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

0910-[NEW]

SUPPORTING STATEMENT

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 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) Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) intend to implement this provision of the law. Effective October 1, 2011 (Pending OMB Approval), FDA will begin a voluntary pilot program as described in this guidance document and will evaluate the outcomes of the pilot program at the end of this period. 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.

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.

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. (See Attached #1 for the eSubmitter report for the electronic submission package.) 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 hopefully 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

The 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 US FDA is nonexistent.

5. **Impact on Small Businesses or Other Small Entities**

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 Small Manufacturers, International, and Consumer Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA provides workshops, on-site 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. FDA has not established how many times a manufacturer can utilize this program. This is one of the elements to be determined at the conclusion of the two year pilot.

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

There are no special circumstances for collecting the information under the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program. This guidance is consistent with principles in 5 CFR 1320.5.

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

8a. Publication in the FEDERAL REGISTER

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 05/20/2010 (75 FR 28257).

FDA received one comment regarding the information collection request. The comment stated that the reporting burden hours may be too low for the first submission and may take less time for subsequent submissions. In addition, this comment stated that the number of reports anticipated to be submitted may be a high estimate by a factor of 10. FDA appreciates the consideration of burden hours by the commenter. The comment, however, did not provide any data to assist FDA to adjust the burden hours for the submission. Absent baseline information at this time, FDA will review the submissions during the pilot period and modify the burden to respondents accordingly.

8b. Outside Consultation

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 2008, FDA consulted the government of Canada and received information that approximately 2,650 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

The following is an estimated annual burden hours for participation in the voluntary program:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	**No. Of Responses per Respondent per year**	**Total Annual Responses**	**Average Burden per Respondent (in hours)**	**Total Hours**
First Year[1]	533	1	533	42[2]	22,386
Recurring	1600	1	1600	3	4,800
				Totals hours for first year	22,386
				Total recurring hours	4,800

[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 67,158 hours in the first year (the analogous number in Table 1, 22,386, 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 4,800 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 respondent for this new pilot program will be setting up a WebTrader account for the first time in the first year. Subsequent years, the estimate 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 both the second and third 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 2008, approximately 2,650 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) 2008 (October 1, 2007 – October 1, 2008) and determined that the total number of inspections finalized in FY2008 for medical devices was 1,965. The break down for the 1,965 compliance decisions is as follows:

Compliance Decision[2]	**Number**	**Approximate Percentage**
Official Action Indicated	148	8%
Voluntary Action Indicated	775	40%
No Action Indicated	1025	52%
Pending Final Decision	17	1%

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 FY2008 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 52% of all compliance decisions resulted in a NAI decision, FDA estimates that 1,378 of the

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

[2] June 15, 2006, Compliance Program 7382.845 Inspection of Medical Device Manufacturers Part V http://www.fda.gov/cdrh/comp/guidance/7382.845.html#p5p5.pdf

facilities certified under ISO 13485:2003 by Health Canada (52% of the total 2,650 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 1378, or approximately 1400, 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 1400 audit reports as calculated above), then the total number of audit reports FDA expects to receive approximately 1,600 reports a year.

12b. Annualized Cost Burden Estimate

	No. of Respondents	**Average Burden per Respondent (in hours)**	**Hourly Wage Rate**	**Total Cost Annualized**
First Year	533	42	$150	$3,357,900
Recurring Year 2	1600	3	$150	$720,000
			Total	$4,077,900.00

FDA estimates the cost to respondents for the burden hours associated with this collection of information to be approximately $3.358 million in the first year and $720,000 each year thereafter. We estimated reporting costs by multiplying the burden in hours (22,386) in the first year and (4,800) 720,000 annually thereafter by the hourly rate of $150 for this type of work.

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

There are capital, start-up, operating or maintenance cost associated with this information collection. The costs are $30 per year to establish and maintain the Electronic Submission Gateway verification certificate. However, in order to avoid double counting in ROCIS the actual first year burden costs have been annualized by dividing by 3. Therefore the first year costs are estimated to be $30 times the approximately 533 respondents which would result in an estimated $15,990 for the first year and $48,000 (1600 x 30) each year thereafter. The total capital, start-up, operating or maintenance costs are therefore $111,900.

Again, this cost may be minimized if the Respondent already has a verification certificate for that year for other electronic submissions to FDA but FDA is assuming that all respondents for this new pilot program will be incurring this cost for this program.

14. <u>Annualized Cost to the Federal Government</u>

	Cost per FTE	Number of FTEs	Total FTE Cost	IT Cost	Total Cost to the Fed Gov't
First Year FY2012	$250,000	4	$1,000,000	$36,000	$1,036,000
Second Year FY2013	$265,000	4	$1,060,000		$1,060,000
Third Year FY2014	$280,900	4	$1,123,600		$1,123,600
Total					$3,219,600

Costs to the government for the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program include:

1) Employee Resources: FDA estimates that one fully supported full time equivalent (FTE) position within CDRH in FY 2012 will total $250,000. Based on a cost of $250,000 per position, FDA estimates the need for 4 FTEs resulting in a FY 2012 cost of $1,000,000. FDA estimates that one fully supported FTE for CDRH FY 2013 will be $265,000. Therefore, 4 FTEs result in a FY 2013 cost of $1,060,000. FDA estimates that one fully supported FTE for CDRH FY 2014, assuming a similar 6% increase in cost, will be $280,900. Therefore, 4 FTEs result in a FY 2013 cost of $1,123,600.

2) Cost estimates for a one time expense to initiate the Information Technology solution: Estimates for the different contractors to establish the electronic submission process and review for the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program.

   - Adding a new electronic submission as a General Documents to the eSubmitter system. Cost: $16K

   - Processing new Document Type for transmissions and review via the Centers Tracking System Cost: $20K

   The total cost to modify the existing electronic submission systems: $36K

3) Total cost for 3 years will be $3,219,600. Dividing that cost over the 3 year period will result in $1,073,200 estimated annualized cost to the Federal Government.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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 statement identified in Item 19 of OMB Form 83-I.