DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Disease Prevention and Health Promotion

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

National Nutrition Monitoring Advisory Council: Notice of Meeting

SUMMARY: The National Nutrition Monitoring Advisory Council intends to hold its seventh meeting on October 24 from 9 a.m. to approximately 5:00 p.m. E.S.T., and October 25 from 9:00 a.m. to 1:00 p.m. E.S.T., in the Williamsburg Room (104A) in the Jamie Whitten USDA Administration Building, 14th Street and Independent Avenue, S.W., Washington, D.C. 20250. The meeting will be held pending the availability of Fiscal Year 1996 funds. It will be open to the public; seating is limited.

FOR FURTHER INFORMATION CONTACT: Dr. Linda Meyers, HHS Co-Executive Secretary to the Council, U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Room 2132, Switzer Building, 330 C Street, S.W., Washington, D.C. 20201, (202) 205–9007.

SUPPLEMENTARY INFORMATION: The Nutrition Monitoring Advisory Council was established by Public Law 101–445 to evaluate the scientific and technical quality of the Ten-year Comprehensive Plan for the National Nutrition Monitoring and Related Research Program and the effectiveness of the coordinated program and to provide guidance to the Secretaries of USDA and HHS that include recommendations for strengthening the Program.

The Council meeting agenda will include updates and discussion on progress related to the Ten-Year Plan for Nutrition Monitoring and Related Research and discussion of the Council's annual report to the Secretaries.

The public may file statements with the Council before or after the meeting by addressing them to either of the contact persons listed above. Please call Linda Meyers (202/205–9007) by October 14 if you will require a sign language interpreter.

Done at Washington, D.C. this 25th day of September, 1995.

James A. Harrell,

Acting Director, Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services.

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BILLING CODE 4160–17–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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:

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. October 20, 1995, 8 a.m., Corporate Bldg., ground floor conference room, 9200 Corporate Blvd., Rockville, MD. A limited number of overnight accommodations have been reserved at the Gaithersburg Marriott Washingtonian Hotel, 9751 Washingtonian Blvd., Gaithersburg, MD. Attendees requiring overnight accommodations may contact the hotel at 301–590–0044 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, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 3 p.m.; closed committee deliberations, 3 p.m. to 6 p.m.; Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Gastroenterology and Urology Devices Panel, code 12523.

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 October 13, 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 general issues related to a premarket approval application for an electromagnetic device intended to treat benign prostatic hyperplasia using localized heat.

Closed committee deliberations. FDA staff will present to the committee trade secret and/or confidential commercial information regarding medical devices. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. October 23, 1995, 8:30 a.m., and October 24, 1995, 7:30 a.m., DoubleTree Hotel, Ballroom, 1750 Rockville Pike, Rockville, MD. A limited number of overnight accommodations have been reserved at the hotel. Attendees requiring overnight accommodations may contact the hotel

at 301–468–1100 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, October 23, 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.; closed committee deliberations, October 24, 1995, 7:30 a.m. to 8:30 a.m.; 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.; Alfred W. Montgomery, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area) Obstetrics and Gynecology Devices Panel, code 12524.

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 October 4, 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 October 23, 1995, the committee will consider a list of devices used for in vitro fertilization and other assisted reproduction technologies. The committee will provide expert advice on these devices that will be used to develop 510(k) guidance. On October 24, 1995, the committee will consider a draft guidance document on the preparation of an investigational device exemption for thermal endometrial ablation devices. Single copies of the list of in vitro fertilization devices and the guidance document for thermal endometrial ablation devices are available to the public after October 1, 1995, by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041.

Closed committee deliberations. On October 24, 1995, FDA staff will present to the committee trade secret and/or confidential commercial information regarding various medical devices used in obstetrics and gynecology that are currently being evaluated by FDA. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. October 26 and 27, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open committee discussion, October 26, 1995, 8 a.m. to 8:15 a.m.; open public hearing, 8:15 a.m. to 8:45 a.m., unless public participation does not last that long; open committee discussion, 8:45 a.m. to 1:30 p.m.; closed committee deliberations, 1:30 p.m. to 2:30 p.m.; open committee discussion, 2:30 p.m. to 6 p.m.; closed committee deliberations, October 27, 1995, 8 a.m. to 12:30 p.m.; open public hearing, 12:30 p.m. to 1 p.m., unless public participation does not last that long; open committee discussion, 1 p.m. to 5:15 p.m.; Nancy T. Cherry or Sandy M. Salins, Center for Biologics Evaluation and Research (HFM–21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Vaccines and Related Biological Products Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines 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 October 18, 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 October 26, 1995, the committee will hear presentations on recent acellular pertussis trials sponsored by the Public Health Service, and on a new strategic plan for the year 2004 developed by the Center for Biologics Evaluation and Research. The committee will also consider whether a single formulation for pneumococcal conjugate vaccines should be adopted for children in the United States. On October 27, l995, the committee will discuss a draft Points to Consider document addressing the evaluation of combination vaccines. Copies of the document will be available at the meeting.

Closed committee deliberations. On October 26 and 27, l995, the committee will review trade secret and/or confidential commercial information relevant to pending investigational new drug applications or product licensing applications. These portions of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

Medical Imaging Drugs Advisory Committee

Date, time, and place. October 26 and 27, 1995, 8 a.m., Holiday Inn, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Type of meeting and contact person. Open public hearing, October 26, 1995, 8 a.m. to 9 a.m., unless public participation does not last that long; closed committee deliberations, 9 a.m. to 11 a.m.; open committee discussion, 11 a.m. to 4 p.m.; open committee discussion, October 27, 1995, 8 a.m. to 4 p.m.; Leander B. Madoo (HFD–9), Center for Drug Evaluation and Research, 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), Medical Imaging Drugs Advisory Committee, code 12540.

General function of committee. The committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in diagnostic and therapeutic procedures using radioactive pharmaceuticals and contrast media used in diagnostic radiology.

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 12, 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 hold a preliminary discussion in preparation for drafting of future ''Points to Consider for Diagnostic Imaging Agents''.

Closed committee deliberations. The committee will be briefed on confidential commercial information relevant to pending IND's and NDA's. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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 will depend upon the specific meeting involved. The dates and times reserved for the separate 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.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

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: September 26, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95–24354 Filed 9–29–95; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[ORD–079–N]

New and Pending Demonstration Project Proposals Submitted Pursuant to Section 1115(a) of the Social Security Act: June 1995

AGENCY: Health Care Financing Administration (HCFA).

ACTION: Notice.

SUMMARY: This notice lists new proposals for Medicaid demonstration projects submitted to the Department of Health and Human Services during the month of June 1995 under the authority of section 1115 of the Social Security Act. This notice also lists proposals that were approved, disapproved, pending, or withdrawn during this time period. This notice also lists a new proposal that was submitted to the Department in March 1995 but was inadvertently