

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Potential Tobacco Product Violations Reporting Form” 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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On May 14, 2014, the Agency submitted a proposed collection of information entitled “Potential Tobacco Product Violations Reporting Form” 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 0910-0716. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 18, 2014.

**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-1601]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Annual Reporting for Custom Device Exemption

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Annual Reporting for Custom Device Exemption” 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, 8455 Colesville Rd., COLE-14526, Silver

Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On May 14, 2014, the Agency submitted a proposed collection of information entitled “Annual Reporting for Custom Device Exemption” 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 0910-0767. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 21, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-17482 Filed 7-24-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0019]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Customer/Partner Service Surveys

**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 August 25, 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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0360. 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, [PRASStaff@fda.hhs.gov](mailto: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.

#### Customer/Partner Service Surveys—(OMB Control Number 0910-0360)—Extension

Under section 903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393), FDA is authorized to conduct research and public information programs about regulated products and responsibilities of the Agency. Executive Order 12862, entitled, “Setting Customer Service Standard,” directs Federal Agencies that “provide significant services directly to the public” to “survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services.” FDA is seeking OMB clearance to conduct a series of surveys to implement Executive Order 12862. Participation in the surveys is voluntary. This request covers customer/partner service surveys of regulated entities, such as food processors; cosmetic, drug, biologic, and medical device manufacturers; consumers; and health professionals. The request also covers “partner” (State and local governments) customer service surveys.

FDA will use the information from these surveys to identify strengths and weaknesses in service to customers/partners and to make improvements. The surveys will measure timeliness, appropriateness, and accuracy of information; courtesy; and problem resolution in the context of individual programs.

FDA estimates conducting 15 customer/partner service surveys per year, each requiring an average of 15 minutes for review and completion. We estimate respondents to these surveys to be between 100 and 20,000 customers. Some of these surveys will be repeats of earlier surveys for purposes of monitoring customer/partner service and developing long-term data.

In the **Federal Register** of April 17, 2014 (79 FR 21765), 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:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Type of survey	Number of respondents	Annual frequency per response	Average burden per response	Total hours
Mail, telephone, Web-based .....	50,000	1	<sup>2</sup> 0.25	12,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Fifteen (15) minutes.

Dated: July 18, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2014–17590 Filed 7–24–14; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2007–N–0220]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry—Pharmacogenomic Data Submissions**

**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—Pharmacogenomic Data Submissions” 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** On May 9, 2014, the Agency submitted a proposed collection of information entitled “Guidance for Industry—Pharmacogenomic Data Submissions” 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 0910–0557. The approval expires on July 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at <http://www.reginfo.gov/public/do/PRAMain>.

Dated: July 21, 2014.  
**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
 [FR Doc. 2014–17481 Filed 7–24–14; 8:45 am]  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–N–1006]

**Revised Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the Electronic Common Technical Document Specifications; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications.” The draft guidance announced in this notice is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that certain submissions under the FD&C Act and Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of the final version of the guidance on that topic. The draft guidance outlines Electronic Common Technical Document (eCTD) specification requirements for certain submissions to new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologics license applications (BLAs), and investigational new drug applications (INDs) and is being issued for public comment. This draft guidance revises and replaces a previous draft guidance entitled “Providing Regulatory Submissions in

Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” that was issued in January 2013 (2013 draft guidance on eCTD Specifications). When finalized, this revised draft guidance will supersede the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” that was issued in June 2008.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 23, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Virginia Hussong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1161, Silver Spring, MD 20993, email: [virginia.hussong@fda.hhs.gov](mailto:virginia.hussong@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New