

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects: Public Health Service Acquisition Regulation—PHSAR Part 380—Special Program Requirements Affecting PHS Acquisitions, and Part 352—Solicitation Provisions and Contract Clauses—0990-0128—Extension—This clearance request addresses recordkeeping and reporting requirements in the Public Health Service Acquisition Regulation (PHSAR) for acquisitions involving safety and health, drugs and medical supplies, reusable cylinders, laboratory animals and the Indian Self-Determination Act. *Respondents:* State or local governments, Businesses or other for-profit, non-profit institutions, Small businesses; *Burden Information for Drugs and Medical Supplies—Total Number of Respondents:* 50; *Annual Frequency of Response:* three times; *Average Burden per Response:* 2 hours; *Estimated Annual Burden for Drugs and Medical Supplies Requirement:* 300 hours—Burden Information for Indian Self-Determination Act—*Total Number of Respondents:* 591; *Annual Frequency of Response:* one time; *Average Burden per Response:* 2 hours; *Estimated Annual Burden for Indian Self-Determination Act Requirement:* 1,182 hours—Burden Information for Reusable Cylinders—*Total Number of Respondents:* 16; *Annual Frequency of Response:* five times; *Average Burden per Response:* 1 hour; *Estimated Annual Burden for Reusable Cylinders Requirement:* 80 hours—Burden Information for Laboratory Animals—*Total Number of Respondents:* 51; *Annual Frequency of Response:* one time; *Average Burden per Response:* 10 hours; *Estimated Annual Burden for Laboratory Animals Requirement:* 510 hours—Burden Information for Safety and Health—*Total Number of Respondents:* 59; *Annual Frequency of Response:* one time; *Average Burden per Response:* 8 hours; *Estimated Annual Burden for Health and Safety Requirement:* 472 hours—Burden Information for Additional Payment

Provisions—Total Number of Respondents: 454; *Annual Frequency of Response:* three times; *Average Burden per Response:* 1 hour; *Estimated Annual Burden for Additional Payment Requirement:* 1,362 hours—*Total Burden:* 3,906 hours.

Send comments to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue S.W., Washington, DC 20201. Written comments should be received within 60 days of this notice.

Dated: April 15, 1997.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

[FR Doc. 97-10503 Filed 4-22-97; 8:45 am]

BILLING CODE 4150-04-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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: Nonprescription Drugs Advisory Committee with Representation from the Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: The committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products for use in the treatment of a broad spectrum of human symptoms and diseases.

Date and Time: The meeting will be held on May 13, 1997, 8:30 a.m. to 5 p.m. An open public hearing portion is scheduled from 8:30 a.m. to 9:30 a.m.

Location: Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Andrea Neal or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear presentations and discuss data

submitted regarding the switch from prescription to over-the-counter status of new drug application (NDA) 16-640/S072, Questran® Powder (cholestyramine resin) and NDA 19-669/S020, Questran® Light (cholestyramine resin with aspartame), Bristol Myers Squibb, for the reduction of elevated serum cholesterol.

Procedure: The meeting is open to the public. 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 May 8, 1997. Those desiring to make formal presentations should notify the contact person before May 8, 1997, 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: April 17, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-10476 Filed 4-22-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 the Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

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 neurological disease.

Date and Time: The meeting will be held on May 8, 1997, 8:30 a.m. to 5 p.m. An open public hearing portion is scheduled from 1 p.m. to 2 p.m.

Location: Holiday Inn—Bethesda, Versailles Ballrooms I, II, and III, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Ermona B. McGoodwin or Danyiel D'Antonio,

Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5455, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12543. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the safety and effectiveness of new drug application (NDA) 20-654 Myotrophin® (human mecasermin (recombinant deoxyribonucleic acid (DNA) origin) Injection, Cephalon-Chiron Partners) for the treatment of amyotrophic lateral sclerosis (ALS).

Procedure: The meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be made to the contact person by May 2, 1997. Those desiring to make formal presentations should notify the contact person before May 2, 1997, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the May 8, 1997, Peripheral and Central Nervous System Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Peripheral and Central Nervous System Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

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

Dated: April 18, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97-10541 Filed 4-22-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

MEETING: The following advisory committee meeting is announced:

Biological Response Modifiers Advisory Committee

Date, time, and place. May 6, 1997, 3 p.m., National Institutes of Health Campus, Bldg. 29, conference room 121, 8800 Rockville Pike, Bethesda, MD 20852.

Type of meeting and contact person. This meeting will be held by a telephone conference call. A speaker telephone will be provided in the conference room to allow public participation in the meeting. Open public hearing, 3 p.m. to 4 p.m., unless public participation does not last that long; open committee discussion, 4 p.m. to 4:30 p.m.; closed committee deliberations, 4:30 p.m. to 5:30 p.m.; William Freas or Rosanna L. Harvey, 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), Biological Response Modifiers Advisory Committee, code 12388.

General function of the committee. The committee reviews and evaluates data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended

for use in the prevention and treatment of a broad spectrum 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 April 29, 1997, 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 the site visit review report for the Laboratory of Molecular Medical Genetics and the research program of an individual in the Division of Cellular and Gene Therapy.

Closed committee deliberations. The committee will discuss the intramural scientific research program. This portion of the meeting will be closed to prevent disclosure of personal information concerning individuals associated with the research program, disclosure of which would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)).

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 the meeting(s) 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