TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Pre-Assessment	1600	1	25/60	667
Post-Assessment	1600	1	25/60	667
Follow-up Assessment	1600	1	25/60	667
Total	.....	.....	.....	2001

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–14230 Filed 6–17–14; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: U.S. Department of Health and Human Services.

ACTION: 30-Day notice of submission of information collection approval from the Office of Management and Budget and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, U.S. Department of Health and Human Services has submitted a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.).

DATES: Comments on the ICR must be received on or before July 18, 2014.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Report Clearance Officer, *Sherrette.Funn@HHS.GOV* or (202) 690–6162.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

The Agency received no comments in response to the 60-day notice published in the **Federal Register** of April 3, 2014 (79 FR 18692).

Below we provide U.S. Department of Health and Human Services projected average estimates for the next three years: [1]

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension

Affected Public: Individuals and households, businesses and organizations.

Average Expected Annual Number of activities: 15

Respondents: 200,000 per activity

Annual responses: 3,000,000 annually

Frequency of Response: Once per request

Average minutes per response: 10

Burden hours: 500,000 hours annually

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 Office of Management and Budget control number.

Darius Taylor,

Information Collection Clearance Officer.

[FR Doc. 2014–14187 Filed 6–17–14; 8:45 am]

BILLING CODE 4150–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Products, Exemptions From Substantial Equivalence Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

[1] The 60-day notice included the following estimate of the aggregate burden hours for this generic clearance federal-wide:

Average Expected Annual Number of activities: 15.

Average number of Respondents per Activity: 200,000.

Annual responses: 3,000,000.

Frequency of Response: Once per request.

Average minutes per response: 10.

Burden hours: 500,00 hours annually.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 18, 2014.

ADDRESSES: 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 emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0684. Also include the FDA 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 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).

In the **Federal Register** of December 19, 2013 (78 FR 76838), FDA published a 60-day notice requesting public comment on the proposed collection of

information. Six comment submissions were received, some of which included multiple comments.

(Comment) Regarding the clarity of information collected, several comments indicated some confusion between the information being collected and the information needed to support an exemption request.

(Response) Section 1107.1(a) sets out the general requirements for requesting an exemption, but a manufacturer will need to determine how to meet the requirements for any of its new products that use the pathway. FDA intends to consider issuing a regulation or guidance to further clarify terms as experience is gained with the pathway.

(Comment) A few comments questioned the quality of the information being requested.

(Response) We disagree that the information required in an exemption request is not sufficient. We believe the information requested is what FDA needs to make a determination on an exemption request. Furthermore, several commenters also agreed with the sufficiency of the information needed to support an exemption request.

(Comment) Many comments addressed the accuracy of FDA's estimate of the burden for requesting a modification to an exemption request and questioned whether this burden was underestimated. Additionally, there was reference to the submittal of duplicative information.

(Response) FDA disagrees with these comments. We believe the burden estimates are appropriate and reflect the information needed by FDA when reviewing an exemption request. FDA also disagrees that there is duplicative information requested. The regulations implement the requirements of the FD&C Act for the exemption pathway to market. The commenters may be referring to the other notification and reporting requirements related to additives, such as those in section 904(c) of the FD&C Act (21 U.S. C. 387d(c)), but those requirements are not in the scope of this information collection.

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 (in hours)	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 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 (21 U.S.C. 387g). FDA's estimates are based on experience with and information on other FDA-regulated products and indications from industry.

Dated: June 11, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–14253 Filed 6–17–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1439]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))'' has been approved by the Office of Management and