DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0723]

Agency Information Collection Activities; Proposed Collection; 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 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 revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on an electronic process for submitting reports of corrections and removals (806 reports) that are associated with medical and radiation emitting products regulated by FDA's Center for Devices and Radiological Health (CDRH). The electronic process is expected to both enhance consistency of submission data and speed submission processing.

DATES: Submit either electronic or written comments on the collection of information by August 27, 2013.

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:

Regarding the collection of information: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

Regarding reports of corrections and removals: Ronny D. Brown, Division of Risk Management Operations, Office of Compliance, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2611, Silver Spring, MD 20993, 301–796–6163, *Ronny.Brown@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 provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910–0359)—Revision

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 (the FD&C 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 CDRH under part 806 (21 CFR 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 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 Electronic Submission Gateway is posted at *http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.* You can also email questions about the system to FDA's Electronic Submissions Gateway Help Desk: *esgreg@gnsi.com.*

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 & maintenance costs
Electronic process set-up (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 Electronic Submission Gateway. 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.

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.

Dated: June 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0748]

Agency Information Collection Activities: Proposed Collection; Comment Request; Focus Groups About Drug Products as Used by the Food and Drug Administration

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 the information collection resulting from focus groups about drug products as used by FDA.

DATES: Submit either electronic or written comments on the collection of information by August 27, 2013.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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 provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice