

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 FDA may request additional information if necessary to make a determination and may consider the exemption request withdrawn if the information is not provided within the requested timeframe.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.

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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, PRASStaff@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

information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: December 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0150]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims" 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, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On September 10, 2013, the Agency submitted a proposed collection of information entitled "Guidance for Industry on Hypertension Indication: Drug Labeling for Cardiovascular Outcome Claims" 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 0910-0670. The approval expires on December 31, 2016. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: December 12, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0796]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Testing Communications on Medical Devices and Radiation-Emitting 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 January 21, 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 0910-0678. 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, PRASStaff@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.

Testing Communications on Medical Devices and Radiation-Emitting Products—(OMB Control Number 0910-0678)—(Extension)

FDA is authorized by section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)) to conduct educational and public information programs relating to the safety of regulated medical devices and radiation-emitting products. FDA must conduct needed research to ensure that such programs have the highest likelihood of being effective. Improving communications about medical devices and radiation-

emitting products will involve many research methods, including individual in-depth interviews, mall-intercept interviews, focus groups, self-administered surveys, gatekeeper reviews, and omnibus telephone surveys.

The information collected will serve three major purposes. First, as formative research it will provide critical knowledge needed about target audiences to develop messages and campaigns about medical device and radiation-emitting product use. Knowledge of consumer and health care professional decision making processes will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

Annually, FDA projects about 30 studies using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08–1.5 hours). FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of July 9, 2013 (78 FR 41066), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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