ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
General population	90-Day Follow-Up Survey	320	1	18/60
CMEP-Respect grantees	90-Day SDN Submission	4	12	5/60
General Population	180-day Follow-up Survey	320	1	18/60
CMEP-Respect grantees	180-Day SDN Submission	4	12	5/60

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–13396 Filed 6–9–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1558]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 10, 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 0910–0673. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products—(OMB Control Number 0910–0673)—(Extension)

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the 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 new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. Section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) authorizes FDA to establish the form for the submission of information related to substantial equivalence. In a level 1 guidance document issued under the Good Guidances Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA's interpretation of the statutory sections related to substantial equivalence.

In the **Federal Register** of December 27, 2013 (78 FR 78974), 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. Two of the six comment submissions were in favor of FDA's regulation of tobacco products. Three comment submissions were considered to contain PRA-related comments and three comment submission were not considered to contain PRA-related comments. The three comment submissions not considered to contain PRA-related comments are beyond the scope of this **Federal Register** notice.

(Comment 1) One commenter supported FDA in its mission to regulate tobacco products for the benefit of public health and safety and indicated that language in the guidance be strengthened to assist in FDA reviews. The commenter also suggested that the respondents provide additional information to minimize future Freedom of Information Act requests.

(Response 1) FDA agrees that the request in this collection of information is necessary to fulfill the requirements of the FD&C Act. The type of data for a given new product may vary depending on whether the characteristics of the product are the same or different from a predicate tobacco product, and the information is needed to allow FDA to make informed decisions when reviewing a substantial equivalence application.

(Comment 2) Several commenters indicated that FDA has improperly implemented the substantial equivalence provisions of the statute (the FD&C Act, as amended by the Family Smoking Prevention and Tobacco Control Act (FSPTCA)), and maintain that FDA is asking for reports that are neither authorized nor relevant to a substantial equivalence determination.

(Response 2) FDA disagrees with the comment. The information FDA is requesting is related to new products using the substantial equivalence pathway to assist FDA in making a determination of whether a product is substantially equivalent.

(Comment 3) Several commenters asserted that FDA was not asking for enough information, while other commenters asserted that FDA was asking for too much information.

(Response 3) FDA believes that the collection of information is necessary and the burden estimates are appropriate and reflect the amount of time a respondent would need to prepare a substantial equivalence submission.

(Comment 4) One commenter noted that under FDA's interpretation, every new, including modified, product

automatically will be evaluated. Other commenters questioned FDA's implementation and Congress' intent of the FSPTCA and its definition of substantial equivalence and new products.

(Response 4) The FD&C Act as amended by the FSPTCA establishes the definition of ''new tobacco product'' and the premarket pathways, of which substantial equivalence is one. FDA believes the information collection estimates are appropriate and reflect estimates of the time it would take to put together and report the information needed in a substantial equivalence submission required by the statute.

(Comment 5) One commenter stated that the commenter believes that substantial equivalence reports should be exempt from environmental assessment requirements.

(Response 5) The National Environmental Policy Act and FDA implementing regulations require environmental assessment requirements.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act sections	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
905(j)(1)(A)(i) and 910(a)	1,000	1	1,000	360	360,000

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA's expectations regarding the tobacco industry's use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the substantial equivalence requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387j(a)). FDA estimates that it will receive 1,000 section 905(j) reports each year and that it will take a manufacturer approximately 360 hours to prepare a report of substantial equivalence for a new tobacco product. Therefore, FDA estimates the burden for submission of substantial equivalence information will be 360,000 hours.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13434 Filed 6–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0619]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Humanitarian Use Devices

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 information collection requirements for humanitarian use devices (HUDs).

DATES: Submit either electronic or written comments on the collection of information by August 11, 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Medical Devices; Humanitarian Use Devices—21 CFR 814 (OMB Control Number 0910–0332)—Extension

This collection of information implements the HUD provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the FD&C Act, FDA is authorized to exempt an HUD from the effectiveness requirements of sections 514 and 515 of the FD&C Act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be available to a