U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463. Application(s) and/or proposal(s) and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the application(s) and/or proposal(s), the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Purpose: The Safety and Occupational Health Study Section will review, discuss and evaluate grant application(s) in response to NIOSH's standard grants review and funding cycles pertaining to research issues in occupational safety and health and allied areas.

It is the intent of NIOSH to support broad based research endeavors in keeping with the Institute's program goals which will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects which will lead to improvements in the delivery of occupational safety and health services and the prevention of work-related injury and illness. It is anticipated that research funded will help implement the Institute's vision statement: Delivering on the Nation's Promise: Safety and Health at Work for All People. . .Through Research and Prevention. Research funded will examine and evaluate current and emerging problems in occupational safety and health in a variety of settings for health and injured workers.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Pervis C. Major, Ph.D., Scientific Review Administrator, Office of Extramural Coordination and Special Projects, Office of the Director, NIOSH, 1095 Willowdale Road, Morgantown, West Virginia 26505. Telephone 304/285–5979.

Dated: May 9, 1997.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 97–12724 Filed 5–14–97; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0160]

Agency Information Collection Activities; Submission for OMB Review; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by June 16, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–80), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Food Labeling; Nutrient Content Claims and Health Claims; Restaurant Foods

Section 403(r) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)) provides that food labeling may contain nutrient content claims or health claims only if they are in compliance with regulations issued by FDA. FDA has issued regulations in §§ 101.10, 101.13, and 101.14 (21 CFR 101.10, 101.13, and 101.14) that set forth the requirements for restaurants making nutrient content claims and health claims regarding their food products. Section 101.10 requires that nutrition labeling in accordance with § 101.9 (21 CFR 101.9) shall be provided upon request for any restaurant food or meal for which a nutrient content claim or health claim is made. This regulation further provides that a restaurant may comply with the requirements of § 101.9 by providing information on the nutrient amounts that are the subject of the claim (e.g., ''low fat, this meal provides less than 10 grams of fat'' may serve as the functional equivalent of the complete nutritional information as described in § 101.9). For compliance purposes, a restaurant is required by §§ 101.13 and 101.14 to provide appropriate regulatory officials with information that provides a reasonable basis to conclude that the food complies with the definition for the claim. For example, a restaurant may choose to offer an item purchased from a commercial manufacturer where the item is appropriately labeled by the manufacturer as ''low fat.'' In such a case, the restaurant would not have to collect any additional information. Regulatory officials will use the information provided by the restaurant in lieu of analysis to determine whether nutrient content claims or health claims made by a restaurant concerning its food products are in compliance with the requirements of §§ 101.10, 101.13, and 101.14. FDA expects that restaurants will choose the least burdensome option that complies with the regulations.

FDA estimates the burden resulting from the records retention and disclosure requirements of §§ 101.10, 101.13, and 101.14 as follows:

ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.10 101.13(q)(5)(ii) 101.14(d)(2)(vii)(B) and (d)(3)	265,000	1.5	397,500	0.25	99,375

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
101.10	265,000	1.5	397,500	0.75	298,125

ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
101.13(q)(5)(ii) and 101.14(d)(2)(vii)(B)					

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

FDA estimates that there will be no more than 265,000 establishments to which these regulations will apply. This estimate is based on data from the National Restaurant Association. The estimates also reflect the fact that some firms, e.g., large restaurant chains, use the same standardized foods and labeling for more than one establishment, thereby reducing the average burden per establishment. FDA estimates that the average records retention hour burden would be no more than 0.7 hour and the average disclosure hour burden would be no more than 0.25 hour for no more than 1.5 products per establishment. The estimated number of products is based on the average of 1 claim per menu or other device, such as sign or placard, and 1.5 menus or other devices per establishment.

Although FDA's total burden estimate of 397,500 hours has not changed, an estimate for reporting burden (99,375 hours) has been added to reflect the time necessary to comply with the disclosure requirements of these regulations. In FDA's previous estimate (61 FR 40320 at 40331, August 2, 1996), these hours were included as part of the recordkeeping estimate. Because FDA now believes it is more appropriate to characterize disclosure as a reporting burden, the recordkeeping estimate has been reduced accordingly.

Dated: April 25, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12697 Filed 5–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Blood Products Advisory Committee Meeting

Date, time, and place. May 20, 1997, 12:30 p.m., Woodmont I Bldg., conference room B, 1401 Rockville Pike, Rockville, MD.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open committee discussion, 12:30 p.m. to 1 p.m.; open public hearing, 1 p.m. to 2 p.m., unless public participation does not last that long; closed committee deliberations, 2 p.m. to 4 p.m.; Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3514, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Blood Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before May 19, 1997, 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 required to make their comments.

Open committee discussion. This portion of the meeting is to allow for any significant public or administrative announcements to be made prior to convening into the closed committee deliberations.

Closed committee deliberations. The committee will discuss confidential and personal privacy information relevant to the scientific site visit report of the Laboratory of Plasma Derivatives, Division of Hematology, Office of Blood Research and Review, Center for Biologics Evaluation and Research. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(6)).

FDA regrets that it was unable to publish this notice 15 days prior to the May 20, 1997, Blood Products Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Blood Products Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions