DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration on Aging

[Program Announcement No. AoA–00–05]

Fiscal Year 2000 Program Announcement; Notice Requesting Applications

AGENCY: Administration on Aging, HHS

ACTION: Announcement of a request for applications to carry out Racial and Ethnic Approaches to Community Health 2010 (REACH 2010). An important goal of REACH 2010 is to eliminate health disparities among elderly racial and/or ethnic minority groups. Areas of concentration are: diabetes, cardiovascular diseases, and adult immunizations.

SUMMARY: Under this program announcement, the Administration on Aging (AoA) will hold a competition for grant awards of four (4) cooperative agreements to plan for implementation of community level interventions which can eliminate health disparities among elderly members of racial and ethnic minority groups. The purpose of REACH 2010 is to assist communities to organize and prepare an infrastructure for the development and conduct of community-based disease prevention and health promotion models.

The deadline date for the submission of applications is August 21, 2000. Eligibility for grant awards is limited to public and/or nonprofit agencies, organizations, and institutions with experience in health education and promotion for elderly populations. More specifically, the standard of eligibility requires that the applicant, together with the other organizations composing a community coalition, have extensive knowledge about the health concerns of the designated older minority population they plan to serve and proven records of accomplishment serving and working with the community group(s) identified.

Application kits are available by writing to the U.S. Department of Health and Human Services, Administration on Aging, Office of Program Development, 330 Independence Avenue, S.W., Room 4268, Washington, DC 20201, or by calling (202) 619–3428.

Dated: July 14, 2000.

Jeanette C. Takamura,

Assistant Secretary for Aging

[FR Doc. 00–18494 Filed 7–20–00; 8:45 am]

BILLING CODE 4154–01–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee for Energy-Related Epidemiologic Research: Conference Call Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following conference call meeting.

Name: Advisory Committee for Energy-Related Epidemiologic Research (ACERER).

Time and Date: 1 p.m.–3 p.m., August 4, 2000.

Place: The conference call will originate at the National Center for Environmental Health (NCEH), CDC, in Atlanta, Georgia. Please see **SUPPLEMENTARY INFORMATION** for details on accessing the conference call.

Status: Open to the public, limited only by the availability of telephone ports.

Purpose: This committee is charged with providing advice and recommendations to the Secretary, HHS; and to the Director, CDC, and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), on establishment of a research agenda and the conduct of a research program pertaining to energy-related epidemiologic studies.

Matters to be Discussed: The conference call agenda is to reach consensus on the review and report submitted to the ACERER by its Subcommittee for Management Review of the Chernobyl Studies.

Agenda items are subject to change as priorities dictate.

SUPPLEMENTARY INFORMATION: This conference call is scheduled to begin at 1 p.m., Eastern Time. To participate in the conference call, please dial 1–877–475–9228 and enter conference code 195001. You will then be automatically connected to the call.

FOR FURTHER INFORMATION CONTACT: Michael J. Sage, Executive Secretary, ACERER, and Associate Director for Planning, Evaluation, and Legislation, NCEH, CDC, 4770 Buford Highway, NE, (F–29), Atlanta, Georgia 30341–3724, telephone 770/488–7020, fax 770/488–7024.

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 ATSDR.

Dated: July 17, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–18600 Filed 7–20–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1379]

Agency Information Collection Activities; Proposed Collection; Comment Request; Procedures for the Safe Processing and Importing of Fish and Fishery Products

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 extending the existing reporting and recordkeeping requirements for processors and importers of fish and fishery products under the provisions of FDA's fish and fishery products regulations.

DATES: Submit written comments on the collection of information by September 19, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (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 Schlosburg, Office of Information Resources Management (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: (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.

Procedures for the Safe Processing and Importing of Fish and Fishery Products (OMB Control Number 0910–0354)—Extension

FDA regulations in part 123 (21 CFR part 123) mandate the application of Hazard Analysis and Critical Control Point (HACCP) principles to the processing of seafood. HACCP is a preventive system of hazard control designed to help ensure the safety of foods. The regulations were issued under FDA's statutory authority to regulate food safety, including section 402(a)(1) and (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) and (a)(4)), and became effective on December 18, 1997.

Certain provisions in part 123 require that processors and importers of seafood collect and record information. The HACCP records compiled and maintained by a seafood processor primarily consist of the periodic observations recorded at selected monitoring points during processing and packaging operations, as called for in a processor's HACCP plan (e.g., the values for processing times, temperatures, acidity, etc. as observed at critical control points). The primary purpose of HACCP records is to permit a processor to verify that products have been produced within carefully established processing parameters (critical limits) that ensure that hazards have been avoided. HACCP records are normally reviewed by appropriately trained employees at the end of a production lot or at the end of a day or week of production to verify that control limits have been maintained, or that appropriate corrective actions were taken if the critical limits were not maintained. Such verification activities are essential to ensure that the HACCP system is working as planned. A review of these records during the conduct of periodic plant inspections also permits FDA to determine whether the products have been consistently processed in conformance with appropriate HACCP food safety controls.

Section 123.12 requires that importers of seafood products take affirmative steps and maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. These records are also to be made available for review by FDA as provided in § 123.12(c).

The time and costs of these recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the type and number of products involved, and the nature of the equipment or instruments required to monitor critical control points. The burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry.

The burden estimate in Table 1 includes only those collections of information under the seafood HACCP regulations that are not already required under other statutes and regulations. For example, the current food manufacturing practices provisions in 21 CFR part 110 already require that all food processors ensure good sanitary practices and conditions, monitor the quality of incoming materials, monitor and control food temperatures to prevent bacterial growth, and perform certain corrective actions and verification procedures. Furthermore, the estimate does not include collections of information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors. Consequently the estimates in Table 1 account only for new information collection and recording requirements attributable to part 123. FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping[2]	Total annual records	Hours per recordkeeper[3]	Total hours	Total operating and maintenance costs
123.6(a), (b), and (c)	243	1	243	16	3,888	$58,320
123.6(c)(5)	4,850	4	19,400	0.30	5,820	$87,300
123.8(a)(1) and (c)	4,850	1	4,850	4	19,400	$291,000
123.12(a)(2)(ii)	1,000	80	80,000	0.20	16,000	$240,000
123.6(c)(7)	4,850	280	1,358,000	0.30	407,400	$6,111,000
123.7(d)	1,940	4	7,760	0.10	1,940	$29,100
123.8(d)	4,850	47	227,950	0.10	22,795	$341,925
123.11(c)	4,850	280	1,358,000	0.10	135,800	$2,037,000
123.12(c)	1,000	80	80,000	0.10	8,000	$120,000
123.12(a)(2)	50	1	50	4	200	$3,000
123.10	243	1	24	24	5,832	$87,480
Annual burden hours					627,075	$9,406,125

[1]There are no capital costs associated with this collection of information.
[2]Based on an estimated 280 working days per year.
[3]Estimated average time per 8-hour work day unless one time response.
The above estimates include the information collection requirements in the following sections:
§ 123.16 Smoked Fish—process controls (see § 123.6(b))
§ 123.28(a) Source Controls—molluscan shellfish (see § 123.6(b))

§ 123.28(c), (d) Records—molluscan shellfish (see § 123.6(c)(7))

Dated: July 14, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–18459 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Dermatologic and Ophthalmic Drugs 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). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs 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 18 and 19, 2000, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18 and 19, 2000, the committee will discuss two new drug applications (NDA's): NDA 18–662, Accutane® (isotretinoin) capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne; and NDA 21–177, (new formulation) isotretinoin capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne.

Procedure: 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 7, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2000, 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.

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

Dated: July 11, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–18457 Filed 7–20–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1394]

Medical Devices; CLIA Waiver Criteria; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to review the criteria used to determine whether specific laboratory tests are waived from certain requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The purpose of the public workshop is to obtain additional comments on the criteria and process the agency should use to determine when a particular test is waived.

Date and Time: The public workshop will be held on August 14 and 15, 2000, from 9 a.m. to 5 p.m. each day.

Location: The public workshop will be held at the Washingtonian Center Marriott Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD 20878, 301–590–0044.

Contact: Clara A. Sliva, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–827–0496, FAX 301–827–1401, e-mail: CAS@cdrh.fda.gov.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentations to the contact person by August 4, 2000. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850, by September 14, 2000.

If you need special accommodations due to a disability, please contact Clara A. Sliva at least 7 days in advance of the meeting.

SUPPLEMENTARY INFORMATION:

A. Background

CLIA specifies that laboratory requirements be based on the complexity of the tests performed and establishes criteria for categorizing a test as waived. Responsibility for determining whether a particular test is waived was transferred from the Centers for Disease Control and Prevention (CDC) to FDA on January 31, 2000. In the **Federal Register** of September 13, 1995 (60 FR 47534), CDC published proposed clarifications to the statutory criteria for waiver. CDC based the proposal on guidelines CDC developed to assist the manufacturers in submitting waiver requests. The proposed regulations recommend a methodology for demonstrating that a test system proposed for waived status be so ''simple'' and ''accurate'' as to render the likelihood of erroneous results negligible. The Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law No. 105–115) modified 42 U.S.C. 263a (d)(3) of the Public Health Service Act by adding the phrase ''by the user'' to clarify that waived tests include those which employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible. FDAMA also clarified that waived tests include those that are cleared by FDA for home use.

Following transfer of responsibility for waiver determinations from CDC to FDA, manufacturers now submit premarket applications for products and requests for complexity categorization of these products to one agency. FDA is currently following the same policies applied by CDC to the waiver criteria prior to the transfer; FDA is performing the ''same work'' the ''same way.'' Under the current process, FDA generally will waive: (1) Any test system that meets the specifications described in the guidelines published in the proposed rule of September 13, 1995, and (2) any test system that provides scientifically valid data verifying that the statutory criteria for waiver have been met.