Dated: June 12, 1995.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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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:

Gastrointestinal Drugs Advisory Committee

Date, time, and place. July 12, 1995, 9 a.m., Holiday Inn—Bethesda, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. 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.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, or Valerie M. Mealy, Advisors and Consultants Staff (HFD–9), 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Gastrointestinal Drugs Advisory Committee, code 12538.

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 gastrointestinal 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 June 30, 1995, 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 new drug application (NDA) 20–458, Lemmon Co., zinc acetate to be indicated for use in Wilson's disease. The advisory committee will also consider draft ''Points to Consider'' from the Division of Anti-Infective Drug Products on *Helicobacter pylori* studies to prevent peptic ulcer recurrence.

National Mammography Quality Assurance Advisory Committee

Date, time, and place. July 18 and 19, 1995, 9 a.m., Hyatt Regency—Bethesda, Cabinet-Judiciary Suite, One Bethesda Metro Center, Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–657–1234 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, July 18, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open subcommittee discussions, 10 a.m. to 5 p.m.; open subcommittee discussions, July 19, 1995, 9 a.m. to 2 p.m.; open committee discussion, 2 p.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.

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 July 11, 1995, 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 July 19, 1995, the committee will discuss the ongoing work of the three subcommittees: Access to Mammography Services, Physicists Availability, and Cost Benefit of Compliance.

Open subcommittee discussions. On July 18 and 19, 1995, the three subcommittees will meet concurrently. The subcommittees will discuss the ongoing work which is necessary to make the determinations and subsequently prepare the reports as mandated in the Mammography Quality Standards Act. Upon completion, the subcommittee reports will be reviewed by the committee prior to submission to the Secretary of Health and Human Services and Congress.

Ophthalmic Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. July 20 and 21, 1995, 8:30 a.m., Bethesda Pooks Hill Marriott, Congressional Ballroom, 5151 Pooks Hill Rd., Bethesda, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel at 301–897–9400 and reference the FDA Panel meeting block. Reservations will be confirmed at the group rate based on availability. Attendees with a disability requiring special accommodations should contact Ed Rugenstein, Sociometrics, Inc., 301–608–2151. The availability of appropriate accommodations cannot be assured unless prior written notification is received.

Type of meeting and contact person. Open public hearing, July 20, 1995, 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, July 21, 1995, 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 12 m.; Sara M. Thornton, Center for Devices and Radiological Health

(CDRH) (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ophthalmic Devices Panel, code 12396.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

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 July 7, 1995, 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 July 20, 1995, the Division of Ophthalmic Devices will propose a redraft of the myopia refractive laser guidance document and request discussion and comments from the public and the panel and panel recommendations on designated sections. Single copies of the proposed redraft are available from Sara M. Thornton (address above). On July 21, 1995, the Contact Lens Branches will present an overview of the draft premarket notification (510(k)) guidance document for lens care products to be used as a special control for reclassification of contact lens care products. The committee will discuss and recommend the classification status for vision trainers. There will also be general updates from the Contact Lens Branches, Intraocular Implants Branch, and Diagnostic and Surgical Devices Branch within CDRH.

Oncologic Drugs Advisory Committee

Date, time, and place. July 24 and 25, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, July 24, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open committee discussion, July 25, 1995, 8 a.m. to 11:30 a.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD–9), 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), Oncologic Drugs Advisory Committee, code 12542.

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 treatment of cancer.

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 July 19, 1995, 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 July 24, 1995, the committee will discuss: (1) NDA 20–036, Aredia® (pamidronate disodium for injection, Ciba Pharmaceuticals Division, Ciba-Geigy Corp.), ''for the treatment of bone metastases associated with multiple myeloma,'' and (2) NDA 20–509, Gemzar® (gemcitabine hydrochloride, Eli Lilly), ''as first line treatment for patients with advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas,'' and ''for patients with 5-FU-refractory pancreatic cancer.'' On July 25, 1995, the committee will discuss product license application PLA 94–0799 Intron®A, (interferon alpha 2b, recombinant, Schering, Inc.), for ''post-operative adjuvant therapy in malignant melanoma.''

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, rm. 12A–16, 5600 Fishers Lane, 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, rm. 1–23, 12420 Parklawn Dr., 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 (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: June 13, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

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Health Resources and Services Administration

RIN 0905–ZA90

Program Announcement and Proposed Project Requirements, Review Criteria, and Funding Preference for Cooperative Agreement for a Model Hispanic Health Careers Opportunity Program for Fiscal Year 1995

The Health Resources and Services Administration (HRSA) announces that applications will be accepted for a fiscal year (FY) 1995 Cooperative Agreement for a Model Hispanic Health Careers Opportunity Program (HCOP) under the authority of section 740, title VII of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992. Comments are invited on the proposed project requirements, review criteria and funding preference.

Approximately $300,000 will be available in FY 1995 for this program. It is anticipated that one competing award will be made at a level of $300,000 per year over a three year period.

Purpose and Eligibility

Section 740 authorizes the Secretary to make grants to and enter into contracts with schools of allopathic medicine, osteopathic medicine, public health, dentistry, veterinary medicine, optometry, pharmacy, allied health, chiropractic and podiatric medicine and public and nonprofit private schools which offer graduate programs in clinical psychology and other public or private nonprofit health or educational entities to carry out programs which assist individuals from disadvantaged backgrounds to enter and graduate from such schools. Assistance may be used for the following five legislative purposes:

1. Recruitment—activities designed to identify, recruit and select individuals from disadvantaged backgrounds for education in the health or allied health professions, e.g., motivational activities, distribution of information, exposure to role models, and counseling.

2. Preliminary Education—education designed to expand the academic ability and otherwise prepare student participants from disadvantaged backgrounds during their preprofessional training that they may subsequently complete the regular course of education in a health professions school or school of allied health. This education must be offered prior to entry in a health professions or allied health professions school and may not include courses already taught as part of the regular course of education leading to a degree.

3. Facilitating Entry—activities designed to enhance the competitiveness of student participants from disadvantaged backgrounds for admission to health professions schools or schools of allied health, such as improving performance on admissions tests, counseling concerning the application process, and assisting admissions committees in the evaluation of disadvantaged applicants.

4. Retention—activities designed to help student participants from disadvantaged backgrounds, who have been accepted to or are enrolled in health professions schools or schools of allied health, to complete their education. These activities may include tutorial assistance, counseling, and assistance in adjusting to the environment of the school. Activities may not include courses already taught as part of the school's curriculum.

5. Financial Aid Information Dissemination—the distribution of information to student participants from disadvantaged backgrounds about financial aid available in health professions schools, schools of allied health or schools and entities which provide training necessary to qualify for enrollment in health professions schools or schools of allied health.

Applicants may request support for up to three years.

The Model Hispanic HCOP cooperative agreement is being proposed in an effort to achieve the following goals: (1) To establish and test a comprehensive Model Hispanic HCOP (addressing all of the HCOP purposes) in a metropolitan area with a high concentration of Hispanic citizens. No such model currently exists. In addition to the formulation of academic-community educational partnerships, this model provides for community infrastructure building. The proposed model encompasses strong linkages throughout the community involving community organizations, official agencies, educational institutions at all levels and health professionals throughout the community, and (2) To increase the number of Hispanic participants in HCOP programs.

This cooperative agreement also addresses section 740(c) of the HCOP legislation which requires ''the Secretary to ensure that services and activities under HCOP awards are equitably allocated among the various racial and ethnic populations.''

Proposed Project Requirements

I. The Model Hispanic HCOP will establish an educational continuum from high school graduation through graduation from a health or allied health professions school through development and implementation of activities related to all five of the legislative purposes.

II. A plan for selecting students including criteria for selection must be developed and implemented.

III. Activities related to all of the five legislative purposes undertaken must be evaluated. Modifications must be made in activities based on evaluation.

IV. Activities and experiences related to the establishment of the Model Hispanic HCOP must be documented in a format that would allow for future replication by HCOP applicants.

Substantial Federal Programmatic Involvement

It is anticipated that the federal government will have substantial programmatic involvement with the planning, development and administration of the Model Hispanic HCOP and its outputs by:

1. Providing technical assistance and reviewing changes needed in the approved application.

2. Reviewing and advising regarding training content and methodologies.

3. Participating in the review and advising regarding formal linkage arrangements which have been established for the purpose of conducting the Model Hispanic HCOP.

4. Reviewing the validity of and assisting in the modification of student participant selection criteria and processes.

5. Providing information relative to proven evaluation methods, including data collection methods, data analysis techniques and participant tracking systems.

6. Reviewing and advising regarding program evaluation methods, including data collection activities, data analysis techniques and participant tracking systems.

7. Reviewing and advising regarding the documentation of the activities and experiences related to establishment of the Model Hispanic HCOP.

8. Providing data and information about federal programs that may impact the Model Hispanic HCOP.

9. Participating in the review of sub-contracts awarded under the Cooperative Agreement.