

notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the agency estimates it will receive 2,375 responses annually for each.

Recall Status Reports

Requests that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This collection of information will generate approximately 9,500 responses annually.

In the **Federal Register** of October 12, 2004 (69 FR 60630), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-16846 Filed 8-23-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0327]

Agency Information Collection Activities; Proposed Collection; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

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 requirements relating to the blood establishment registration and product listing requirements and Form FDA 2830.

DATES: Submit written or electronic comments on the collection of information by October 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. 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:

Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Blood Establishment Registration and Product Listing, Form FDA 2830—21 CFR Part 607 (OMB Control Number 0910-0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or device must register

with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business, and all such establishments submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a) requires certain establishments that engage in the manufacture of blood products to register and to submit a list of blood products in commercial distribution. Section 607.21 requires the establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a blood product listing at that time. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December of each year. Section 607.22 requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for annual registration, and for blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26 requires certain changes to be submitted as amendments to the establishment registration within 5 days of such changes. Section 607.30 requires establishments to update their blood product listing information every June and December, or at the discretion of the registrant at the time the change occurs. Section 607.31 requires that additional blood product listing information be provided upon FDA request. Section 607.40 requires foreign blood product establishments to register and submit the blood product listing information, the name and address of the establishment, and the name of the individual responsible for submitting blood product listing information as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply. Form FDA 2830 is used to collect this information.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and

independent laboratories that engage in quality control and testing for registered blood product establishments.

FDA estimates the burden of this collection of information based upon

information obtained from the Center for Biologics Evaluation and Research's database and FDA experience with the blood establishment registration and product listing requirements.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form FDA 2830	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25, and 607.40	Initial registration	100	1	100	1	100
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Reregistration	2,775	1	2,775	0.5	1,388
607.21, 607.25, 607.30, 607.31, and 607.40	Product listing update	180	1	180	0.25	45
Total						1,533

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

Dated: August 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2006.

FDA has a special interest in ensuring that women, minority groups, and

individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this notice.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons in table 1 of this document:

TABLE 1.

Contact Person	Committee/Panel
Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ-400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2022, or e-mail: <i>NJP@CDRH.FDA.GOV</i>	Certain Device Panels of the Medical Devices Advisory Committee
Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: <i>CAF@CDRH.FDA.GOV</i>	National Mammography Quality Assurance Advisory Committee
Collin L. Figueroa, Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, e-mail: <i>CXF@CDRH.FDA.GOV</i>	Device Good Manufacturing Practice Advisory Committee
Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: <i>RVK@CDRH.FDA.GOV</i>	Technical Electronic Product Radiation Safety Standards Committee

FOR FURTHER INFORMATION CONTACT:

Kathleen L. Walker, Center for Devices and Radiological Health (HFZ-17), Food and Drug Administration, 2098 Gaither

Rd., Rockville, MD 20850, 240-276-0450, ext. 114, e-mail: *KLW@CDRH.FDA.GOV*.

SUPPLEMENTARY INFORMATION:

I. Vacancies

FDA is requesting nominations of voting members for vacancies listed as follows: