additional information. Using the same hourly cost of labor, providing additional information is estimated to result in an additional cost of \$259.

Under the Tobacco Control Act, completion of the substantial equivalence pathway for marketing a new tobacco product requires submission of a report under section 905(j)(1)(A)(ii). This is a basic requirement that is expected to take 3 hours. Valued at a wage of \$86.20, it would then cost \$259 to submit one report under section 905(j)(1)(A)(ii).

In the case that one exemption request covers one product and the exemption is granted without a request for additional information, the substantial equivalence exemption pathway (consisting of an exemption request, including an environmental assessment, and a subsequent report under section 905(j)(1)(A)(ii) for a product embodying one modification) would take 27 hours at a cost of \$2,328. These are elective costs in that firms will not choose this pathway unless the potential savings relative to demonstrating substantial equivalence justifies the risk of submitting an exemption request that is ultimately denied. The preliminary time burden estimate for submitting a substantial equivalence report under section 905(j)(1)(A)(i) was 360 hours. This estimate is currently being updated based on the initial submissions to the Agency, but for a new tobacco product satisfying the criteria for an exemption, we anticipate that the burden of preparing a substantial equivalence report and an environmental assessment will continue to be appreciably higher than the burden described previously for utilizing the exemption pathway.

Based on FDA's expectation that 500 exemption requests will be received per year, the absolute cost of preparing exemption requests would be \$517,224 for the requirements of § 1107.1(b)(1) through § 1107.1(b)(8) and an additional

\$517,224 for the environmental assessments. The absolute cost of replying to requests for additional information would be \$38,792 if, as anticipated, we ask for additional information supporting 150 of the 500 requests. If these exemptions are cited in the 905(j)(1)(A)(ii) reports for 750 new products, those reports would cost an additional \$193,959. If all these exemptions were granted, the total savings attributable to this rule would be the difference between the cost of bringing all 750 products to market through the substantial equivalence pathway and the sum of the four costs enumerated above. However, the cost savings is expected to be lower because it is unlikely that all the requested exemptions would be granted.

In order to grant an exemption, FDA must find, among other things, that a report demonstrating substantial equivalence would not be necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health. Furthermore, an exemption could be rescinded if found to be inappropriate, and the process for rescission would depend on whether there is a serious risk to public health. Therefore, FDA does not anticipate that setting up this mechanism for obtaining substantial equivalence exemptions will result in costs to public health.

Under this final rule, there may still be some uncertainty on the part of manufacturers about what kinds of product modifications may be granted an exemption and how much supporting evidence will be required as the basis for an exemption. If some manufacturers are more conservative in requesting exemptions than FDA would be in granting them, they may not fully avail themselves of the potential cost savings. Alternatively, if some manufacturers are too optimistic about what types of modifications will be exempt, they will incur higher costs because they will have to submit substantial equivalence reports in addition to having submitted unsuccessful exemption requests.

FDA acknowledges the theoretical possibility that overall submission costs could increase as the result of this uncertainty. This would happen if so many unsuccessful exemption requests were submitted that the excess costs associated with them exceeded any cost savings from exemptions that were granted. This situation is unlikely to occur, especially in the long run. The cost of submitting an exemption request is expected to be low relative to the potential savings. As time goes on and manufacturers gain experience with

submission costs and the requirements that must be met for exemptions, they might continue to submit unsuccessful exemption requests, but this would increasingly be a well-informed choice based on an accurate estimation of the probability of being granted an exemption and the excess cost of preparing an unsuccessful request compared with the cost savings attributable to an exemption. Moreover, it is possible that some of the information compiled for an exemption request would be reused as part of a demonstration of substantial equivalence, thus reducing the effort expended in preparing both types of submissions.

#### G. Conclusion

In summary, the substantial equivalence exemption requirements laid out in this final rule offer an additional channel for legally introducing new tobacco products that result from minor modifications of tobacco products that can be sold under the FD&C Act. Successfully introducing a product through this channel is expected to reduce costs. If manufacturers do not want to risk having to submit substantial equivalence reports in addition to having submitted unsuccessful exemption requests, they may choose to maintain the status quo and not pursue substantial equivalence exemptions.

#### H. Regulatory Flexibility Act

The Tobacco Control Act requires that tobacco product manufacturers obtain either a marketing authorization order under section 910(c) or an order under section 910(a)(2) finding the new tobacco product to be substantially equivalent to an appropriate predicate tobacco product before introducing a new product into interstate commerce. Although this requirement is costly, the option of requesting an exemption as set forth in this final rule provides an alternative pathway that potentially reduces costs. Manufacturers of new tobacco products may choose not to use this alternative pathway to market their products. Therefore, this final rule imposes no incremental burden from which to provide relief and will not have a significant impact on a substantial number of small entities.

#### VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the paragraphs that follow

with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title:* Exemptions from Substantial Equivalence Requirements for Tobacco Products, Final Rule.

*Description:* In this final rule, a pathway would be established by FDA for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act. As it acquires more information about the additives in tobacco products from which to establish categories of exemptions, FDA may issue additional regulations or guidance on this subject. This rule would implement section 905(j)(3) of the FD&C Act, under which FDA may exempt tobacco products that are modified by adding or deleting a tobacco additive, or 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 FD&C Act, (2) a report 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.

The rule also explains that an exemption request may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that manufacturer's product and the request (and supporting information) must be submitted in an electronic format that FDA can process, review, and archive. In addition, the request and all supporting information must be legible and in (or translated into) the English language.

Under the rule, an exemption request must be submitted with supporting documentation and contain the manufacturer's address and contact information; identification of the tobacco product(s); a detailed explanation of the purpose for the modification; a detailed description of the modification; a detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the FD&C Act; a detailed explanation of why a report under section 905(j)(1)(A)(i) intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health; a certification summarizing the supporting evidence and providing the rationale for why the

modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability; other information justifying an exemption; and an environmental assessment under part 25 prepared in accordance with § 25.40.

As described previously, the request must contain a certification by a responsible official summarizing the supporting evidence and providing the rationale for the official's determination that the modification will not increase the product's toxicity, addictiveness, or appeal to/use by minors; and include other information justifying an exemption. This information will enable FDA to determine whether the exemption request would be appropriate for the protection of the public health. This final rule also includes a procedural mechanism for rescinding an exemption where necessary to protect the public health. In general, FDA would rescind an exemption only after providing the manufacturer notice of the proposed rescission and an opportunity for an informal hearing under part 16 (21 CFR part 16). However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 if the continuance of the exemption presents a serious risk to public health. In that case, FDA would provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

FDA will review the information submitted in support of the request and determine whether to grant or deny the request based on whether the criteria specified in the statute are satisfied. If FDA determines that the information submitted is insufficient to enable it to determine whether an exemption is appropriate, FDA may request additional information from the manufacturer. If the manufacturer fails to respond within the timeframe

requested, FDA will consider the exemption request withdrawn.

*Description of Respondents:* Manufacturers of tobacco products who are requesting an exemption from the substantial equivalence requirements of the FD&C Act, as amended by the Tobacco Control Act.

*Comments:* FDA received several comments related to the PRA in response to its proposed rule (76 FR 737). Several comments noted that the hours per response were the same for both an exemption request and the submission of a 905(j) substantial equivalence report, which indicated that the exemption pathway would not be less burdensome than the substantial equivalence report. Some comments stated that the estimated hours suggested a very burdensome process, and other comments suggested that the estimated hours were too low given the information required by § 1107.1.

The estimated hours per response in the NPRM were based on Agency experience and approved information collections for other types of submissions to the FDA, although those also vary greatly depending on the statutory requirements and there was no exact parallel for this process. The estimated hours for the exemption request also reflected considerations that initial exemption requests may take longer to prepare, until knowledge and experience with the pathway develops. We believed that 360 hours per exemption request would be at the high end of the estimated hours per response, but did not want to underestimate the hours per response particularly at the outset of the process before experience with requesting exemptions develops. The comments to the NPRM provided FDA with a much better sense of the range of modifications that are made to tobacco products and after reviewing the information, we believe we overestimated the hours that would be

needed to prepare an exemption request. Our revised estimates reflect the fact that the preparation and submission of an exemption request differs significantly from preparation of a substantial equivalence report under section 905(j)(1)(A)(i). For example, the preparation of an exemption request does not require a comparison to a predicate or inclusion of information on multiple characteristics, but rather requires more limited information for the product that is the subject of the exemption request and on the modification of the additive.

Additionally, several comments to the proposed rule stated that the number of exemption requests may be much higher than the 50 indicated in the proposed rule with some comments suggesting as high as hundreds or thousands depending on the scope of modifications that might use the pathway. After considering potential use of this process as indicated by the comments, we are increasing that number of requests to 500 on a yearly basis.

One comment also suggested that the proposed rule was not compliant with the PRA because there was no practical utility for the information collected and there is no plan for the efficient and effective use of the information to be collected. We disagree with these comments because, as several comments to the proposal noted, the regulation follows the statutory language, including the findings that FDA must make when determining whether it may make an exemption determination. The information that the rule requires is information that FDA needs in order to make the required findings, for example, information as to whether the modification is minor. Without the information required by the rule, FDA will not have the information necessary to determine whether an exemption is appropriate.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR section or FD&C act section	Number of respondents	Number of response er respondent	Total annual responses	Average burden per response	Total hours
1107.1(b) .....	500	1	500	12	6,000
1107.1(c) .....	150	1	150	3	450
25.40 .....	500	1	500	12	6,000
905(j)(1)(A)(ii) .....	750	1	750	3	2,250
Total .....	.....	.....	.....	.....	14,700

Table 1 describes the annual reporting burden as a result of the provisions set forth in this final rule. Based on

comments and information on the NPRM, FDA estimates that it will receive 500 exemption requests

annually and that it will take a manufacturer 12 hours to prepare an exemption request. FDA estimates that

it would need to request additional data for 150 of these requests in part due to the fact that it is a new process, and that it will take 3 hours to prepare a response to a request for additional data. FDA anticipates using the rescission authority to respond to one issue of concern related to an exemption determination each year (the burden hours for § 1107.1(d) are included under part 16 hearing regulations and are not included in the burden estimates in Table 1 of this document).

FDA is also including an estimation of the burden associated with preparing the report required by section 905(j)(1)(A)(ii) of the FD&C Act. FDA estimates that it will take 3 hours to prepare the report required by section 905(j)(1)(A)(ii), which requires a manufacturer to submit a report at least 90 days prior to making an introduction or delivery into interstate commerce for commercial distribution of a tobacco product, with the basis for the manufacturer's determination that the tobacco product is modified within the meaning of the exemption provision (section 905(j)(3)), the modifications are to a product that is commercially marketed and in compliance with the FD&C Act, the modifications are covered by exemptions granted under section 905(j)(3), and action taken to comply with any applicable requirements of section 907. FDA is also including an estimation of the burden associated with preparing an environmental assessment under part 25 prepared in accordance with the requirements of § 25.40, as referenced in § 1107.1(b)(9). FDA estimates that it will take 12 hours to prepare the environmental assessment.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

## IX. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various

levels of government. Accordingly, the Agency concludes that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

## X. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**).

1. U.S. Census Bureau, 2007 Economic Census, "Sector 31: EC073111: Manufacturing: Industry Series: Detailed Statistics by Industry for the United States: 2007," release date: October 30, 2009, access date: August 30, 2010, ([http://factfinder.census.gov/servlet/IBQTable?\\_bm=y&-ds\\_name=EC073111&-NAICS2007=312210&-312221&-312229&-ib\\_type=NAICS2007&-geo\\_id=&-industry=312221&-lang=en&-fds\\_name=EC0700A1](http://factfinder.census.gov/servlet/IBQTable?_bm=y&-ds_name=EC073111&-NAICS2007=312210&-312221&-312229&-ib_type=NAICS2007&-geo_id=&-industry=312221&-lang=en&-fds_name=EC0700A1)).
2. U.S. Bureau of Labor Statistics, "Occupational Employment Statistics: May 2009 National Industry-Specific Occupational Employment and Wage Estimates NAICS 312200—Tobacco Manufacturing," May 14, 2010, [http://data.bls.gov/cgi-bin/print.pl/oes/current/naics4\\_312200.htm](http://data.bls.gov/cgi-bin/print.pl/oes/current/naics4_312200.htm).

## List of Subjects

### 21 CFR Part 16

Administrative practice and procedure.

### 21 CFR Part 1107

Tobacco products, Substantial equivalence, Exemptions.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 1107 are amended to read as follows:

## PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

- 1. The authority citation for 21 CFR part 16 continues to read as follows:

**Authority:** 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

### § 16.1 [Amended]

- 2. Section 16.1 is amended in paragraph (b)(2) by adding in numerical sequence "§ 1107.1(d), relating to

rescission of an exemption from the requirement of demonstrating substantial equivalence for a tobacco product."

- 3. Add part 1107 to subchapter K to read as follows:

## PART 1107—ESTABLISHMENT REGISTRATION, PRODUCT LISTING, AND SUBSTANTIAL EQUIVALENCE REPORTS

### Subpart A—Exemptions

Sec.

1107.1 Exemptions.

### Subpart B [Reserved]

**Authority:** 21 U.S.C. 387e(j) and 387j.

### Subpart A—Exemptions

#### § 1107.1 Exemptions.

(a) *General requirements.* Under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e(j)(3)), FDA may exempt from the requirements relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 910 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387j), tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if FDA determines that:

(1) Such modification would be a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act (a legally marketed tobacco product);

(2) A report under section 905(j)(1) intended to demonstrate 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.

(b) *Request for an exemption under section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act.* A request for an exemption from the requirement of demonstrating substantial equivalence may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product. To request an exemption, the manufacturer must submit the request and all information supporting the request in an electronic format that FDA can process, review, and archive. If the manufacturer is unable to submit an exemption request in an electronic format, the manufacturer may submit a written request to the Center for Tobacco Products explaining in detail why the manufacturer cannot submit

the request in an electronic format and requesting an alternative format. Such request must include an explanation of why an alternative format is necessary. All submissions, including requests to submit the information in an alternative format, requests for exemptions, and all supporting information must be legible and in the English language. An exemption request must contain:

(1) The manufacturer's address and contact information;

(2) Identification of the tobacco product(s);

(3) A detailed explanation of the purpose of the modification;

(4) A detailed description of the modification, including a statement as to whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive;

(5) A detailed explanation of why the modification is a minor modification of a tobacco product that can be sold under the Federal Food, Drug, and Cosmetic Act;

(6) A detailed explanation of why a report under section 905(j)(1) of the Federal Food, Drug, and Cosmetic Act intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health;

(7) A certification (*i.e.*, a signed statement by a responsible official of the manufacturer) summarizing the supporting evidence and providing the rationale for the official's determination that the modification does not increase the tobacco product's appeal to or use by minors, toxicity, addictiveness, or abuse liability;

(8) Other information justifying an exemption; and

(9) An environmental assessment under part 25 of this chapter prepared in accordance with the requirements of § 25.40 of this chapter.

(c) *Exemption determination.* FDA will review the information submitted and determine whether to grant or deny an exemption request based on whether the criteria in section 905(j)(3) of the Federal Food, Drug, and Cosmetic Act are met. FDA may request additional information if necessary to make a determination. FDA will consider the exemption request withdrawn if the information is not provided within the requested timeframe.

(d) *Rescission of an exemption.* FDA may rescind an exemption if it finds that the exemption is not appropriate for the protection of public health. In general, FDA will rescind an exemption only after notice and opportunity for a hearing under part 16 of this chapter is

provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under part 16 of this chapter if the continuance of the exemption presents a serious risk to public health. In that case, FDA will provide the manufacturer an opportunity for a hearing as soon as possible after the rescission.

#### Subpart B—[Reserved]

Dated: June 29, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-16766 Filed 7-1-11; 8:45 am]

BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 201

[Docket No. FDA-1978-N-0018] (formerly Docket No. 1978N-0038)

RIN 0910-AF43

#### Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use

##### *Correction*

In rule document 2011-14766 appearing on pages 35620-35665 in the issue of Friday, June 17, 2011, make the following correction:

##### § 201.327 [Corrected]

In § 201.327, on page 35661, in the third column, § 201.327(i)(1)(ii)(A)(2) and (3) should read as follows:

(2)  $V_i(\lambda) = 10^{0.094 * (298-\lambda)}$  ( $298 < \lambda \leq 328$  nm)

(3)  $V_i(\lambda) = 10^{0.015 * (140-\lambda)}$  ( $328 < \lambda \leq 400$  nm)

[FR Doc. C1-2011-14766 Filed 7-1-11; 8:45 am]

BILLING CODE 1505-01-D

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[Docket No. USCG-2011-0198]

RIN 1625-AA00

#### Safety Zone; Upper Mississippi River, Mile 856.0 to 855.0, Minneapolis, MN

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone for

all waters of the Upper Mississippi River, from Mile 856.0 to 855.0, Minneapolis, Minnesota, and extending the entire width of the river. This safety zone is needed to protect participants and event personnel during the U.S. Wakeboard Nationals occurring on the Upper Mississippi River. Entry into this zone is prohibited unless specifically authorized by the Captain of the Port Upper Mississippi River or a designated representative during the period of enforcement.

**DATES:** This rule is effective from 8 a.m. on July 20, 2011 through 6 p.m. CDT on July 24, 2011.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0198 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0198 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, call or e-mail Chief Petty Officer Bryan Klostermeyer, Sector Upper Mississippi River Response Department at telephone (314) 269-2566, e-mail [Bryan.K.Klostermeyer@uscg.mil](mailto:Bryan.K.Klostermeyer@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest."

Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not using the notice of proposed rulemaking (NPRM) process. The Coast Guard received notice of the U.S. Wakeboard Nationals event on May 11, 2011. This short notice did not allow the time needed to publish a NPRM and provide a comment period. Delaying this rule by publishing a NPRM would be impracticable because this rule is