

FOR FURTHER INFORMATION CONTACT: Charity B. Smith, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1686.

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.

Part 1210 Regulations Under the Federal Import Milk Act (21 CFR Part 1210) (OMB Control Number 0910-0212—Extension)

Under the regulations implementing the Federal Import Milk Act (21 U.S.C. 141-149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet

certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50 °F. In addition, the regulations require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

FDA estimates the burden of complying with the information collection provisions of these regulations as follows:

ESTIMATED ANNUAL REPORTING BURDEN

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	1	1	1	0.5	0.5
FDA 1993/Application for permit	1210.20	1	1	1	0.5	0.5
FDA 1994/Tuberculin test	1210.13	0	0	0	N/A	0
FDA 1995/Physical examination of cows	1210.12	0	0	0	N/A	0
FDA 1996/Sanitary inspection of dairy farms	1210.11	1	300	300	1.5	450
FDA 1997/Sanitary inspections of plants	1210.14	1	1	1	2.0	2.0
Totals						453

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

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
21 CFR 1210.15	1	1	1	.05	0.05

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

No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they

would occur in the normal course of activities. No burden has been estimated for Forms FD 1994 and 1995 because they are not currently being used. The Secretary of Health and Human Services has the discretion to allow Form FD 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FD 1994 and 1995. To date, Form FD-1815 has been submitted in lieu of these forms.

Dated: September 10, 1996.
William K. Hubbard,
Associate Commissioner for Policy Coordination.
[FR Doc. 96-24365 Filed 9-23-96; 8:45 am]
BILLING CODE 4160-01-F

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings 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.

MEETINGS: The following advisory committee meetings are announced:

Joint Meeting of the Nonprescription Drug Advisory Committee and the Arthritis Drugs Advisory Committee

Date, time, and place. October 9, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kennerly K. Chapman or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or e-mail ChapmanK@fda.cder.gov, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, or Arthritis Advisory Committee, code 12532. Please call the hotline for information concerning any possible changes.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (OTC) (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Arthritis Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in arthritic conditions.

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 October 2, 1996, 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. The committees will discuss new drug application (NDA) 20-373, S+ Ibuprofen (dexibuprofen, Sterling Winthrop/Bayer) 200-milligram caplet, indicated for the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, back ache, menstrual cramps, minor pain of arthritis, and for the temporary reduction of fever for OTC status.

Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. October 9, 1996, 9:30 a.m., Holiday Inn—Gaithersburg, Walker Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Type of meeting and contact person. Open public hearing, 9:30 a.m. to 10:30 a.m., unless public participation does not last that long; open committee discussion, 10:30 a.m. to 5 p.m.; Leander B. Madoo, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Pulmonary-Allergy Drugs Advisory Committee, code 12545. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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 October 1, 1996, 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. The committee will discuss Genentech's clinical labeling supplement to modify the current prescribing information for

Pulmozyme® (dornase alfa) pertaining to cystic fibrosis patients with forced vital capacity of the lung, less than 40 percent of predicted capacity.

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary-Allergy Drugs Advisory Committee

Date, time, and place. October 10 and 11, 1996, 8:30 a.m., Holiday Inn—Bethesda, Versailles Ballrooms II and III, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, October 10, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; open public hearing, October 11, 1996, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Kennerly K. Chapman or Leander B. Madoo, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Nonprescription Drugs Advisory Committee, code 12541, Pulmonary-Allergy Drugs Advisory Committee, code 12545. Please call the hotline for information concerning any possible changes.

General function of the committees. The Nonprescription Drugs Advisory Committee reviews and evaluates available data concerning the safety and effectiveness of OTC (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases. The Pulmonary-Allergy Drugs Advisory Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms.

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 October 1, 1996, 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. On October 10, 1996, the committees will

jointly consider NDA 20-463, Nasalcrom® (Cromolyn Sodium Nasal Solution, United States Pharmacopeia) for OTC treatment of seasonal allergic rhinitis sponsored by McNeil Consumer Products Co. On October 11, 1996, the committees will jointly consider the prescription to OTC switch of NDA 19-589, Vancenase AQ® Nasal Spray (Beclomethasone Dipropionate) for the treatment of seasonal allergic rhinitis sponsored by Schering-Plough Pharmaceutical Co.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. October 21 and 22, 1996, 9 a.m., and October 23, 1996, 8 a.m., Sheraton Reston Hotel, meeting rooms 1 and 2, 11810 Sunrise Valley Dr., Reston, VA. A limited number of overnight accommodations have been reserved at the Sheraton Reston Hotel. Attendees requiring overnight accommodations may contact the hotel at 703-620-9000 and reference the FDA committee meeting block. Reservations will be confirmed at the group rate based on availability.

Type of meeting and contact person. Open public hearing, October 21, 1996, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; open committee discussion, October 22, 1996, 9 a.m. to 5 p.m.; open committee discussion, October 23, 1996, 8 a.m. to 9 a.m.; open public hearing, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; Charles K. Showalter, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), National Mammography Quality Assurance Advisory Committee, code 12397. Please call the hotline for information concerning any possible changes.

General function of the committee. The committee advises on developing appropriate quality standards and regulations for the use of mammography facilities.

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 October 7, 1996, 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. On October 21 and 22, 1996, the committee will discuss regulation of interventional mammography under the Mammography Quality Standards Act (MQSA) of 1992. On October 23, 1996, the committee will discuss: (1) The request of the American Board of Certification in Radiology to be designated as eligible to certify interpreting physicians under the MQSA and (2) controversial areas of the proposed final regulations (see 61 FR 14856, April 3, 1996 (21 CFR part 900)). Copies of the proposed final regulations may be requested in writing from MQSA, c/o KRA Corp., 1010 Wayne Ave., suite 850, Silver Spring, MD, 20910, or FAX 301-495-9410.

FDA public advisory committee meetings 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 will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: September 18, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96-24453 Filed 9-23-96; 8:45 am]

BILLING CODE 4160-01-F

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Fogarty International Center Advisory Board Meeting

Pursuant to Public Law 92-463, as amended, notice is hereby given of the thirty-fourth meeting of the Fogarty International Center (FIC) Advisory Board, October 8, 1996, in the Lawton Chiles International House (Building 16) at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to 12:00 p.m.

The agenda will begin with a report by the Director, FIC. The meeting will focus on emerging infectious diseases and will include the following presentations: the Presidential Decision Directive on Emerging Infectious Diseases; National Institute of Allergy and Infectious Diseases/FIC collaboration in emerging infectious diseases; a follow-up on the International Colloquium on Ebola Virus; and an update on the status of the International Conference on Malaria planned for January 1997. There also will be a report on the June Meeting of the Advisory Committee to the Director, NIH and the Meeting of Representatives of NIH Advisory Councils.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code and section 10(d) of Public Law 92-463, as amended, the meeting will be closed to the public from 1:00 p.m. to adjournment for the review of applications for awards under the Senior International Fellowship Program, the Minority International Research Training Program and the International Program in Environmental and Occupational Health; the Fogarty International Research Collaboration Awards and HIV, AIDS and Related Illnesses Collaboration Awards; and Nominations for the Scholars-in-Residence Program.

Paula Cohen, Committee Management Officer, Fogarty International Center, National Institutes of Health, Building 31, Room B2C08, 31 CENTER DR MSC 2220, Bethesda, Maryland 20892-2220, telephone: 301-496-1491, will provide

a summary of the meeting and a roster of the committee members upon request.

Irene Edwards, Executive Secretary, Fogarty International Center Advisory Board, Building 31, Room B2C08, telephone: 301-496-1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Cohen at least 2 weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.989, Senior International Awards Program)

Dated: September 17, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96-24439 Filed 9-23-96; 8:45 am]

BILLING CODE 4140-01-M

Division of Research Grants; Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Division of Research Grants Special Emphasis Panel (SEP) meetings:

Purpose/Agenda: To review individual grant applications.

Name of SEP: Microbiological and Immunological Sciences.

Date: October 24, 1996.

Time: 8:30 a.m..

Place: Holiday Inn, Bethesda, MD.

Contact Person: Dr. Marcel Pons, Scientific Review Administrator, 6701 Rockledge Drive, Room 4196, Bethesda, Maryland 20892, (301) 435-1217.

Name of SEP: Biological and Physiological Sciences.

Date: October 30, 1996.

Time: 1:30 p.m.

Place: NIH, Rockledge 2, Room 6166, Telephone Conference.

Contact Person: Dr. Abubakar A. Shaikh, Scientific Review Administrator, 6701 Rockledge Drive, Room 6166, Bethesda, Maryland 20892, (301) 435-1042.

Name of SEP: Chemistry and Related Sciences.

Date: November 6, 1996.

Time: 1:00 p.m.

Place: NIH, Rockledge 2, Room 5156, Telephone Conference.

Contact Person: Dr. Chhandra Ganguly, Scientific Review Administrator, 6701 Rockledge Drive, Room 5156, Bethesda, Maryland 20892, (301) 435-1739.

Name of SEP: Chemistry and Related Sciences.

Date: November 12, 1996.

Time: 2:00 p.m.

Place: NIH, Rockledge 2, Room 5156, Telephone Conference.

Contact Person: Dr. Chhandra Ganguly, Scientific Review Administrator, 6701

Rockledge Drive, Room 5156, Bethesda, Maryland 20892, (301) 435-1739.

The meetings will be closed in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 17, 1996.

Paula N. Hayes,

Acting Committee Management Officer, NIH.

[FR Doc. 96-24438 Filed 9-23-96; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4086-N-50]

Office of the Assistant Secretary for Housing; Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due by November 25, 1996.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development 451-7th Street, SW., Room 9116, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Barbara D. Hunter, Telephone number (202) 708-3944 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork