[FR Doc. 03–9212 Filed 4–14–03; 8:45 am]
BILLING CODE 4184–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the cumulative list of orphan drug and biological designations as of December 31, 2002. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fritsch, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 2002, and, therefore, brings the June 7, 2002 (67 FR 39409) publication up to date. This list is available upon request from the Dockets Management Branch (see **ADDRESSES**). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this notice. In addition, the list is updated monthly and is available upon request from OPD or the FDA's Dockets Management Branch (see **ADDRESSES**). The current list is also available on the Web site at http://www.fda.gov/orphan.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (see **ADDRESSES**).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: April 4, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9226 Filed 4–14–03; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy 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: Pulmonary-Allergy 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 May 15, 2003, from 8 a.m. to 5 p.m.

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

Contact Person: Kimberly Littleton Topper, 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 FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss biologics license application (BLA) 103976, XOLAIR Omalizumab (Humanized Monoclonal Antibody to Human IgE) by Genentech, Inc., for the treatment of allergic asthma.

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 May 8, 2003. 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 May 8, 2003, 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.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kimberly Littleton Topper at least 7 days in advance of the meeting.

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

Dated: April 8, 2003.

Linda Arey Skladany,

Associate Commissioner for External Relations.

[FR Doc. 03–9225 Filed 4–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0368]

Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format; General Considerations; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until June 16, 2003, the comment period for the draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations'' that appeared in the **Federal Register** of September 5, 2001 (66 FR 46464). The agency is taking this action in response to several informal requests for an extension of the comment period.

DATES: Submit written or electronic comments on the draft guidance by June 16, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. 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. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Randy Levin, Center for Drug Evaluation and Research (HFD–001), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20857, 301–594–5400; or Robert Yetter, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 5, 2001 (66 FR 46464), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Submitting Marketing Applications According to the ICH/CTD Format; General Considerations.'' This guidance provides information on how to organize new drug applications, abbreviated new drug applications, and biologics license applications based on the International Conference on Harmonization M4 guidance on organizing the Common Technical Document for the registration of pharmaceuticals for human use. Interested persons were given until November 5, 2001, to submit written or electronic comments on the draft guidance. In response to several informal requests from drug and biologic manufacturers, FDA has decided to reopen the comment period on the draft guidance until June 16, 2003, to allow interested persons additional time to submit comments.

II. Comments

Interested persons may, on or before June 16, 2003, submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any written comments, 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.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document at either http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: April 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–9224 Filed 4–14–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: March 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of March 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject, city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
AIRD, EILEEN B ..... RIDGEWOOD, NJ	04/20/2003
ALMAZAN, MARIA ..... LA CANADA, CA	04/20/2003
AMADOR, CARLOS ..... MIAMI, FL	04/20/2003
AMY, LESLIE W ..... RAYBROOK, NY	04/20/2003
BAIRD, KARIN LYNN ..... YUCAIPA, CA	04/20/2003
BARON, ADOLFO ..... MIAMI, FL	04/20/2003
BENTHALL, MARK JOSEPH ... ST LOUIS, MO	04/20/2003
BOOKER, THELMA A ..... ATCHISON, KS	04/20/2003
BREARY, CHESTER H JR ..... ORIENT, OH	04/20/2003
BRINGAS, AL ..... YAZOO CITY, MS	04/20/2003
CANABAL-ENRIQUEZ, JOSE .. YAUCO, PR	04/20/2003
CANET, FRANCISCO	04/20/2003