

Affairs (HFE-1), Food and Drug Administration, Parklawn Bldg., 5600 Fishers Lane, rm. 16-85, Rockville, MD 20857, 301-827-4404, FAX 301-827-3052, or e-mail "clewis@bangate.fda.gov".

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to provide an opportunity for consumers to discuss their concerns and thereby participate in agency decision and policymaking on key health care and consumer protection issues. To register for the meeting and obtain directions, please call, fax, or e-mail the contact person (address above). Include the name, title, telephone and fax numbers of the person attending, and the name of the organization being represented.

If special accommodations are required due to a disability, please contact Carol M. Lewis at least 7 days in advance of the meeting.

Dated: August 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-21573 Filed 8-13-97; 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 public advisory committees of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Joint meeting of the Nonprescription Drugs Advisory Committee and Pulmonary-Allergy Drugs Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 19, 1997, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Andrea G. Neal or Leander B. Madoo, 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), codes 12541 and 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committees will jointly consider new drug application (NDA) 20-840, Beconase® Allergy Nasal Spray (belcomethasone dipropionate 0.042%, monohydrate, Glaxo Wellcome, Inc.) for over-the-counter treatment and prevention of the symptoms of seasonal allergic rhinitis in patients 12 years of age and older.

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 5, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 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: August 7, 1997.

William B. Schultz,

Acting Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97-21571 Filed 8-13-97; 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 Committee: Nonprescription Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 18, 1997, from 8:30 a.m. to approximately 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Andrea G. Neal, 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 discuss issues relating to the labeling and dosing of over-the-counter (OTC) pediatric analgesic/antipyretic drug products. The Committee will discuss topics such as: (1) What is an appropriate lower age limit for the dosing of OTC analgesic/antipyretic drug products; and (2) the safety implications of the OTC availability of children's analgesic/antipyretic suspension products and double concentrated infant drops with overlapping age directions.

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 12, 1997. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 12, 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: August 7, 1997.

William B. Schultz,

Acting Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97-21574 Filed 8-13-97; 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 Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 18 and 19, 1997, 8 a.m. to 5:30 p.m.

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

Contact Person: Jannette O'Neill-Gonzalez, 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 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18, 1997, the committee will discuss: (1) New drug application (NDA) 20-817, Rivizor™ Tablets (vorozole, Janssen Research Foundation), indicated for "the treatment of advanced breast cancer in postmenopausal women (natural or artificially-induced menopause) with disease progression following antiestrogen therapy"; and (2) NDA Supplement 20-451/S002, Photofrin® (porfimer sodium, QLT Photo Therapeutics Inc.), indicated for: "a) reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial nonsmall cell lung cancer (NSCLC), and b) treatment of endobronchial carcinoma in situ or microinvasive NSCLC in patients for whom surgery and radiotherapy are not indicated." On September 19, 1997, the committee will discuss: (1) NDA 20-826, Paxene® (paclitaxel, Baker-Norton Pharmaceuticals, Inc.), "indicated after failure of first line or subsequent systemic chemotherapy for the treatment of advanced AIDS-related Kaposi's Sarcoma"; and (2) NDA Supplement 16-295/S029, Droxia® (hydroxyurea, Bristol-Myers Squibb), "indicated in the treatment of sickle cell anemia in adult patients to prevent painful crises and to reduce the need for blood transfusions."

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 4, 1997. Oral presentations from the public will be scheduled between approximately 8:05 a.m. and 9:05 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 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: August 7, 1997.

William B. Schultz,

Acting Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97-21572 Filed 8-13-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0158]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Petition for Generally Recognized As Safe Affirmation" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 9, 1997 (61 FR 25632), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910-

0132. The approval expires on July 31, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: August 7, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-21435 Filed 8-13-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N-0135]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Animal Proteins Prohibited in Ruminant Feed" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B-19, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 5, 1997 (62 FR 30936), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). OMB has now approved the information collection and has assigned OMB control number 0910-0339. The approval expires on July 31, 2000. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Dated: August 8, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97-21563 Filed 8-13-97; 8:45 am]

BILLING CODE 4160-01-F