already been affected by the final rule. Thus, 15,487 SKUs remain to be affected by the OTC drug product labeling final rule, minus approximately 2,000 OTC sunscreen drug product SKUs. All of these except the sunscreen drug products will need to have the new labeling format by May 16, 2005, for products initially introduced or initially delivered for introduction into interstate commerce after that date. For these reasons, FDA considers the number of products remaining to be affected by the OTC drug products labeling final rule to be close to the number of products that were affected at the time the final rule published on March 17, 1999. FDA finds that the number of products remaining to be affected by the final rule is similar to the number of products that were estimated as initially affected in the collection of information in the final rule. Accordingly, in this notice FDA is using the same numbers of respondents, annual frequency per response, and total annual responses it estimated in 1999.

FDA believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries already since the final rule was issued in 1999. FDA's experience is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hours per inquiry. Second, FDA has issued a guidance for industry entitled ''Labeling OTC Human Drug Products—Updating Labeling in RLDs and ANDAs'' (67 FR 64402, October 18, 2002), which included a number of labeling examples to assist holders of RLDs (reference listed drugs, i.e., the applicable innovator) and ANDAs for OTC drug products to implement the new OTC drug product labeling regulation. Third, FDA has issued two draft guidances for industry entitled ''Labeling OTC Drug Products (Small Entity Compliance Guide)'' (69 FR 71420, December 9, 2004) and ''Labeling OTC Human Drug Products—Questions and Answers'' (70 FR 2415, January 13, 2005). These guidances provide extensive additional information and examples how to implement the new OTC drug product labeling requirements.

The guidance documents should have reduced some of the hours per response and total hours for some NDA and ANDA holders and manufacturers who market products under the OTC drug monographs. However, FDA is not currently able to estimate how much the time has been reduced. Accordingly, in this notice FDA is listing the same hours per response and total hours as appeared in the final rule.

In the **Federal Register** of January 4, 2005 (70 FR 362), FDA requested comments on the proposed collections of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
201.66[1]	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)[1]	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

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

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6088 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0102]

Referral of KEMSTRO (Baclofen) and DROXIA (Hydroxyurea) for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation on September 1, 2004, and October 20, 2004, respectively. FDA is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BCPA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for KEMSTRO (baclofen) and DROXIA (hydroxyurea). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the

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