## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Understanding Social Disparities in Chronic Disease Health Outcomes, Program Announcement Number DP–05–132; Correction

*Correction:* Notice of program announcement number DP–05–132 was published in the **Federal Register** on August 12, 2005, Volume 70, Number 155, pages 47214–47215. The meeting has been cancelled.

*Time and Date:* 3 p.m.–5 p.m., September 1, 2005 (Closed).

*Meeting Location:* Teleconference.

For Further Information Contact: Gwen Cattledge, PhD, Scientific Review Administrator, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS–K92, Atlanta, GA 30341, Telephone (770) 488–4655.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

**Diane Allen,**

*Director, Acting Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 05–17592 Filed 8–31–05; 11:41 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifier: CMS–10041]**

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY:** Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration.

The mandate for the collection of information for the Long-Term Care Awareness Project originates with a presidential initiative in the FY 2000 budget for CMS. The overall goal of this initiative is to help Americans and their families with long-term health needs through a ''national campaign to educate Medicare beneficiaries about coverage available under the new program and how to evaluate long-term care options.'' Current and future beneficiaries now have the opportunity to receive information from a wide variety of printed material, telephone information, and other electronic resources. This collection of information is necessary to design and test evidence-based communication strategies for a national campaign to address the long-term health care planning needs of all Americans.

CMS is requesting OMB review and approval of this collection by October 3, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by October 1, 2005.

*Type of Information Collection Request:* Reinstatement, with change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Long-Term Care Awareness Campaign Demonstration Project; *Use:* Data will be collected to pilot test a national campaign to educate current and future Medicare beneficiaries and their families about long-term care needs. Project findings will be used to design and implement a nationwide campaign. Respondents will be from ages 50–70; *Form Number:* CMS–10041 (OMB#: 0938–0847); *Frequency:* One-time; *Affected Public:* Individuals or Households; *Number of Respondents:* 4,500; *Total Annual Responses:* 4,500; *Total Annual Hours:* 1,350.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/regulations/pra* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received by the designees referenced below by October 1, 2005:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Melissa Musotto, CMS–10041, and,

OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 25, 2005.

**Michelle Shortt,**

*Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 05–17524 Filed 9–1–05; 8:45 am]

**BILLING CODE 4120–03–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2005N–0335]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Recall Authority

**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 medical device recall authority.

**DATES:** Submit written or electronic comments on the collection of information by November 1, 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:** Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**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.

**Medical Device Recall Authority—21 CFR Part 810 (OMB Number 0910–0432)—Extension**

This collection implements medical device recall authority provisions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h) and part 810 (21 CFR part 810). Section 518(e) of the act gives FDA the authority to issue an order requiring the appropriate person, including manufacturers, importers, distributors, and retailers of a device, to immediately cease distribution of such device, to immediately notify health professionals and device-user facilities of the order, and to instruct such professionals and facilities to cease use of such device, if FDA finds that there is reasonable probability that the device intended for human use would cause serious adverse health consequences or death.

Section 518(e) of the act sets out a three-step procedure for issuance of a mandatory device recall order. First, if there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA may issue a cease distribution and notification order requiring the appropriate person to immediately do the following: (1) Cease distribution of the device, (2) notify health professionals and device user facilities of the order, and (3) instruct those professionals and facilities to cease use of the device. Second, FDA will provide the person named in the cease distribution and notification order with the opportunity for an informal hearing on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. Third, after providing the opportunity for an informal hearing, FDA may issue a mandatory recall order if the agency determines that such an order is necessary.

The information collected under the recall authority will be used by FDA to ensure that all devices entering the market are safe and effective, to accurately and immediately detect serious problems with medical devices, and to remove dangerous and defective devices from the market.

The respondents to this proposed collection of information are manufacturers, importers, distributors, and retailers of medical devices.

FDA estimates the burden of this collection of information 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 |
|---|---|---|---|---|---|
| 810.10(d) | 2 | 1 | 2 | 8 | 16 |
| 810.11(a) | 1 | 1 | 1 | 8 | 8 |
| 810.12(a) and (b) | 1 | 1 | 1 | 8 | 8 |
| 810.14 | 2 | 1 | 2 | 16 | 32 |
| 810.15(a) through (d) | 2 | 1 | 2 | 16 | 32 |
| 810.15(e) | 10 | 1 | 10 | 1 | 10 |
| 810.16 | 2 | 12 | 24 | 40 | 960 |
| 810.17 | 2 | 1 | 2 | 8 | 16 |

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| Total | | | | | 1,082 |

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

The following burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—FDA estimates that it will take approximately 8 hours for the person named in a cease distribution and notification order to gather and submit the information required by this section. The total estimated annual burden is 16 hours.

Section 810.11(a)—Based on experience in similar situations, FDA expects that there will be only one request for a regulatory hearing per year and that it will take approximately 8 hours to prepare this request.

Section 810.12(a) and (b)—Based on experience in similar situations, FDA expects that there will be only one written request for a review of a cease distribution and notification order per year and that it will take approximately 8 hours to prepare this request.

Section 810.14—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to develop a strategy for complying with the order.

Section 810.15(a) through (d)—Based upon its experience with voluntary recalls, FDA estimates that it will take approximately 16 hours to notify each health professional, user facility, or individual of the order.

Section 810.15(e)—Based upon its experience with voluntary recalls, FDA estimates that there will be approximately 5 consignees per recall (10 per year) who will be required to notify their consignees of the order. FDA estimates that it will take them about 1 hour to do so.

Section 810.16—FDA estimates that it would take no more than 40 hours to assemble and prepare a written status report required by a recall. The status reports are prepared by manufacturers 6 to 12 times each year. Therefore, each manufacturer would spend no more than 480 hours each year preparing status reports. If there were two FDA invoked recalls each year, the total burden hours estimated would be 960 hours each year.

Section 810.17—Based on experience with similar procedures, FDA estimates that it would take 8 hours to draft a written request for termination of a cease distribution and notification or mandatory recall order.

Dated: August 26, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05–17499 Filed 9–1–05; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### Blood Products Advisory Committee; Notice of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

*Name of Committee*: Blood Products Advisory Committee.

*General Function of the Committee*: To provide advice and recommendations to the agency on FDA's regulatory issues.

*Date and Time*: The meeting will be held on September 29, 2005, from 8 a.m. to 5 p.m.

*Location*: Food and Drug Administration, conference room 1066, 5630 Fishers Lane, Rockville, MD.

*Contact Person*: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting.

*Agenda*: On September 29, 2005, the committee will discuss new drug application (NDA) 21–882 proposed trade name EXJADE (deferasirox) Tablets for Oral Suspension, Novartis Pharmaceutical Corp., proposed for the indication of the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis). Following this discussion, the committee will hear an overview of the research programs in the Laboratory of Hemostasis and the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research (CBER), and in closed session will discuss the report from the laboratory site visit of February 25, 2005.

*Procedure*: On September 29, 2005, from 8 a.m. to 4:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 22, 2005. Oral presentations from the public will be scheduled between approximately 11:15 a.m. and 12:15 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 22, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

*Closed Committee Deliberations*: On September 29, 2005, from approximately 4:15 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss a review of internal research programs in the Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald Jehn or Pearline K. Muckelvene at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).