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.

[FR Doc. 2013–15468 Filed 6–27–13; 8:45 am]

BILLING CODE 4160–01–P

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

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.

Focus Groups About Drug Products as Used by the Food and Drug Administration—(OMB Control Number 0910–0677)—Extension

Focus groups provide an important role in gathering information because they allow for a more in-depth understanding of individuals' attitudes, beliefs, motivations, and feelings than do quantitative studies. Focus groups serve the narrowly defined need for direct and informal opinion on a specific topic and as a qualitative research tool have three major purposes:

- To obtain information that is useful for developing variables and measures for quantitative studies,
- To better understand people's attitudes and emotions in response to topics and concepts, and
- To further explore findings obtained from quantitative studies.

FDA will use focus group findings to test and refine its ideas and to help develop messages and other communications, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

FDA's Center for Drug Evaluation and Research, Office of the Commissioner, and any other Centers or Offices conducting focus groups about regulated drug products may need to conduct focus groups on a variety of subjects related to consumer, patient, or healthcare professional perceptions and use of drug products and related materials, including but not limited to, direct-to-consumer prescription drug promotion, physician labeling of prescription drugs, Medication Guides, over-the-counter drug labeling, emerging risk communications, patient labeling, online sales of medical products, and consumer and professional education.

Annually, FDA projects about 20 focus group studies using 160 focus groups with an average of 9 persons per group, and lasting an average of 1.75 hours each. FDA is requesting this burden for unplanned focus groups so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Focus groups about drug products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	1,440	1	1,440	1.75	2,520

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

Dated: June 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–15469 Filed 6–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0749]

Implanted Blood Access Devices for Hemodialysis; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Implanted Blood Access Devices for Hemodialysis.'' This guidance was developed to support the reclassification of the Implanted Blood Access Devices for Hemodialysis into class II (special controls). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 27, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Implanted Blood Access Devices for Hemodialysis'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance document is being issued in conjunction with a **Federal Register** notice announcing the proposal to reclassify this device type. This draft guidance provides recommendations to assist manufacturers in developing their premarket submissions of implanted blood access devices for hemodialysis regulated under § 876.5540(a)(1) (21 CFR 876.5540(a)(1) and FDA believes