Guidance: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

0910-0700

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 374(g)(7)). Section 228 was amended to add the following provision:

   "21 USC §374 (g)(7)(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods."

   The "Guidance for Industry, Third Parties and Food and Drug Administration Staff: Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program" describes how the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) intend to implement this provision of the law. The proposed collections of information are necessary to satisfy the previously mentioned statutory requirements for implementing this voluntary submission pilot program.

   The guidance also refers to currently approved collections of information found in FDA regulations. 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.

   This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

   Specifically, a device manufacturer, whose establishment has been audited under one of the regulatory systems implemented by the Global Harmonization Task Force (GHTF)

founding members using ISO 13485:2003 Technical Corrigendum 1:2009 (or a national adoption of this standard, e.g., EN ISO 13485:2003/AC:2009, CAN/CAS ISO 13485 13485:2003) "Medical devices – Quality management systems – Requirements for regulatory purposes," may voluntarily submit the resulting audit report to FDA.

The GHTF founding members auditing systems include: the Canadian Medical Devices Conformity Assessment System; Notified Bodies designated by member states of the European Union.; Australian Therapeutics Goods Administration, Office of Manufacturing Quality; and the Japanese Ministry of Health, Labour and Welfare system for Medical Devices and In-vitro Diagnostics.

If, based on that report, FDA determines there is minimal probability -- in light of the relationship between the quality system deficiencies observed and the particular device and manufacturing processes involved -- that the establishment will produce nonconforming and/or defective finished devices, then FDA intends to use the audit results as part of its risk assessment to determine whether that establishment can be removed from FDA's routine work plan for one year from the last day of the ISO 13485:2003 audit. The voluntarily submitted ISO 13485:2003 audit report provides FDA some information on the conformance of the manufacturer with basic and fundamental quality management system requirements for medical devices.

Respondents are for-profit, private sector businesses.

3. Use of Improved Information Technology and Burden Reduction

FDA is utilizing 100% electronic submission for this information collection. The eligible ISO 13485:2003 audit reports, any related responses or communications (regarding the corrections or corrective actions to audit findings) between the manufacturer and the auditor and the copy of the ISO 13485:2003 certificate will be scanned into PDF files and submitted to the FDA through the "FDA eSubmitter" system. In order to utilize the FDA eSubmitter system or any FDA electronic submission process, the manufacturer must first set up an account with WebTrader in order to go through the Electronic Submissions Gateway. The burden and cost of the WebTrader electronic submission tool is included in the estimates below.

FDA has attempted to lessen the burden of this information collection through the eSubmitter electronic program, which will be utilized to submit the information to the FDA. The eSubmitter system has the capacity to file and store past audits so re-submissions of duplicate information will be avoided. The eSubmitter program will also aid manufacturers in walking through the required information that is necessary for a submission to be filed for evaluation. In addition, many other FDA applications are also utilizing eSubmitter. If an applicant already has an account with the WebTrader Electronic Submission Gateway, no additional burden or cost will be incurred outside of the time it takes to make the actual submission of the ISO 13485 Audit Reports and information through the eSubmitter system.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for the inspection of facilities in which medical devices are manufactured in accordance with the Federal Food, Drug, and Cosmetic Act. The information being collected is information that the manufacturer has as a result of a third party auditing body performing an audit for purposes of satisfying a different government's regulatory requirements. There is no estimated burden on the third party auditing body performing the audit under this collection. Therefore, duplication with other data sources available to the U.S. FDA is nonexistent.

5. Impact on Small Businesses or Other Small Entities

   We estimate that approximately 71 percent of respondents are small businesses. It is important to note that participation in the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program is entirely voluntary. As such, there is minimal impact on small businesses that elect to participate in the program. Any impact on small businesses should be offset by the guidance and consumer assistance available through CDRH Learn training tools and the information posted on FDA's website. FDA aids small business by providing guidance and information through the Division of Industry and Consumer Education (DICE) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DICE provides workshops, onsite evaluations, and other technical and nonfinancial assistance to small manufacturers. In addition, questions or problems with the electronic submission process can be directed to the appropriate Technical Help Desk for WebTrader or eSubmitter, which are listed on the FDA website.

6. Consequences of Collecting the Information Less Frequently

   There is no mandatory frequency for the information collection under the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program since it is entirely voluntary. However, manufacturers may choose to submit yearly if they want to be taken off the FDA routine work plan for subsequent years.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

   There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 06/26/2014 (79 FR 36318). No comments were received.

   Based on FDA's experience with the founding regulatory members of the Global Harmonization Task Force, 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 2013, FDA consulted the government of Canada and received information that approximately 3,436 manufacturers or manufacturing sites had been certified by Health Canada. FDA utilized this data from Health Canada's Medical Devices Bureau to assist in the Estimated Annual Reporting Burden. In addition, FDA has consulted Health Canada's Medical Devices Bureau many

times in the development of this program regarding how to best reduce the burden on manufacturers.

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9. Explanation of Any Payment or Gift to Respondents

No payment or gifts shall be provided to respondents under this information collection program.

10. Assurance of Confidentiality Provided to Respondents

Information under the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program is available under the Freedom of Information Act and 21 CFR Part 20. FDA is providing a secure Electronic Submissions Gateway and eSubmitter program by which the FDA can securely handle and store the information collected under this program.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

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
First year, electronic set-up and verification certificate[1]	567	1	567	42[2]	23,814
Audit report submission	1,700	1	1,700	3	5,100
Totals hours for first year					23,814
Total recurring hours					5,100

[1]Actual first year burden hours have been divided by 3 to avoid double counting in the ROCIS system
[2]Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

FDA estimates the reporting burden of this guidance to be 71,442 hours in the first year (the analogous number in Table 1, 23,814, is a result of dividing by three for the Web Trader account set-up burden that occurs only in the first year, to avoid double counting

in the ROCIS system), and 5,100 annual recurring per year thereafter, as shown in Table 1.

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 for this pilot program will be setting up a WebTrader account for the first time in the first year. In 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.

Based on FDA's experience with the founding regulatory members of 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.[1] In 2013, approximately 3,436 manufacturers or manufacturing sites had been certified by Health Canada.

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 – October 1, 2013) and determined that the total number of inspections finalized in FY2013 for medical devices was 2,404. The break down for the 2,404 compliance decisions is as follows:

[1] The majority of these manufacturers are also certified under ISO 13485:2003 by European Union Notified Body accreditation system.

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 that 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 FY2013 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. Since 45% of all compliance decisions resulted in a NAI decision, FDA estimates that 1,546 of the facilities certified under ISO 13485:2003 by Health Canada (45% of the total 3,436 facilities) would have had an inspection classified as an NAI. Since FDA only expects to receive audit reports that would have been classified by FDA as NAI, FDA expects 1,546, or approximately 1,500, audit reports to be submitted.

Since FDA expects that the vast majority of manufacturers that 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% of total audit reports submitted under this program will be from these other manufacturers. Since 90% of the audit reports are expected to be submitted by manufacturers certified by Health Canada (approximately 1,500 audit reports as calculated above), the total number of audit reports FDA expects to receive is approximately 1,700 reports a year.

12b. Annualized Cost Burden Estimate

FDA estimates the average cost burden to be approximately $3,261,327 in the first year and $232,815 in subsequent years. We calculated our estimate by multiplying the total burden hours for the first year and subsequent years, respectively, by the May 2013 wage estimates issued by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm) for “Physical Scientist-All Other” (occupation code 19-2099).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physical Scientist	71,442 (1st year)	$45.65	$3,261,327
Physical Scientist	5,100 (subsequent years)	$45.65	$232,815

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are capital, start-up, operating or maintenance costs associated with this information collection. The costs are $30 per year to establish and maintain the Electronic Submission Gateway verification certificate. Therefore, $30 multiplied by 2,267 equals $68,010. The total capital, start-up, operating or maintenance costs are therefore

The total cost may be lower if the Respondents already have a verification certificate for that year for other electronic submissions to FDA. However, for purposes of this estimate, FDA is assuming that all respondents for this new pilot program will be incurring this cost for this program.

The total capital, start-up, operating or maintenance costs are therefore $111,900.

14. Annualized Cost to the Federal Government

Two full time equivalent (FTE) positions perform reviews for the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program. Based on a cost of $283,487 per position (which is the agency's projected average cost of an FTE including their benefits*), the estimated annual Federal cost is $566,974.

*Based on the Department of Health and Human Services, Fiscal Year 2015, Food and Drug Administration, Justification of Estimates for Appropriations Committees--ALL PURPOSE table (pp. 11-13).

15. Explanation for Program Changes or Adjustments

The number of respondents for "First year, electronic set-up and verification certificate" has increased from 1,600 to 1,700,* causing an adjusted increase of 4,284 total hours. The number of respondents for "Audit report submission" has increased from 1,600 to 1,700, causing an adjusted increase of 300 total hours.

* Actual first year burden hours have been divided by 3 in the burden table to avoid double counting in the ROCIS system.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking an exemption of display of effective date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.