

describe the trust funds' current and projected financial condition, within the next 10 years (the short term) and over the subsequent 65 years (the long term). The Medicare Board of Trustees has directed the Secretary of Health and Human Services (who is one of the Trustees) to establish a panel of technical experts to review the assumptions and methods underlying the HI and SMI annual reports.

The panel's review will include the following four topics:

1. Medicare assumptions (e.g., utilization rates, medical price increases)
2. Projection methodology (how assumptions are used to make cost projections)
3. Long-range growth assumptions for HI and SMI
4. Use of stochastic forecasting techniques.

The Panel will issue its findings in reports to the Secretary and the other Trustees.

The Panel consists of six members who are experts in the fields of economics and actuarial science; Dale Yamamoto, F.S.A., M.A.A.A., F.C.C.A., E.A., B.S.—Chair; Len Nichols, Ph.D.; David Cutler, Ph.D.; Michael Chernen, Ph.D.; James Robinson, F.S.A., M.A.A.A., Ph.D.; and Alice Rosenblatt, F.S.A., M.A.A.A., M.A. The members' terms will end August 12, 2001. Sam Gutterman, F.S.A., F.C.A.S., M.A.A.A., M.A., is a consultant to the Panel.

The Panel's third meeting will be held on September 7, 2000 (9 a.m. to 5 p.m.) and September 8, 2000 (9 a.m. to 1 p.m.). The fourth meeting will be held on October 11, 2000 (9 a.m. to 5 p.m.) and October 12, 2000 (9 a.m. to 1 p.m.). The meetings will be held at the Health Care Financing Administration (HCFA) Headquarters, Conference Center, Room C-112, 7500 Security Boulevard, Baltimore, Maryland. The meetings are open to the public, but attendance is limited to the space available. The Panel's first meeting was held June 28–29, 2000, and the second meeting was held July 26–27, 2000.

At its third and fourth meetings, the Panel will discuss findings from its subgroups on the following five topics:

1. Medicare Assumptions
2. Projection Methodology
3. Long-Range Growth Assumptions
4. Uncertainty (stochastic forecasting, alternative assumptions, sensitivity)
5. Report Presentation Issues/Research and Data.

The Panel will also consider recommendations to the Board of Trustees in each of these areas. At the third meeting, the Panel will also hear presentations from organizations that

develop models similar to the Medicare Trust Funds models.

Individuals or organizations that wish to make 5-minute oral presentations on the agenda issues mentioned in this notice should contact the Executive Director by 5 p.m. on August 25, 2000. The number of oral presentations may be limited to the time available. A written copy of the presenters' oral remarks should be submitted to the Executive Director no later than 5 p.m. on August 31, 2000, for distribution to the Panel members.

Any interested member of the public may submit written comments to the Executive Director and Panel members for review. Comments should be received by the Executive Director by 5 p.m. on August 31, 2000, for distribution to the Panel members.

Individuals requiring sign language interpretation for the hearing impaired and/or other special accommodation, should contact Ariel Winter at (202) 690–6860 by August 25, 2000.

Dated: August 2, 2000.

Margaret A. Hamburg,

Assistant Secretary for Planning and Evaluation.

[FR Doc. 00–20349 Filed 8–10–00; 8:45 am]

BILLING CODE 4154–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Demonstration Projects for the Early Intervention and Prevention of Sexual Violence and Intimate Partner Violence Among Racial and Ethnic Minority Populations, PA# 00074

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 meeting.

Name: Disease, Disability and Injury Prevention and Control Special Emphasis Panel: Demonstration Projects for the Early Intervention and Prevention of Sexual Violence and Intimate Partner Violence Among Racial and Ethnic Minority Populations, PA# 00074.

Times and Dates:

8 a.m.–8:45 a.m. August 21, 2000 (Open)

8:45 a.m.–5:30 p.m. August 21, 2000

(Closed)

8 a.m.–5:30 p.m. August 22, 2000 (Closed)

Place: Crowne Plaza Hotel, Atlanta Airport Virginia Avenue, Atlanta, Georgia 30344. Telephone 404/768–6660.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to P.L. 92–463.

This notice is published less than 15 days prior to the meeting due to administrative delays.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 00074.

Contact Person for More Information:

James S. Belloni, Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, 4770 Buford Hwy., m/s K02, Atlanta, GA 30341. Telephone 770/488–4538, email jsb1@cdc.gov.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: August 4, 2000.

Carolyn J. Russell,

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

[FR Doc. 00–20399 Filed 8–8–00; 2:19 pm]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance 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: National Mammography Quality Assurance 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 28, 2000, 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles A. Finder, 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 Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss FDA oversight of the Mammography Quality Standards Act (the MQSA) inspectors and inspections, the MQSA compliance guidance, and FDA's role under the MQSA in evaluating personnel competency. The committee will also receive updates on the status of accreditation and certification of full field digital mammography, use of small field digital mammography receptors for diagnostic examinations, States as certification agencies under the MQSA, and the Inspection Demonstration Project. The MQSA compliance guidance documents, which are in a question-and-answer format, are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography>. This guidance is being updated continually in response to questions that FDA receives from the public. Additional information regarding guidance updates may be obtained by calling the Information Line.

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 1, 2000. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on September 28, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 1, 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: August 2, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-20342 Filed 8-10-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1392]

Draft Guidance for Industry on Botanical Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Botanical Drug Products." This draft guidance explains the circumstances under which FDA approval of a new drug application (NDA) is required for marketing of a botanical drug product and when such a product may be marketed under an over-the-counter (OTC) drug monograph. It also provides guidance to researchers and manufacturers on conducting initial and expanded clinical investigations of botanical drug products. After evaluating the comments it receives, FDA will issue this guidance in final form to encourage the submission of investigational new drug applications (IND's) for botanical drugs.

DATES: Submit written comments on the draft guidance by October 10, 2000. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist the office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Yuan-yuan Chiu, Center for Drug Evaluation and Research (HFD-800), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5918.

SUPPLEMENTARY INFORMATION:

I. Description of the Guidance

FDA is announcing the availability of a draft guidance for industry entitled "Botanical Drug Products." Botanical products are finished, labeled products that contain vegetable matter, which may include plant material, algae, macroscopic fungi, or combinations of these substances. Botanical products may be intended for use as drugs, foods (including dietary supplements), or cosmetics.

This guidance is intended to encourage the clinical study and submission for marketing approval of botanical drug products. The guidance explains the circumstances under which FDA approval of an NDA is required for marketing a botanical drug and when such a drug may be marketed under an OTC drug monograph. The draft also provides scientific and regulatory guidance to sponsors about conducting initial and expanded clinical investigations of botanical drugs, including those botanical products currently lawfully marketed as foods and dietary supplements in the United States. In particular, the guidance provides information on how the agency will interpret and apply to botanical drugs certain provisions of existing regulations on the submission of IND's (21 CFR part 312).

This level 1 draft guidance is being issued in accordance with FDA's good guidance practices (62 FR 8961, February 27, 1997). The draft guidance represents the agency's current thinking on the development of botanical drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by October 10, 2000. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.