as test results or material review and disposition records, because such records are part of records, if they are necessary, that will be kept for every batch.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Avg. burden per record-keeping	Total hours
111.14, records of personnel practices, including documentation of training	15,000	4	60,000	1	60,000
111.23, records of physical plant sanitation practices, including pest control and water quality	15,000	1	15,000	0.2	3,000
111.35, records of equipment and utensils calibration and sanitation practices	400	1	400	12.5	5,000
111.95, records of production and process control systems	250	1	250	45	11,250
111.140, records that quality control personnel must make and keep	240	1163	279,120	1	279,120
111.180, records associated with components, packaging, labels, and product received for packaging and labeling as a dietary supplement	240	1163	279,120	1	279,120
111.210, requirements for what the master manufacturing record must include	240	1	240	2.5	600
111.260, requirements for what the batch record must include	145	1408	204,160	1	204,160
111.325, records that quality control personnel must make and keep for laboratory operations	120	1	120	15	1,800
111.375, records of the written procedures established for manufacturing operations	260	1	260	2	520
111.430, records of the written procedures for packaging and labeling operations	50	1	50	12.6	630
111.475, records of product distribution and procedures for holding and distributing operations	15,000	1	15,000	0.4	6,000
111.535, records for returned dietary supplements	110	4	440	13.5	5,940
111.570, records regarding product complaints	240	600	144,000	0.5	72,000
Total					929,140

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The average burden per recordkeeping estimates in Table 1 of this document are based on those in the June 25, 2007, final rule, which were based on our institutional experience with other CGMP requirements and on data provided by Research Triangle Institute in the ''Survey of Manufacturing Practices in the Dietary Supplement Industry'' cited in that rule.

The estimates in Table 1 of the number of firms affected by each provision of part 111 are based on the percentage of manufacturers, packagers, labelers, holders, distributors, and warehousers that reported in the survey that they have not established written SOPs or do not maintain records that were later required by the June 25, 2007, final rule. Because we do not have survey results for general warehouses, we entered the approximate number of facilities in that category for those provisions covering general facilities. For the dietary supplement industry, the survey estimated that 1,460 firms would be covered by the final rule, including manufacturers, packagers, labelers, holders, distributors, and warehousers. The time estimates include the burden involved in documenting that certain requirements are performed and in recordkeeping. We used an estimated annual batch production of 1,408 batches per year to estimate the burden of requirements that are related to the number of batches produced annually, such as § 111.260, ''What must the batch production record include?'' The estimate of 1,408 batches per year is near the midpoint of the number of annual batches reported by survey firms.

The length of time that CGMP records must be maintained is set forth in § 111.605. Table 1 of this document reflects the estimated burdens for written procedures, record maintenance, periodically reviewing records to determine if they may be discarded, and for any associated documentation for that activity for records that are required under part 111. We have not included a separate estimate of burden for those sections that require maintaining records in accordance with § 111.605, but have included those burdens under specific provisions for keeping records. For example, § 111.255(a) requires that the batch production records be prepared every time a batch is manufactured, and § 111.255(d) requires that batch production records be kept in accordance with § 111.605. The estimated burdens for both § 111.255(a) and (d) are included under § 111.260 (what the batch record must include).

Dated: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30185 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1588]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Products, Exemptions From Substantial Equivalence Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the

proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on exemptions from substantial equivalence requirements for tobacco products.

DATES: Submit either electronic or written comments on the collection of information by February 18, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Exemptions From Substantial Equivalence Requirements for Tobacco Products (OMB Control Number 0910–0684)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

The FD&C Act, as amended by the Tobacco Control Act, requires that before a new tobacco product may be introduced or delivered for introduction into interstate commerce, a manufacturer must submit a premarket application to FDA, and FDA must issue an order finding that the new product may be introduced or delivered for introduction into interstate commerce (section 910 of the FD&C Act (21 U.S.C. 387j)). An order under section 910 is not required, however, if a manufacturer submits 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, and FDA issues an order finding the new product to be substantially equivalent to the predicate product and in compliance with the requirements of the FD&C Act.

FDA has established a pathway for manufacturers to request exemptions from the substantial equivalence requirements of the FD&C Act in § 1107.1 (21 CFR 1107.1) of the Agency's regulations. As described in § 1107.1(a), 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) The modification would be a minor modification of a tobacco product; (2) a report demonstrating substantial equivalence is not necessary for the protection of public health; and (3) an exemption is otherwise appropriate.

Section 1107.1(b) states that a request for exemption under section 905(j)(3) of the FD&C Act may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product and that the manufacturer must submit the request and all information supporting it to FDA. The request must be made in an electronic format that FDA can process, review, and archive (or a written request must be made by the manufacturer explaining in detail why the company cannot submit the request in an electronic format and requesting an alternative means of submission to the electronic format).

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 for 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 the 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 FD&C Act; (6) a detailed explanation of why a report under section 905(j)(1) of the FD&C 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 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 or use by minors, toxicity, addictiveness, or abuse liability; (8) other information justifying an exemption; and (9) an environmental assessment (EA) under part 25 (21 CFR part 25) prepared in accordance with the requirements of § 25.40.

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4347) states national environmental objectives and imposes upon each Federal agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement for every major Federal action that will significantly affect the quality of the human environment.

The FDA NEPA regulations are contained in part 25. All applications for exemption from substantial

equivalence require the submission of an EA. An EA provides information that is used to determine whether an FDA action could result in a significant environmental impact. Section 25.40(a) and (c) specifies the content requirements for EAs for nonexcluded actions.

The information required by § 1107.1(b) is submitted to FDA so FDA can determine whether an exemption from substantial equivalence to the product is appropriate for the protection of the public health. Section 1107.1(c) states that FDA will review the information submitted and determine whether to grant or deny an exemption based on whether the criteria in section 905(j)(3) of the FD&C Act are met. FDA may request additional information if necessary to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.

Section 1107.1(d) provides that FDA may rescind an exemption where necessary to protect the public health.

Section 905(j)(1)(A)(ii) of the FD&C Act states that if an exemption has been requested and granted, a report must be submitted to FDA that demonstrates 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 the FD&C Act, and all of the modifications are covered by exemptions granted by the Secretary pursuant to section 905(j)(3).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 CFR 1107.1(b): Preparation of tobacco product exemption from substantial equivalence request	500	1	500	12	6,000
21 CFR 1107.1(c): Preparation of additional information for tobacco product exemption from substantial equivalence request	150	1	150	3	450
21 CFR 25.40: Preparation of an environmental assessment	500	1	500	12	6,000
Section 905(j)(1)(A)(ii) of the FD&C Act: If exemption granted, report submitted to demonstrate tobacco product is modified under section 905(j)(3), modifications are to a product that is commercially marketed and compliant product, and modifications are covered by exemptions granted by Secretary pursuant to section 905(j)(3).	750	1	750	3	2,250
Total					14,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 500 requests for exemption will be submitted annually, and that it will take approximately 12 hours to prepare an exemption request. FDA also estimates that up to 30 percent (150) of the initial requests for information may require additional information in support of the initial exemption request, and it is expected that it will take an average of 3 hours to prepare the additional information. FDA also estimates that 750 manufacturers will take approximately 12 hours to prepare and submit an EA under part 25 in accordance with the requirements of § 25.40, as referenced in § 1107.1(b)(9).

FDA estimates that 750 respondents will take 3 hours to prepare a report under section 905(j)(1)(A)(ii) of the FD&C Act, 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. The report will contain the manufacturer's basis that the tobacco product is modified within the meaning of section 905(j)(3) of the FD&C Act, the modifications are to a product that is commercially marketed and compliant with the FD&C Act, the modifications are covered by exemptions granted pursuant to section 905(j)(3), and a listing of actions taken to comply with any applicable requirements of section 907 of the FD&C Act. FDA's estimates are based on experience with and information on other FDA-regulated products and indications from industry.

Dated: December 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–30137 Filed 12–18–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0636]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Unique Device Identification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Unique Device Identification System'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 30, 2013, the Agency submitted a proposed collection of information entitled ''Unique Device Identification System'' to OMB for review and clearance under 44 U.S.C. 3507. 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. OMB has now approved the information collection and has assigned OMB control number 0910–0720. The approval expires on December 31, 2016. A copy of the supporting statement for this