manufacturer, and indications to be studied under the referrals (21 U.S.C. 355a(d)(4)(B)(ii)).

In accordance with section 4 of the BPCA, FDA is announcing that it has referred to the Foundation the written requests for pediatric studies for KEMSTRO (baclofen) and DROXIA (hydroxyurea). On April 30, 2004, FDA issued a written request for pediatric studies to Schwarz Pharma, Inc., the holder of approved applications for KEMSTRO (baclofen) that have market exclusivity. The studies described in the written request were for the treatment of spasticity in the pediatric population. Schwarz Pharma, Inc., declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of KEMSTRO (baclofen) in the pediatric population.

On March 29, 2004, FDA issued a written request for pediatric studies to Bristol-Myers Squibb Co., the holder of approved applications for DROXIA (hydroxyurea) that have market exclusivity. The studies described in the written request were for the treatment of sickle cell disease in the pediatric population. Bristol-Myers Squibb Co. declined to conduct the requested studies. FDA has determined that there is a continuing need for information relating to the use of DROXIA (hydroxyruea) in the pediatric population.

Consistent with the provisions of the BPCA, FDA referred to the Foundation the written requests for the conduct of the pediatric studies for KEMSTRO (baclofen) on September 1, 2004, and DROXIA (hydroxyurea) on October 20, 2004.

Dated: March 22, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6158 Filed 3–28–05; 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 June 6, 2005, from 8 a.m. to 5:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Teresa A. Watkins, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 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 3014512545. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of new drug application (NDA) 50–799, proposed trade name PULMINIQ (cyclosporine, inhalation solution) Chiron Corp., for use in combination with standard immunosuppressive therapy to increase survival and prevent chronic rejection in patients receiving allogenic lung transplants.

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 26, 2005. 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 26, 2005, 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 La'Nise Giles at 301–827–7001 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: March 21, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–6087 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2004D–0187, 2004D–0188, and 2004D–0189]

Guidances for Industry on Premarketing Risk Assessment; Development and Use of Risk Minimization Action Plans; and Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' These guidances provide guidance to industry on risk management activities for drug products, including biological drug products, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The guidances address, respectively, premarket risk assessment; the development, implementation, and evaluation of risk minimization action plans for drug products; and good pharmacovigilance practices and pharmacoepidemiologic assessment of observational data.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidances 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, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. These guidances may also be obtained by mail by calling CBER at 1–800–4709 or 301–827–1800. Send three self-addressed

adhesive labels to assist the office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify each set of comments with the corresponding docket number of the guidance as follows: Docket No. [2004D–0187] ''Premarketing Risk Assessment,'' Docket No. [2004D–0188] ''Development and Use of Risk Minimization Action Plans,'' and Docket No. [2004D–0189] ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: *For ''Premarketing Risk Assessment''*: Barbara Gould, Center for Drug Evaluation and Research (HFD–550), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301–827–2504, or

Patricia Rohan, Center for Biologics Evaluation and Research (HFM–485), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3070.

For ''Development and Use of Risk Minimization Action Plans'': Christine Bechtel, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 1451 Rockville Pike, Rockville, MD 20852, 301–443–5572, or

Mark Weinstein, Center for Biologics Evaluation and Research (HFM–300), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3518.

For ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment'': Patrick Guinn, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5590, or

Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of three guidances for industry entitled ''Premarketing Risk Assessment,'' ''Development and Use of Risk Minimization Action Plans,'' and ''Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment.'' These three guidances were produced in part to fulfill FDA's commitment to certain risk management performance goals agreed to in relation to the Prescription Drug User Fee Act upon its reauthorization in June 2002. As an initial step, FDA announced the availability of three concept papers on March 7, 2003 (68 FR 11120). Each concept paper focused on one aspect of risk management. FDA held a public workshop on April 9 to 11, 2003, to obtain comment on the concept papers. The comments submitted on the concept papers and at the public meeting were considered in developing the draft guidances. The draft guidances were published on May 5, 2004 (69 FR 25130), and the public was provided with an opportunity to comment on them until July 6, 2004. FDA considered all of the comments received in producing the final guidances.

The guidances address risk management issues pertinent to the successive stages of a product's lifecycle, specifically the following topics: (1) During medical product development, (2) during product application review and approval, and (3) during the postmarketing period. The approaches recommended in the guidances are part of a broad, ongoing, and comprehensive effort by the agency to provide additional guidance to industry on measures that can be employed to minimize the risks while preserving the benefits of medical products.

These guidances recommend that sponsors consider specific risk minimization efforts beyond routine risk minimization measures for the few products presenting unusual types or levels of risk. In these circumstances, using strategies that go beyond routine risk assessment and minimization may further improve the product's benefit-risk balance.

FDA understands that risk management programs generate costs and place new burdens on product developers, health care practitioners, and patients. FDA recommends that, whenever possible, sponsors give every consideration to using the least burdensome method to achieve the desired public health outcome.

FDA recommends that as new products are developed, sponsors seek to identify risk signals as early as possible in a product's development cycle, to evaluate the risks, to communicate predictable risk and benefit information effectively and thoroughly, and to employ efforts to manage these risks as efficiently as possible.

These guidances are being issued consistent with FDA's good guidances practices regulation (21 CFR 10.115). The guidances represent the agency's current thinking on this topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the guidances at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket numbers found in brackets in the heading of this document. The guidances and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

These guidances contain information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection(s) of information in the guidances were approved under OMB control numbers 0910–0001 (until March 31, 2005) and 0910–0338 (until August 31, 2005).

IV. Electronic Access

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

Dated: March 24, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6200 Filed 3–24–05; 4:30 pm]

BILLING CODE 4160–01–S