ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Request for Specific Consent	30	1	0.33	9.9

Estimated Total Annual Burden Hours: 9.9

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget,, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.*

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–06931 Filed 3–27–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0723]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reports of Corrections and Removals of Medical Devices and Radiation Emitting Products

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 April 28, 2014.

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 0910–0359. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Reports of Corrections and Removals of Medical Devices and Radiation Emitting Products—(OMB Control Number 0910–0359)—Extension

I. Reports of Corrections and Removals

Under § 806.10 (21 CFR 806.10), each device manufacturer or importer shall submit a written report to FDA of 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 Federal Food, Drug, and Cosmetic Act caused by the device, which may present a risk to health within 10 working days of initiating the correction or removal.

Under § 806.20(a) (21 CFR 806.20(a)), each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA shall keep a record of the correction or removal.

FDA currently accepts by mail reports of corrections and removals (806 reports) associated with medical and radiation emitting products regulated by the Center for Devices and Radiological Health (CDRH) under part 806.

For general information and assistance with 806 reports, contact the CDRH Division of Small Manufacturers, International and Consumer Assistance (DSMICA) by telephone: 1–800–638–2041 or 301–796–7100, or by email: *dsmica@fda.hhs.gov.*

II. Proposed Electronic Submission Process

FDA is now proposing to make available, as a voluntary alternative to paper submissions, an electronic 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.

Establishing a process for using electronic submissions does necessitate some preparation by reporters, which includes obtaining both: (1) A WebTrader account and (2) a digital verification certificate. Many other FDA applications also utilize WebTrader. If an applicant already has an account with the WebTrader Electronic Submission Gateway (ESG) and a digital verification certificate (certificate must be valid for 1 to 3 years), no additional burden or cost will be incurred outside of the time it takes to make the submission of corrections and removals. However, for calculating the burden for this collection, FDA is assuming that all respondents will be establishing a new WebTrader account and purchasing a digital verification certificate.

Establishing a new account for sending electronic submissions may take up to 2 weeks. During that time, new reporters are advised to submit paper reports to avoid inadvertently missing the 10-day timeframes associated with submission of reports under part 806.

Upon approval of the information collection, a submitter would go to *http://www.fda.gov/ForIndustry/FDAeSubmitter/default.htm* to submit an 806 report via the electronic portal. Additional information about FDA's ESG is posted online at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.* You can also email

questions about the system to FDA's ESG Help Desk: *esgreg@gnsi.com.*

III. Online Support and Information

CDRH intends to establish a Web site for online support and information about electronic submissions of 806 reports. The Web site will provide the following information:

- Introduction
- Tracking information
- Contact information
  - Submitter identification
  - Manufacturer information
  - Recalling firm information
  - Importer information
- Correction and removal report information
  - Event
  - Correction and removal product data
  - Domestic consignee information
  - Foreign consignee information
  - Communication documentation
  - Additional documentation (which allows for attaching Word™, Excel™, and PDF™ documents)

Within the online help provided by FDA, users will find yellow light bulb icons. These icons indicate supplemental tips and information.

In the **Federal Register** of June 28, 2013 (78 FR 38992), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two sets of comments, which were fundamentally the same. Comments relevant to the information request are addressed in this document.

(Comment 1) 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 2) 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.* Followup 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 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. 552(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. 552(b)(4)).

(Comment 3) The commenters 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, eCopy, and ISO submissions, and, therefore, would already have compatible systems and would be familiar with FDA's 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 4) The comments state that the collection does not 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 commenters 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 5) 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, followup 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, followup, 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 6) 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 ESG, 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; and
- *http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129334.htm* provides a list of ORA District and Headquarters Recall Coordinators.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity (21 CFR part)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]	Total operating and maintenance costs
Electronic process setup (one time)	1,022	1	1,022	9.25	9,454	$30,660
Submission of corrections and removals (part 806)	1,033	1	1,033	10	10,330	

[1] There are no capital costs associated with this collection of information.
[2] Totals may not sum due to rounding.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity (21 CFR part)	Number of recordkeepers	Number 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

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

FDA's estimate of the reporting and recordkeeping burden is based on our experience with this program and similar programs that utilize the ESG. For respondents who use 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.

Dated: March 24, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–06917 Filed 3–27–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0076]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

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 requirements governing the acceptance of electronic records and electronic signatures.

DATES: Submit either written or electronic comments on the collection of information by May 27, 2014.

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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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 information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or