4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0147]

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 and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

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, 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.

Guidance for Industry and Food and Drug Administration Staff; 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 manner and form for the submission of information related to substantial equivalence (SE). In guidance documents 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 March 5, 2015 (80 FR 11989), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one

comment. The commenter expressed a concern that small manufacturers have the burden of conducting testing without a definitive guide on what will constitute substantial equivalence. FDA has carefully considered the burden associated with the submission of an SE report. The information needed to demonstrate substantial equivalence is dependent on the new product and the predicate product that the manufacturer identifies. Nevertheless, to assist manufacturers in preparing SE reports, FDA has issued guidance documents and participated in outreach such as webinars to provide manufacturers with information. Moreover, manufacturers seeking to demonstrate substantial equivalence may also contact FDA to seek the Agency's input on the specific types of information that the Agency believes will be necessary to support the manufacturer's section 905(j) report. The commenter also supported FDA's development of more streamlined SE Reports but challenged "new requirements on label changes," and requested that FDA promulgate a rule on categorical exclusions (environmental assessments). Although these comments are outside of the scope of this PRA collection, FDA intends to consider them as part of the Agency's other regulatory efforts as appropriate.

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

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Full SE 905(j)(1)(A)(i) and 910(a)	75	1	75	300	22,500
Product Quantity Change SE Report	125	1	125	87	10,875
Same Characteristics SE Report	100	1	100	47	4,700
Totals					38,075

[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 SE requirements of sections 905(j) and 910(a) of the FDC Act (21 U.S.C. 387j(a)). Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be "full" SE reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions," FDA is recommending that certain modifications might be addressed in either a "Same Characteristics SE Report" or "Product Quantity Change Report." FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of SE information will be 38,075 hours.

Dated: July 7, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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