Section 2(h)(1)(B) of the Act), membership (as described in Section 5(b)(c)(2)(C) of the Act), and the finding of products acceptable or not acceptable for clearing. In describing such decisions, the derivatives clearing organization shall specifically disclose whether:

(*1*) Its Board of Directors has rejected a recommendation or superseded an action of the Risk Management Committee; or

(*2*) The Risk Management Committee has rejected a recommendation or superseded an action of its subcommittee (as described in § 39.13(g)(5) of this part).

(C) Nothing in the foregoing shall be construed as requiring a designated contract market, a registered swap execution facility, or a derivatives clearing organization to disclose any "non-public information" (as § 1.3(ggg) of this chapter defines such term), including, without limitation, minutes from meetings of its Board of Directors or committees and information that it may have received on a confidential basis from an applicant for membership.

(2) The registered entity must ensure that the information specified in paragraphs (d)(1)(i) to (vii) of this section is current, accurate, clear, and readily accessible, for example, on its Web site. The registered entity shall set forth such information in a language commonly used in the commodity futures and swap markets and at least one of the domestic language(s) of the jurisdiction in which the registered entity is located.

(e) *Regulatory Program.* (1) As part of its regulatory program, each registered derivatives clearing organization, designated contract market, or registered swap execution facility must establish, maintain, and enforce written procedures to:

(i) Identify, on an ongoing basis, existing and potential conflicts of interest; and

(ii) Make fair and non-biased decisions in the event of a conflict of interest. Such procedures shall include rules regarding the recusal, in applicable circumstances, of parties involved in the making of decisions. The Chief Compliance Officer of a registered derivatives clearing organization or registered swap execution facility shall, in consultation with the Board of Directors of the entity, an equivalent body, or a senior officer of the entity, resolve any such conflicts of interest.

(f) *Limitations on Use or Disclosure of Non-Public Information.* (1) Each registered entity must establish and maintain written policies and procedures on safeguarding non-public information gained through either an ownership interest or through the performance of official duties (including duties associated with self-regulatory or regulatory purposes) by members of its Board of Directors, members of any committee, or officers and other employees.

(2) Such policies and procedures shall comport, at a minimum, with the following principles:

(i) No individual or entity described in paragraph (f)(1) of this section shall use or disclose any non-public information, absent prior written consent from the relevant registered entity. A registered entity shall establish guidelines that specify the information that must be included in the written consent.

(ii) No individual or entity described in paragraph (f)(1) of this section shall, either during or after service with the relevant registered entity:

(A) Use, directly or indirectly, information that the registered entity deems to be non-public information; or

(B) Disclose non-public information to others, except:

(*1*) To others within the relevant registered entity or to outside advisors thereof, provided that such advisors are subject to confidentiality obligations, and that such disclosure is necessary for the performance of official duties by the individual or entity;

(*2*) If required by regulatory authority; or

(*3*) If compelled to so by valid legal process, provided that the individual or entity notifies the relevant registered entity.

Issued in Washington, DC, on December 9, 2010, by the Commission.

David A. Stawick,

Secretary of the Commission.

Note: The following appendices will not appear in the Code of Federal Regulations.

Appendices to Governance Requirements for Derivatives Clearing Organizations, Designated Contract Markets, and Swap Execution Facilities; Additional Requirements Regarding the Mitigation of Conflicts of Interest—Commission Voting Summary and Statements of Commissioners

Appendix 1—Commission Voting Summary

On this matter, Chairman Gensler and Commissioners Dunn, Sommers, Chilton and O'Malia voted in the affirmative; no Commissioners voted in the negative.

Appendix 2—Statement of Chairman Gary Gensler

I support the proposed rule on further governance and conflicts of interest requirements for derivatives clearing organizations (DCOs), designated contract markets (DCMs) and swap execution facilities (SEFs). The proposed rule complements the conflicts of interest provisions that the Commission proposed on October 1st by keeping regulators up to date about the composition of boards, board committees and ownership, promoting transparency in decision-making and ensuring limitations on use or disclosure of non-public information. The proposed rule also provides guidance to industry and the public on appropriate minimum governance fitness standards for DCOs and DCMs, as well as the manner in which market participants must be heard or included in DCO or DCM governance arrangements. The proposed rule would enhance the integrity of clearing and trading and would increase public trust in the facilities on which such important activities occur.

[FR Doc. 2010–31898 Filed 1–5–11; 8:45 am]

BILLING CODE 6351–01–P

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this proposed 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 proposed rule would describe the process and statutory criteria for requesting an exemption and explain how FDA would review requests for exemptions. Once finalized, this regulation will satisfy the requirement in the Tobacco Control Act that FDA issue regulations implementing the exemption provision.

DATES: Submit either electronic or written comments on the proposed rule by March 22, 2011. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by February 7, 2011, (*see* the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: You may submit comments, identified by [Docket No. FDA–2010–N–0646 and/or RIN number 0910–AG39], by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (*see* the "Paperwork Reduction Act of 1995" section of this document).

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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*.

SUPPLEMENTARY INFORMATION:

I. Background

The Tobacco Control Act, enacted on June 22, 2009, amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and provides FDA with the authority to regulate tobacco products (Pub. L. 111–31, 123 Stat. 1776). Among other things, the Tobacco Control Act requires that, before a new tobacco product may be introduced or delivered for introduction into interstate commerce, one of the following must occur: (1) A premarket application under section 910(b) of the FD&C Act (21 U.S.C. 387j(b)) must be submitted to FDA, and FDA must issue an order finding that the new product may be introduced or delivered for introduction into interstate commerce under 910(c) of the FD&C Act; or (2) a report under section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) demonstrating the new tobacco product's substantial equivalence to an appropriate predicate product (as defined in the FD&C Act) must be submitted and FDA must issue an order finding the new product to be substantially equivalent to the predicate product and in compliance with the requirements of the Tobacco Control Act (section 910(a)(2) of the FD&C Act). Section 905(j)(3) of the FD&C Act, as amended, states that 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, from the requirement of demonstrating substantial equivalence if the Agency determines that: (1) Such modification would be a minor modification of a tobacco product that can be sold under the FD&C Act, (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the product to be marketed would be appropriate for the protection of the public health, and (3) an exemption is otherwise appropriate. Section 905(j)(3)(B) of the FD&C Act requires FDA to issue regulations implementing this provision by July 1, 2011.

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

The proposed rule, if finalized, would establish a pathway for manufacturers, including importers, to request exemptions from the substantial equivalence requirements of the Tobacco Control Act. It would not establish categories of minor modifications, or identify specific modifications, that meet the statutory criteria for exemptions. As FDA acquires more information about the additives in tobacco products from which to establish such categorical exemptions, it may issue additional regulations or guidance. FDA requests comment on how best to establish categories for these exemptions.

A manufacturer who obtains an exemption under the procedures of this proposed rule is also required to report to FDA under 905(j)(1)(A)(ii) of the FD&C Act (this requirement is not addressed in this proposed rule). Section 905(j)(1)(A)(ii) of the FD&C Act requires the manufacturer to report 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 manufacturer'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)]" (section 905(j)(1)(A)(ii) of the FD&C Act). In addition, this submission must describe "action taken by [the applicant] to comply with the requirements under section 907 that are applicable to the tobacco product" (section 905(j)(1)(B) of the FD&C Act).

The proposed rule includes a procedural mechanism for rescinding an exemption where necessary to protect the public health. Before rescinding an exemption, FDA proposes to provide the manufacturer notice of the proposed rescission and an opportunity for an informal hearing under part 16 (21 CFR part 16), unless the continuance of the exemption presents a serious risk to public health. If the continuance of the exemption presents a serious risk to public health, FDA would rescind the exemption prior to giving notice and an opportunity for a hearing, and provide notice and opportunity for an informal hearing under part 16 as quickly as possible following the rescission.

II. Overview of the Proposed Rule

As required by section 905(j)(3)(B) of the FD&C Act, this rule would implement section 905(j)(3) of the FD&C Act. Specifically, the rule would provide that 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 the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act; a 905(j) report demonstrating

substantial equivalence to a predicate tobacco product 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. These criteria are specified in the statute.

The proposed rule also explains that an exemption request may be made only by the manufacturer of a legally, commercially marketed tobacco product for a minor modification to that manufacturer's product. FDA is proposing this requirement because it believes that only the manufacturer of the product being modified will have, and be able to provide to FDA, sufficient and complete information about the product and the proposed modification. This includes information about a tobacco product that is trade secret or confidential commercial information and available only to the manufacturer of the product. Such information is necessary to allow FDA to determine whether the tobacco product and modification satisfy the criteria for exemption.

The proposed rule would also require that the exemption request (and supporting information) be submitted in an electronic format that FDA can process, review, and archive. FDA intends to provide and update information on its website on how manufactures may provide the electronic submission to FDA (*e.g.,* information on electronic media and methods of transmission). The proposed rule would also require that the exemption request be legible (FDA must be able to read the document) and in English. These requirements would ensure that FDA could review the exemption request expeditiously and appropriately. Electronic submission of information is consistent with the Government Paperwork Elimination Act (Pub. L. 105–277) requirement that Federal agencies allow individuals or entities to submit information or transact business with the agency electronically. Because of the broad availability of the Internet, FDA does not anticipate any need to submit an exemption request and supporting information in a non-electronic format. However, a company that is not able to submit an exemption request in an electronic format may submit a written request to the Center for Tobacco Products explaining in detail why the company cannot submit the request in an electronic format and requesting an alternative format.

The proposed rule would require that an exemption request be submitted with supporting documentation and contain the manufacturer's address and contact information; a detailed explanation of the purpose for the modification; a detailed description of the modification, including whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive; a detailed explanation of why the modification is considered a minor modification of a tobacco product that can be sold under the FD&C Act; a detailed explanation of why a report 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 public health; a certification by a responsible official of the company, such as the chief executive officer, 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 or use by minors; and other information justifying an exemption.

The rule would require the submission of this information, along with supporting documentation, to enable FDA to determine whether an exemption from having to demonstrate substantial equivalence to an appropriate predicate product would be appropriate for the protection of the public health, as required by the statute (section 905(j)(3) of the FD&C Act). FDA requests comment on what supporting information would be necessary for us to make these determinations. The proposed rule would also require a certification in the form of a signed statement by a responsible official of the company, 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 or use by minors. Because of the importance of this information to an exemption determination, FDA is proposing to require that a responsible official of the company, such as the chief executive officer, certify that the modification will not have these effects.

The proposed regulation explains that FDA would review the information submitted in support of the request and determine whether to grant or deny the request for an exemption based on whether the criteria in the statute are satisfied. The proposed rule also provides that, if FDA determines that the information submitted by the manufacturer is insufficient to enable it to determine whether an exemption is appropriate, FDA may request additional information from the manufacturer. The rule would also provide that if the manufacturer fails to respond within the timeframe requested, FDA will consider the exemption request withdrawn. An exemption determination will be publicly available consistent with the requirements of part 20 (21 CFR part 20); trade secret and confidential commercial information are exempted from disclosure requirements consistent with § 20.61.

As discussed earlier in this document, the proposed rule includes a provision expressly permitting FDA to rescind an exemption if the Agency determines that rescission is necessary to protect the public health. FDA believes it is important that it be able to rescind exemptions in circumstances where the exemption is not appropriate for the public health, such as when FDA's decision to grant an exemption was based on false or incomplete information. FDA is proposing to provide notice and an opportunity for an informal hearing under part 16 to the manufacturer who requested the exemption prior to rescinding an exemption. If, however, the continuance of the exemption presents a serious risk to public health, the proposed rule provides that FDA could rescind the exemption before providing notice and an opportunity for a hearing. In that case, FDA would provide the manufacturer notice and an opportunity for a hearing as soon as possible after the rescission.

Consistent with the requirements of the FD&C Act, 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 (section 901(f) of the FD&C Act). FDA requests comment on what technical assistance or guidance would be helpful to small manufacturers in complying with these requirements. Small tobacco product manufacturers may contact FDA at *smallbiz.tobacco@fda.hhs.gov* for assistance.

III. Effective Date

FDA proposes that any final rule that issues based on this proposal become effective 30 days after the final rule publishes in the **Federal Register**.

IV. Legal Authority

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. 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 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. FDA is issuing this proposed 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.

V. Environmental Impact

The Agency has determined under 21 CFR 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.

VI. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed rule under Executive order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs 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 proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. 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 proposed rule provides a mechanism for potentially reducing costs. If manufacturers of new tobacco products do not expect this option to reduce costs associated with their new product submissions, they will choose not to use it. The Agency therefore proposes to certify that the 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 $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Baseline

FDA compares the effects of this rule to a baseline we will refer to as the post-statute baseline. Under the Tobacco Control Act, in the absence of this or other rulemaking under section 905(j)(3), tobacco product manufacturers must submit to FDA either a premarket application or a report under section 905(j) 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. Although substantial equivalence requirements are not yet in effect, the statutory grace period ends on March 22, 2011. The statutory deadline for issuing regulations under section 905(j)(3) is July 1, 2011, after the end of the grace period. Therefore, under the post-statute baseline we assume that requirements to report under 905(j) will be in effect. Compared with the cost associated with the post-statute baseline, this rule may result in cost savings if some tobacco manufacturers request, and are granted, substantial equivalence exemptions. If for any reason this proposed rule is finalized before the substantial equivalence requirements go into effect, it would simply have no effect until such time that they do.

C. Number of Affected Entities

This proposed 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 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.[1] An unknown number of importers would be affected.[2] Not all new tobacco products are expected to meet the statutory requirements for an exemption. Furthermore, FDA is not establishing categories of minor modifications, or identifying specific modifications, that meet the statutory criteria for exemptions. It is therefore likely that only a subset of the potentially affected manufacturers and importers would choose to request an exemption.

D. 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 would not be eligible for a substantial equivalence exemption. The remaining products would require 905(j) reports, including demonstration of substantial equivalence. Under this proposed rule, an unknown number of those new 905(j) products would be eligible for possible introduction into interstate commerce under a substantial equivalence exemption.

FDA uses scanner data covering late 2007 to late 2009 from AC Nielsen to estimate the number of new tobacco products introduced in a year. A Universal Product Code (UPC) is deemed to be introduced in 2008 if total dollar sales over the final weeks of 2007 were zero, but total dollar sales over 2008 were greater than zero. Because unique UPCs are assigned to different types of packaging for otherwise identical products, most new UPCs do not represent new products, but rather different ways of packaging existing products. To address this issue, FDA

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

[2] Manufacturers, wholesalers, and retailers could all theoretically import tobacco products. Census data do not distinguish firms that import from firms that do not.

sorts the data by brand description, and by product description within each brand description. The product description varies by UPC and contains information about both product characteristics and packaging. Therefore, the product description of every new UPC can be compared with the product descriptions preceding and following it to determine whether the new UPC represents a new package for an existing product or a new product altogether.

Using the scanner data, FDA finds that of 628 new UPCs for cigarettes in 2008, 151 represent new products not present in the 2007 data. Of 215 new UPCs for chewing tobacco, 43 represent new products. Of 36 new UPCs for smoking tobacco (excluding pipe tobacco), 20 represent new products.[3] Of 36 new UPCs for cigarette paper, 19 represent new products. This leads to an estimated 233 new products in 2008. We assume the same average number of new products will continue to be introduced every year going forward. 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.

As outlined previously, some of the estimated 233 new products introduced annually may require premarket authorization under section 910(c), and exemptions would be requested for an unknown number of the remaining products. Although in theory the maximum number of requests equals the number of new products, based on the requirements for an exemption and experience with other regulated products, FDA estimates that in the first years after the procedure is in place, only 50 exemption requests will be submitted per year. This may increase over time as learning takes place. FDA anticipates requesting additional information to support 40 of those requests.

E. Benefits and Costs

The main effect of this proposed rule would be a potential reduction in the costs of introducing new tobacco products compared with the post-statute baseline. Under the baseline scenario, all new products that do not undergo premarket review under section 910(c) must submit a report under section 905(j) that includes the basis for manufacturer's determination that the new tobacco product is substantially equivalent to an appropriate predicate tobacco product. If an exemption request is submitted and granted, a manufacturer would be able to submit a different and potentially shorter 905(j) report in which, under 905(j)(1)(A)(ii), a discussion of the exemption is used in place of the demonstration of substantial equivalence. On a per-product basis, any potential cost savings for the 905(j) report, net of the cost of requesting the exemption, would be the savings attributable to this rule.

FDA estimates that it would take 360 hours to prepare an exemption request. 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 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 by 360 hours yields a cost per exemption request of $31,033. FDA anticipates that when it asks a manufacturer to provide additional information in support of an exemption request, it will take an average of 50 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 $4,310. These are elective costs. Firms will not choose to submit a request unless any potential cost savings in a 905(j) report justifies the cost.

Using FDA's estimate that we expect to receive 50 requests per year, the total cost of all exemption requests submitted would be $1,551,700. There would be an additional cost of $172,400 if, as anticipated, we ask for additional information supporting 40 of the 50 requests. FDA requests comment on these cost estimates.

Because substantial equivalence report requirements are not yet being enforced, and there is no guidance beyond the contents of the Tobacco Control Act, FDA does not attempt to estimate the cost of preparing a 905(j) report that includes the demonstration of substantial equivalence or the cost of preparing a 905(j) report citing an exemption. Some manufacturers may find that, for a particular product, preparing a 905(j) report that includes the basis for the manufacturer's determination that its new tobacco product is substantially equivalent to an appropriate predicate tobacco product would be costlier than submitting an exemption request and citing the exemption in a 905(j) report. Such a manufacturer may consider submitting an exemption request. If a manufacturer finds that the exemption process would not reduce costs for legally introducing a new tobacco product, it would maintain the post-statute status quo and submit a 905(j) that includes the basis for the manufacturer's determination that its new tobacco product is substantially equivalent to an appropriate predicate tobacco product. FDA requests comment on these conclusions.

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 a mechanism for obtaining substantial equivalence exemptions would result in costs to public health. FDA requests comment on this approach.

Under this proposed rule, there may be uncertainty on the part of manufacturers as to 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 any 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 demonstrate substantial equivalence in their 905(j) 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

[3] The smoking tobacco category refers to tobacco products, other than cigarettes, cigars and accessories, which are intended to be smoked. Smoking tobacco products are further identified in the data as cigarette tobacco (roll-your-own), smoking tobacco, or pipe tobacco. Since pipe tobacco is not currently subject to the Tobacco Control Act, products clearly identified as such are excluded from the analysis.

associated with them exceeded any cost savings from exemptions that were granted. This situation is unlikely to occur, especially as time goes on and manufacturers gain information on submission costs and the requirements that must be met for exemptions. Manufacturers might continue to submit unsuccessful exemption requests, but it 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.

F. Conclusion

In summary, the substantial equivalence exemption requirements laid out in this proposed 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 Tobacco Control Act. Introducing a new product through this channel may potentially reduce costs. If manufacturers find that obtaining an exemption would not reduce costs, or if they do not want to risk having to demonstrate substantial equivalence in their 905(j) reports in addition to having submitted unsuccessful exemption requests, they may choose to maintain the post-statute status quo and not pursue substantial equivalence exemptions.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing each collection of information. FDA requests comment on the burden and practical utility of the information being requested. Comment is also requested on whether the information being requested is duplicative of other collections.

Title: Exemptions From Substantial Equivalence Requirements for Tobacco Products.

Description: In this proposed rule, a pathway would be established by FDA for manufacturers to request exemptions from the substantial equivalence requirements of the Tobacco Control 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, allowing FDA to 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 the modification would be a minor modification of a tobacco product that can be sold under the FD&C Act. 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 proposal, an exemption request must be submitted with supporting documentation and contain the manufacturer's address and contact information, information about the modification; and an explanation of why a report intended to demonstrate substantial equivalence is not necessary. The request must also 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 would enable FDA to determine whether the exemption request would be appropriate for the protection of the public health.

This proposed 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. 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 would 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 would consider the exemption request withdrawn.

Description of Respondent: 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.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
1107.1(b)	50	1	50	360	18,000
1107.1(c)	40	1	40	50	2,000
Total					20,000

Table 1 describes the annual reporting burden as a result of the provisions set forth in this proposed rule. Based on information related to premarket provisions for other FDA-regulated products and anticipated interest from industry in this provision, FDA estimates that it would receive 50 exemption requests annually and that it

would take a manufacturer 360 hours to prepare an exemption request. FDA estimates that it would need to request additional data for 40 of these requests, and that it will take 50 hours to prepare this 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 21 CFR 1107.1(d) are included under part 16 hearing regulations, and are not included in the burden estimates in table 1 of this document).

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection (*see* **ADDRESSES**) to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.*

VIII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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 tentatively concludes that the proposed 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.

IX. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**), 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: EC0731I1: 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=EC0731I1&-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.*

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, it is proposed that 21 CFR parts 16 and 1107 be 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. In § 16.1 (b)(2) add 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.

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 (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 company 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. In addition, the request 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) A detailed explanation of the purpose for the modification;

(3) 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;

(4) 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;

(5) 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;

(6) A certification (i.e., a signed statement by a responsible official of the company) 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/use by minors, toxicity, or addictiveness/abuse liability; and

(7) Other information justifying an exemption.

(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 21 CFR part 16 of this chapter is provided. However, FDA may rescind an exemption prior to notice and opportunity for a hearing under 21 CFR 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.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–34 Filed 1–5–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 230

RIN 0596–AC84

Community Forest and Open Space Conservation Program

AGENCY: Forest Service, USDA.

ACTION: Proposed rule, request for comments.

SUMMARY: Public comments are solicited for this proposed rule which implements the Community Forest and Open Space Conservation Program (CFP) authorized by Section 8003 of the Food, Conservation, and Energy Act of 2008. The CFP legislation is an amendment to the Cooperative Forestry Assistance Act of 1978. The CFP is a competitive grant program whereby local governments, Tribal Governments, and qualified non-profit organizations are eligible to apply for grants to establish community forests. The program's two purposes are to assist communities in acquiring forestland that would provide public recreation, environmental and economic benefits, and forest-based educational programs, and to protect forestland that has been identified as a national, regional, or local priority for protection. Existing provisions in Forest Service regulations pertaining to the Stewardship Incentive Program will be removed as deauthorized by the Farm Security and Rural Investment Act of 2002, and this proposed rule will be substituted in lieu thereof.

DATES: Comments must be received in writing by March 7, 2011 Pursuant to the Paperwork Reduction Act, comments on the information collection burden that would result from this proposal must be received by March 7, 2011.

ADDRESSES: Written comments concerning this notice should be addressed to Community Forest Program, U.S. Forest Service, State and Private Forestry, Cooperative Forestry, 1400 Independence Avenue, SW., Code 1123, Washington, DC 20250. Comments may also be sent via email to *communityforest@fs.fed.us,* or via facsimile to (202) 205–1271. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at U.S. Forest Service, 1400 Independence Avenue, SW., Code 1123, Washington, DC 20250. Those wishing to inspect comments are encouraged to call ahead to (202) 205–1389 to facilitate entry to the building.

Comments concerning the information collection requirements contained in this action should reference OMB No. 0596–New, the docket number, date, and page number of this issue of the **Federal Register**. Comments should be sent to the address listed in the above paragraph.

FOR FURTHER INFORMATION CONTACT: Maya Solomon, U.S. Forest Service, State and Private Forestry, Cooperative Forestry, (202) 205–1376. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Background and Need for Proposed Rule

Congress authorized the Community Forest and Open Space Conservation Program (hereafter "CFP") to address the needs of communities to protect and maintain their forest resources. In the CFP authorization, Congress found that people derive health benefits from having access to forests for recreation and exercise. Congress also found that forests protect public water supplies and may provide financial benefits from forest products. The CFP is a competitive grant program whereby local governments, Tribal Governments, and qualified non-profit organizations are eligible to apply for grants to establish community forests through fee-simple land acquisitions. "Fee-simple" means full ownership and acquisition of real property, versus a partial interest such as conservation easement. By creating community forests through land acquisition, communities and Tribes can sustainably manage forests for these and many other benefits, including wildlife habitat, stewardship demonstration sites for forest landowners, and environmental education.

While the CFP title includes the term "open space," the authorizing language does not discuss the term. The only land cover Congress references is "forests." As a result, in this proposed rule, the term "open space" is also not used, and is assumed that the only type of "open space" on which Congress wanted CFP to focus is "forests."

The Forest Service believes that these proposed regulations for CFP will facilitate administration of the program and provide uniform criteria for program participation. The program will