announcements on the HHS/CDC Web site, Internet address: *http://www.cdc.gov* (Click on ''Funding'' then ''Grants and Cooperative Agreements''), and on the Web site of the HHS Office of Global Health Affairs, Internet address: *http://www.globalhealth.gov*.

Dated: August 17, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.

[FR Doc. 05–16838 Filed 8–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0442]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food and Drug Administration Recall Regulations (Guidelines)

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 September 23, 2005.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Food and Drug Administration Recall Regulations (Guidelines)—(OMB Control Number 0910–0249)—Extension

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7 (21 CFR part 7), subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall; providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, a copy of any recall communication(s), and a contact official; notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm; submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things evaluation return reply cards, effectiveness checks and product returns; and providing the opportunity for a firm to request in writing that FDA terminate the recall.

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2003. The resulting number of recalls from this database search (2,375) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to 201,875 burden hours.

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates on average the burden of collection for recall information to be as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Recall Strategy	2,375	1	2,375	15	35,625
Firm Initiated Recall & Public Warnings Recall Communications	2,375	1	2,375	20	47,500
Recall Status Reports & Followup	2,375	4	9,500	10	95,000
Termination of a Recall	2,375	1	2,375	10	23,750
Total					201,875

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

The annual reporting burdens are explained as follows:

Recall Strategy

Requests firms to develop a recall strategy including provision for public warnings and effectiveness checks. Under this portion of the collection of information, the agency estimates it will receive 2,375 responses annually.

Firm Initiated Recall and Recall Communications

Requests firms that voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, and biologicals to immediately notify the appropriate FDA district office of such actions. The firm is to provide complete details of the recall reason, risk, evaluation, quantity produced, distribution information, firm's recall strategy, and a contact official as well as requires firms to

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]

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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