TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Activity	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Pretest	30	1	30	0.167	5
Experiment	4,000	1	4,000	0.167	668
Total					893

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

FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here.

Dated: May 4, 2005.

Jeffery Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9328 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Neurological Devices Panel of the Medical Devices 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: Neurological Devices Panel of the Medical Devices 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 17, 2005, from 8:30 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will hear a presentation on the FDA Critical Path Initiative and a presentation by the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health outlining their responsibility for the review of postmarket study design. The committee will also hear an update on the status of recent devices brought before the committee. Subsequently, the committee will discuss, make recommendations, and vote on a premarket approval application for a selective head cooling system intended for use in infants 36 weeks of gestation or older at risk for moderate to severe hypoxic-ischemic encephalopathy (HIE) to prevent or reduce the severity of HIE. Background information for the topic, including the agenda and questions for the committee, will be available to the public 1 business day before the meeting on the Internet at *http://www.fda.gov/cdrh/panelmtg.html*.

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 June 3, 2005. Oral presentations from the public will be scheduled for approximately 30 minutes at the beginning of committee deliberations and for approximately 30 minutes near the end of the deliberations. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by June 3, 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 AnnMarie Williams at 240–276–0450, ext. 113 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: May 3, 2005.

Lester M. Crawford,

Acting Commissioner of Food and Drugs.

[FR Doc. 05–9296 Filed 5–9–05; 8:45am]

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 July 13 and 14, 2005, from 8 a.m. to 5:30 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Teresa A. Watkins, 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, e-mail: *watkinst@cder.fda.gov*, 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: On July 13, 2005, the committee will discuss the implications

of recently available data related to the safety of long-acting beta-agonist bronchodilators. On July 14, 2005, the committee will discuss the continued need for the essential use designations of prescription drugs for the treatment of asthma and chronic obstructive pulmonary disease under 21 CFR 2.125.

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 July 1, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 13, 2005, and between approximately 11 a.m. and 12 noon on July 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 1, 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: April 29, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–9229 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0062]

Draft Guidance for Industry on the Food and Drug Administration's ''Drug Watch'' for Emerging Drug Safety Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''FDA's 'Drug Watch' for Emerging Drug Safety Information.'' This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients. This information will appear on an FDA Web page to be called the ''Drug Watch.''

DATES: Submit written or electronic comments on the draft guidance by August 8, 2005. 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Deborah J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–5400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''FDA's 'Drug Watch' for Emerging Drug Safety Information.'' This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients.

In the last several months, members of patient groups, the medical community, and Congress have raised concerns regarding the way in which FDA has handled certain drug safety issues, most recently in connection with the withdrawal of Vioxx from the market and with the management of the risks of suicide associated with pediatric use of antidepressants. As a result, FDA is carefully evaluating its institutional approach to drug safety issues, focusing especially on the ways in which the agency responds to new safety concerns and resolves scientific disagreements about product safety between agency components. As part of this process, FDA is also reexamining its risk communication program, including how and when we communicate significant emerging safety information to healthcare professionals and patients.[1]

FDA has long provided information on drug risks and benefits to healthcare professionals and patients. In the past, we provided that information when we were certain of its significance or it prompted a regulatory action, such as a labeling change. We have now decided to make important drug safety information available to healthcare professionals and patients in a new format and earlier than we have in the past. This information will appear on an FDA Web page called the ''Drug Watch.''

II. The Drug Watch Program

The goal of the Drug Watch program is to ensure that patients and healthcare professionals have quick access to the most up-to-date and accurate product information available in an easily accessible form. The Drug Watch Web page will post significant emerging safety information that FDA has received about certain drugs (or classes of drugs) while the agency continues to actively evaluate the information. The Drug Watch page is not intended to be a list of drugs that are particularly risky or dangerous for use; listing of a drug on the Drug Watch should not be construed as a statement by FDA that the drug is dangerous or that it is inappropriate for use. All drugs have risks, and prescribers must balance the risks and benefits of a drug when making judgments about an individual patient's therapy. However, sometimes after a drug is approved, rare but serious new side effects emerge as the drug is more widely used or is prescribed for off-label uses. Sometimes these emerging risks appear to be life-threatening, while in other cases they may appear to be less serious. In most instances, however, there is a period of uncertainty while FDA and the drug's sponsor evaluate new, emerging safety information to determine whether the safety concern in fact relates to the drug, and whether regulatory or other action is appropriate. The purpose of the Drug Watch is to provide a forum from which FDA can communicate emerging safety information to the public while we

[1] For information about the other steps FDA is taking see *http://www.fda.gov/bbs/topics/news/2004/NEW01131.html*.