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 has made 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 International and Consumers 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. 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 03/20/2017 (82 FR 14367). FDA received no comments.

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 the updated wage rate for a Regulatory Affairs Professional.* 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	$61	$1,263,554

* Based on The Regulatory Affairs Professional Society (RAPS) overall base annual compensation of $126,163 for a U.S. regulatory affairs professional (http://www.raps.org/news-trends/scope-of-practice/2014/). The hourly rate of $61 above assumes a 40-hour work week and is rounded to the nearest dollar.

** 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 $213,944* 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 $1,623,608 per year.

*Based on the FY 2017 FDA Budget Request – Executive Summary – All Purpose Table table.

15. Explanation for Program Changes or Adjustments

This is a request for extension only. There have been no program changes or adjustments to the burden estimate.

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.