Reports of Corrections and Removals

0910-0359

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

   FDA is requesting approval for the collection of information regarding reports of corrections and removals required under 21 CFR part 806, which implements section 519(g) (21 U.S.C. 360i(g)) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301, et seq.), as amended by the Food and Drug Modernization Act of 1997 (FDAMA) (Public Law 105-115). A description of the information collection requirements are provided as follows:

   Submission of corrections and removals--21 CFR 806.10
   Under § 806.10, within 10 working days of initiating any action initiated to correct or remove a device to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health, device manufacturers or importers must submit a written report to FDA of the correction or removal.

   Records of corrections and removals—21 CFR 806.20(a)
   Under § 806.20(a), device manufacturers or importers that initiate a correction or removal that is not required to be reported to FDA must keep a record of the correction or removal.

2. Purpose and Use of the Information Collection

   The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals to determine whether recall action is adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

3. Use of Improved Information Technology and Burden Reduction

   In the Federal Register of March 20, 1997 (62 FR 13430), FDA published a final rule establishing procedures for electronic records, electronic signatures, and electronic submissions. Manufacturers or importers may use appropriate technology in accordance with this rule to comply with the reports of corrections and removals requirements.

Additionally, FDA is making available, as a voluntary alternative to paper submissions, an electronic Web-based process for submitting 806 reports. The electronic process is expected to enhance consistency of submission data and to speed submission processing. Submission by mail will remain available and will be augmented by the new electronic submission process. FDA estimates that 99% of the respondents will use electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

   FDA is the only federal agency responsible for the collection of this information. No data exist from any other source that can be used to report corrections and removals subject to these regulations.

5. Impact on Small Businesses or Other Small Entities

   We estimate that approximately 80 percent of respondents are small businesses. FDA aids small business by providing guidance and information through the Division of Small Manufacturers, International, and Consumers Assistance (DSMICA) and the Device Registration and Listing Branch within the Center for Devices and Radiological Health. DSMICA provides workshops, onsite evaluations, and other technical and nonfinancial assistance to small manufacturers. The workshops make available publications and educational materials, which include medical device establishment and listing requirements. The Division also maintains a toll-free telephone number and a website, which firms may use to obtain regulatory compliance information.

   FDA's small business representatives in its six regional offices and scientific and administrative staff also aid small businesses subject to medical device regulations by providing assistance upon request or through public meetings.

6. Consequences of Collecting the Information Less Frequently

   FDA does not require a specific frequency for this collection; respondents will submit the information occasionally. A manufacturer or importer of a device submits a written report to FDA only when it undertakes a corrective or removal action to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act that may pose a risk to health.

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 06/28/2013 (78 FR 38992). We received two sets of comments, which were fundamentally the same.

   [Comment] The comments state that the proposed collection of information and the electronic process of collecting reports of corrections and removals do not appear to be necessary for the proper performance of FDA's functions. However, they do not provide

supporting details for this assertion. The comments also state that the proposal to allow information to be reported via an electronic process promises to deliver efficiency advantages to the Agency. The comments request that FDA identify improvements in resources or processing time as a result of the electronic collection methods.

[Response] We believe that the information collection is necessary for the proper performance of FDA's functions. The information collected in the reports of corrections and removals is used by FDA to identify marketed devices that have serious problems and to ensure that FDA has current and complete information regarding these corrections and removals to help determine whether recall action is appropriate and adequate. Failure to collect this information would prevent FDA from receiving timely information about devices that may have a serious effect on the health of users of the devices.

While we expect the electronic submission of corrections and removals to improve the efficiency with which FDA processes the reports, we have not quantified data specific to time-savings for FDA and we note that such quantification is beyond the scope of the information collection request. We believe that submitters will find the electronic submission process to be user-friendly and that it will enhance the consistency of submission data. We estimate that an electronic report will take the same amount of time for the submitter as a paper report takes. We also note that electronic submission is voluntary and a submitter may still send a paper report.

[Comment] The comments state that it is unclear how the collected information will be used and made available to the public. They ask whether all information that is collected via electronic means will be made available to the public and whether there is a process that can be used by reporters to identify certain information as confidential. One commenter expressed concerns regarding whether information such as phone and email conversations, agreements on dispositions, etc., would be made available on the public Web site.

[Response] The addition of the electronic submission process does not change how the data will be used or disclosed to the public as compared to a paper submission, it simply provides a different means to submit the same information collected previously via paper submission. The data elements that are displayed publicly can be viewed at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm. Follow-up phone and email conversations, etc., are not part of the electronic submission system. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Reports and other information submitted to FDA under 21 CFR part 806 are releasable if they fall within the scope of the Agency's regulation concerning "Public Information" (21 CFR part 20). However, FOIA exempts disclosures of certain government records from mandatory public disclosures (5 U.S.C. 522(b)(1)-(b)(9)). One such provision exempts from public disclosure "trade secrets" and "confidential commercial or financial information" that is privileged (5 U.S.C. 522(b)(4)).

[Comment] The comments feel that the burden is underestimated because the burden estimate assumes that reporters have compatible systems to transfer and upload

information and that reporters are already familiar with FDA's electronic submission system. The comments state that the electronic submission process shifts the data entry burden from FDA to the reporter.

[Response] We disagree. Most firms that report under part 806 have already used eSubmitter for other types of submissions, such as electronic medical device reporting (eMDR), eCopy, and ISO submissions, and, therefore, would already have compatible systems and would be familiar with FDA's Electronic Submissions Gateway (ESG).

The addition of electronic submission does not shift burden from FDA to respondents because respondents already enter the data manually for submission in paper or email format. An electronic submission includes the same data elements, required by part 806, that are included in a paper submission.

[Comment] The comments state that the collection doesn't consider the internal systems that a reporter may have to establish to meet the electronic reporting requirements (validating computer systems, developing new procedures, training staff, etc.). The comments feel that these issues will add an incremental burden for users to implement and, possibly, maintain the electronic reporting process.

[Response] Validation testing and basic training on the system are included in the estimated hourly burden for set up of the electronic process. Reporting does not require additional training or new procedures; the system prompts users for the required information. The comment does not provide suggestions for specific changes to the estimated burden or any data to support an increase of burden hours.

[Comment] The comments express concerns about communication between FDA and the reporter regarding electronic submissions of corrections and removals. The comments question whether the Agency will provide feedback to manufacturers, follow-up requests, monthly reporting, or termination requests in the "electronic record." The comments request clarification regarding how electronic submission will enhance the consistency of submission data.

[Response] The electronic submission option does not change how FDA will communicate with firms that submit reports of corrections and removals. The electronic submission system is only for reports of corrections and removals under part 806. It does not include feedback, follow-up, monthly reporting, or terminations requests. The comments seem to assume that the "electronic record" will now be kept by FDA. However, the recordkeeping requirements have not changed for firms that submit reports of corrections and removals under part 806. The predefined data elements of the electronic 806 report will inherently enhance the consistency of submission data by ensuring complete reporting, thus, minimizing the need to solicit missing data.

[Comment] The comments request the release of the data fields and proposed online support information for reporters to review and provide comments.

[Response] Screen captures of the data fields are available in the public docket (http://www.regulations.gov, in Docket No. FDA-2013-N-0723). The online support information is available as follows:

- http://www.fda.gov/forindustry/electronicsubmissionsgateway/ for information and support for the electronic submissions gateway, including information about setting up a WebTrader account
- ESGHelpDesk@fda.hhs.gov is the email address for getting technical help with submissions
- http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm193862.htm provides tutorials for navigation and use of the eSubmitter application
- http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm provides a list of ORA District and Headquarters Recall Coordinators

9. Explanation of Any Payment or Gift to Respondents

No payment or gifts in any manner or form shall be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. Reports and other information submitted to FDA under 21 CFR part 806 are releasable if they fall within the scope of the agency's regulation concerning "Public Information" (21 CFR part 20). However, FOIA exempts disclosures of certain government records from mandatory public disclosures (5 U.S.C. 522(b)(1-9)). One such provision exempts from public disclosure "trade secrets" and "confidential commercial or financial information" that is privileged (5 U.S.C. 522(b)(4)).

11. Justification for Sensitive Questions

This information collection does not include questions of a sensitive nature, such as those regarding sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA's estimate of the reporting and recordkeeping burden is based on agency records and our experience with this program, as well as similar programs that utilize FDA's Electronic Submission Gateway.

Table 1.—Estimated Annual Reporting Burden

Activity (21 CFR Part)	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Electronic process set-up[2]	1,022	1	1,022	3.08	3,148
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330

[1] Totals may not sum due to rounding.

[2] We estimate the approximately 99% of respondents will submit corrections and removals using the electronic process. The actual burden hours for set-up of the electronic process listed in the reporting burden table are divided by three to avoid double counting in the ROCIS system. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the set-up of the electronic process.

Table 2.—Estimated Annual Recordkeeping Burden

Activity (21 CFR Part)	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records of corrections and removals (part 806)	93	1	93	10	930

12b. Annualized Cost Burden Estimate

We estimated the annual cost burden based on an updated wage rate for a Regulatory Affairs Professional* (current, $45.46; previous estimate, $36 per hour). The estimate includes electronic process set-up (9,454 hours**), preparation and assembly of submissions of corrections and removals (10,330 hours), and maintenance of records under part 806 (930 hours).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs***
Regulatory Affairs Professional	20,714	$45.46	$941,658

*The estimated wage rate for a Regulatory Affairs Professional is an average of the annual wage rates listed in several sources including Salary.com, eHow.com, MDDIonline.com, and Recruiter.com. The hourly wage rate assumes a 40-hour work week.

** The actual burden hours for set-up of the electronic process listed in the reporting burden table are divided by three to avoid double counting in the ROCIS system. However, the one-time Average Burden per Response is 9.25 hours, resulting in a total one-time burden of 9,454 hours for the set-up of the electronic process.

***Total is rounded to the nearest dollar.

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

    For respondents for who submit corrections and removals using the electronic process, the operating and maintenance costs associated with this information collection are approximately $30 per year to purchase a digital verification certificate (certificate must be valid for 1 to 3 years). This burden may be minimized if the respondent has already purchased a verification certificate for other electronic submissions to FDA. However, FDA is assuming that all respondents who submit corrections and removals using the electronic process will be establishing a new WebTrader account and purchasing a digital verification certificate. We therefore estimate the total operating and maintenance costs to be $30,660 annually (1,022 respondents x $30).

14. Annualized Cost to the Federal Government

    FDA estimates that the Federal government will use seven full time equivalent positions (FTEs) to ensure compliance with the Reports of Corrections and Removals regulations required by section 519(g) of the FD&C Act. An FTE is projected to cost FDA/CDRH $209,632* annually, which consists of the employee's salary and any overhead which accompanies that employee. Therefore, the average cost to the government is estimated to be $1,467,424 per year.

    *Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

    Adjustments:

    The average annual number of reporting respondents has increased since the last approval from 666 to 1,033. This adjustment resulted in an increase of 3,670 hours to the reporting burden.

    The average annual number of recordkeeping respondents has increased since the last approval from 90 to 93. This adjustment resulted in an increase of 30 hours to the recordkeeping burden.

    Revision:

    Additionally, FDA is revising this ICR making available an electronic Web-based process for submitting reports of corrections and removals. We have therefore added a line-item to the reporting burden table for set-up of the electronic process. This resulted in an additional increase of 5,918 hours.

    We have also accounted for the purchase of a 1 to 3 year digital verification certificate for respondents who use the new electronic process. This has resulted in an increase of $30,660 in the operating and maintenance cost.

16. Plans for Tabulation and Publication and Project Time Schedule

    No tabulation of the data is planned or anticipated.

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

FDA is not seeking approval to prevent the display of expiration date or OMB approval of this request.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.