Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514—(OMB Control No. 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a final rule July 28, 1999 (64 FR 40746), amending part 514 (21 CFR part 514) to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADA's), supplemental NADA's and encourages dose range labeling. Substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended uses under the conditions of use suggested in its proposed labeling. It is defined as evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by qualified experts that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. The provisions of § 514.4(a) provide the agency with greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. The agency believes this regulation over time, will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug.

Description of Respondents: Respondents to this collection of information are persons and businesses, including small businesses. In the **Federal Register** of August 16, 2000 (65 FR 49989), the FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. No comments were received on the estimated annual reporting burden. We therefore believe the total burden estimate of 544,036 hours for the annual reporting and recordkeeping burden should remain unchanged.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
514.4(a)	190	4.5	860	632.6	544,036

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting burden is based on consultation by the Center for Veterinary Medicine with several of the major research and development firms that conduct the majority of studies submitted to establish substantial evidence of effectiveness of new animal drugs and agency records.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29325 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Roundtable; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following meeting: Consumer roundtable to discuss consumer protection priorities for the agency. The roundtable will provide an opportunity for FDA to engage in an open dialogue with individual consumer stakeholders on a variety of regulatory and consumer oriented issues. The roundtable is part of the agency's ongoing consultation with stakeholders.

Date and Time: The meeting will be held on December 13, 2000, 9 a.m. to 4 p.m.

Location: The meeting will be held at the Penthouse Conference Room, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Contact: Karen R. Mahoney, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4393, FAX 301–827–2866, e-mail: *kmahoney@oc.fda.gov*.

Registration: Preregistration is required as space is limited. Send registration information (including name, title, organization name, address, telephone, fax number, and e-mail) to the contact person by December 6, 2000.

If you need special accommodations due to a disability, please contact Karen R. Mahoney (address above) at least 7 days in advance.

Background information on this meeting will be available on the FDA Internet site at *http://www.fda.gov/opacom/hpmeetings.html*.

Transcripts: Transcripts 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.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29424 Filed 10–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs 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: Oncologic Drugs 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 December 13, 2000, 8:30 a.m. to 5:30 p.m. and December 14, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 2000, the committee will discuss: (1) New drug application (NDA)20–726/S–006, Femara® (letrozole) Tablets, 2.5 mg, Novartis Pharmaceuticals Corp., indicated as first-line therapy in postmenopausal women with advanced breast cancer; and (2) NDA 21–240, histamine hydrochloride injection (1 mg/ml), Maxim Pharmaceuticals, Inc., indicated for adjunctive use with interleukin-2 (aldesleukin) in the treatment of adult patients with advanced metastatic melanoma that has metastasized to the liver. On December 14, 2000, the committee will discuss: (1) Biologics license application (BLA) 99–0786, Campath®, (alemtuzumab), Millenium and Ilex Partners, LP., and Millenium Pharmaceuticals, indicated for the treatment of patients with chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy; and (2) single patient exemptions to the use of nonapproved oncology drugs and biologics.

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 December 6, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on December 13, 2000, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on December 14, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 6, 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. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by December 6, 2000, to address issues specific to the submission or topic before the committee.

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

Dated: November 8, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–29285 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2000.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 6, 2000; 9:00 a.m.—5:00 p.m.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

The meeting is open to the public.

The full Commission will meet on Wednesday, December 6, from 9:00 a.m. to 5:00 p.m. Agenda items will include, but not be limited to: a presentation of the Petitioners Attorney Perspective, a summary of the National Vaccine Program Office (NVPO) Vaccine Risk Communication Workshop, a presentation on the Parent Understanding of Immunication Survey Results, and a FDA Workshop summary on Evaluation of New Vaccines. Updates from the Department of Justice and the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on December 6, 2000. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in the Conference Room at the DoubleTree Hotel on December 6, 2000. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Lee, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6593.

Agenda items are subject to change as priorities dictate.

Dated: November 13, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–29327 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2000.

Name: Council on Graduate Medical Education (COGME).

Date and Time: December 13, 2000; 8:30 a.m.–4:30 p.m.; December 14, 2000; 8:30 a.m.–10:30 p.m.

Place: Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

The meeting is open to the public.

Agenda

The agenda will include: Welcome and opening comments from the Administrator, Health Resources and Services Administration; the Associate Administrator for Health Professions; and the Acting Executive Secretary of COGME. New COGME members will be introduced. The Council will be given an update on the COGME and the National Advisory Council on Nurse