TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000

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

Dated: December 22, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30452 Filed 12–29–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0797]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

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 29, 2015.

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 0910–0700. 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: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program—(OMB Control Number 0910–0700)—Extension

Under section 228 of the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), as amended by section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(g)(7)), the owner or operator of an establishment may submit an audit report that assesses conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice.

The ''Guidance for Industry, Third Parties and FDA Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program'' describes how FDA's Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are implementing this provision of the law and providing public notice as required. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission program. The collected information is used for setting risk-based inspectional priorities.

In the **Federal Register** of June 26, 2014 (79 FR 36318), 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[1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
(One time only burden) First year, electronic setup and verification certificate [1]	1,700	1	1,700	[2] 42	71,400	$51,000
(Recurring burden) Audit report submission	1,700	1	1,700	3	5,100	51,000

[1] There are no capital costs associated with this information collection.

[2] Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

Based on FDA's experience with the founding regulatory members of the Global Harmonization Task Force (GHTF), FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers who are certified by Health Canada under ISO 13485:2003.

In addition, FDA only expects firms that do not have major deficiencies or observations in their ISO 13485:2003 audits to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program. FDA analyzed its inspection data from Fiscal Year (FY) 2013 (October 1, 2012 to October 1, 2013) and determined that the total number of inspections finalized in FY 2013 for medical devices was 2,404. The breakdown for the 2,404 compliance decisions is as follows:

TABLE 2—COMPLIANCE DECISIONS FY 2013

Compliance decision	Number	Approximate percentage
Official Action Indicated	169	7
Voluntary Action Indicated	902	38
No Action Indicated	1083	45
Pending Final Decision	249	10

Because FDA only expects firms who do not have major deficiencies or observations to be willing to submit their audit reports to FDA under the Voluntary Audit Report Submission Program, FDA only expects to receive audit reports that would have been classified by FDA as No Action Indicated (NAI).

Assuming that the percentage breakdown of compliance decisions for all inspections conducted in FY 2013 can be extrapolated and applied to audits of manufacturers certified under ISO 13485:2003 by Health Canada, FDA can estimate the number of Canadian establishments that would have had an inspection classified as an NAI. Because 45 percent of all compliance decisions resulted in an NAI decision, FDA estimates that 1,546 of the facilities certified under ISO 13485:2003 by Health Canada (45 percent of the total 3,436 facilities) would have had an inspection classified as an NAI.

Because FDA expects that the vast majority of manufacturers who will participate in the Voluntary Audit Report Submission Program will be manufacturers certified by Health Canada under ISO 13485:2003, FDA expects the number of reports to be submitted from manufacturers certified by regulatory systems established by other founding GHTF members to be minimal. For purposes of calculating the reporting burden, FDA estimates that approximately 10 percent of total audit reports submitted under this program will be from these other manufacturers. Because 90 percent of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,500 audit reports), the total number of audit reports FDA expects to receive in a year is approximately 1,700 audit reports.

FDA estimates from past experience with the Electronic Submission Gateway system, WebTrader, that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the respondent already has an established account in WebTrader for other electronic submissions to FDA, but FDA is assuming that all respondents to this new pilot program will be setting up a WebTrader account for the first time in the first year. For subsequent years, the burden hours are estimated at 1 hour to renew the yearly required verification certification.

FDA further estimates that the gathering, scanning, and submission of the audit reports, certificates, and related correspondence would take approximately 2 hours utilizing the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter submission process, resulting in 42 hours per response for the first year. For subsequent years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter submission process, resulting in 3 hours per response each year thereafter.

There are operating and maintenance costs associated with this information collection. The costs are $30 per year to establish and maintain the Electronic Submission Gateway verification certificate.

This guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073, and the collections of information for the Inspection by Accredited Persons Program have been approved under OMB control number 0910–0569.

Dated: December 23, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30513 Filed 12–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0672]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prominent and Conspicuous Mark of Manufacturers on Single-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 reprocessed, single-use device labeling.

DATES: Submit either electronic or written comments on the collection of information by March 2, 2015.

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