

as a result of future USDA/FSIS actions. Therefore, the average estimated burden is based on the following: (1) A facility devoting 100 percent of its business (or 300 hours for recordkeeping annually) to food irradiation; and (2) facilities devoting 10 percent of their business or 60 hours (2 x 30 hours) for recordkeeping annually, to food irradiation or $(300 + 60)/3 = 120 \times 3$ firms x 1 hour = 360 hours annually.

As stated in the 60-day notice, no burden was estimated for the labeling requirements in §§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Therefore in this notice, table 1 from the 60-day notice (64 FR 73054 at 73055) estimated annual reporting burden is not included.

Dated: March 16, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Arthritis 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). At least one portion of the meeting will be closed.

Name of Committee: Arthritis 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 April 11, 2000, 8 a.m. to 5 p.m.

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

Contact Person: Kathleen R. Reedy or LaNise S. Giles, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD

20857, 301-827-7001, or e-mail: reedyk@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12532. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologics license application 99-0884, Enbrel™ (etanercept, Immunex), for an indication in patients with early rheumatoid arthritis.

Procedure: The meeting is open to the public from 8 a.m. to 2:30 p.m. 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 April 3, 2000. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 3, 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.

Closed Committee Deliberations: The meeting will be closed from 2:30 p.m. to 5 p.m. to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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

Dated: March 15, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00-7006 Filed 3-21-00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science; 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: Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Science.

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 April 26, 2000, 8:30 a.m. to 5:30 p.m.

Location: 5630 Fishers Lane, Center for Drug Evaluation and Research Advisory Committee conference room 1066, Rockville, MD.

Contact Person: Kimberly Littleton Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, e-mail: TOPPERK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss specific scientific issues where the additional expertise of the subcommittee is needed to aid the agency in refining draft guidances for orally inhaled and nasal drug products in the areas of: (1) Chemistry, manufacturing, and controls; and (2) in vitro and in vivo bioavailability/bioequivalence.

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 April 19, 2000. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 19, 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: March 14, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

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