CONTACT PERSON FOR MORE INFORMATION: Joseph R. Coyne, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.bog.frb.fed.us for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: December 31, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–34239 Filed 12-31-97; 10:42 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) announces the following workshop.

Name: Workshop on Public and Occupational Health Concerns at Rocky Flats, Colorado.

Time and Date: 3 p.m.–9 p.m., January 7, 1998.

Place: Doubletree Hotel, 8773 Yates Drive, Westminster, Colorado 80030–3678, telephone 303/427–4000.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: The purpose of this workshop is to provide guidance to public health researchers on the inclusion of communities in the planning, conduct, and application of research.

History has demonstrated, when medical and public health science is planned and conducted in the absence of considering the social context of its work, people have been harmed. As a result, society has responded with laws and regulations to protect human subjects who participate in research. Lacking in this discussion has been the issue of planning and conducting research that involves and impacts communities. This workshop will provide a unique opportunity to open dialogue between government, communities, and researchers. This dialogue should result in a proposed framework through which CDC promotes public health, advances democratic principles, establishes an ethical basis for community-based research, enhances scientific credibility, and provides mechanisms for building public trust while advancing the science of public health.

Matters to be Discussed: Agenda items will include presentations on the Dose Reconstruction Project, the National Institute for Occupational Safety and Health studies, and the Workers Medical Surveillance project. Time will be set aside for public comments and discussions, with Agency staff, followed by the workshop being divided into breakout sessions: (1) Environmental Health Issues and (2) Occupational Health Issues.

Agenda items are subject to change as priorities dictate.

Contact Persons for More Information: Michael J. Sage, Deputy Chief, Radiation Studies Branch (RSB), or Carolyn M. Hart, RSB, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770/488–7040, FAX 770/488–7044.

Dated: December 30, 1997.

Julia M. Fuller,

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

[FR Doc. 97–34238 Filed 12-31-97; 12:53 pm]

BILLING CODE 4163–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0513]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on provisions concerning orphan drugs.

DATES: Submit written comments on the collection of information by March 6, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 reinstatement 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 listed below.

With respect to the following collection of information, FDA invites comments on: (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.

Orphan Drugs—(21 CFR Part 316)—(OMB Control Number 0910–0167—Reinstatement)

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aa through 360dd) give the FDA statutory authority to: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs, (2) designate eligible drugs as orphan drugs, (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval, and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the act and sets forth procedures FDA will use in administering the act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the nonclinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.26 allows an applicant to amend the application under certain circumstances. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

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
316.10, 316.12, and 316.14	0	0	0	0	0
316.20, 316.21, and 316.26	90	1.78	160.20	125	20,025
316.22	5	1	5	2	10
316.27	5	1	5	4	20
316.30	450	1	450	2	900
316.36	.2	3	.6	15	9
Total					20,964

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 5 years, that 90 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (21 CFR 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: December 23, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–10 Filed 1–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0512]

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 (the PRA).

DATES: Submit written comments on the collection of information by February 4, 1998.

ADDRESSES: Submit written comments on the collection of information to 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. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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

Use of Impact-Resistant Lenses in Eyeglasses and Sunglasses—21 CFR