4160-01-P

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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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) (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 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	No. of Respondents	No. 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.

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