In the **Federal Register** of May 23, 2003 (68 FR 28237), FDA announced the availability of a guidance entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The guidance provided voluntary recommendations on the process for firms that wish to export dairy products to Chile. FDA is taking this action in response to discussions with Chile that have been adjunct to the negotiations of the United States-Chile Free Trade Agreement. As a result of those discussions, Chile recognized FDA as the competent food safety authority in the United States to identify U.S. dairy product manufacturers and processors eligible to export to Chile and concluded that it will not conduct individual inspections of U.S. firms identified by FDA as eligible to export to Chile.

Therefore, FDA intends to establish and maintain a list identifying U.S. manufacturers/processors that have expressed interest to FDA in exporting dairy products to Chile, are subject to FDA jurisdiction, and are not the subject of a pending judicial enforcement action (i.e. an injunction or seizure) or an unresolved warning letter. Under this guidance, FDA recommends that U.S. firms that want to be placed on the list send information to FDA (i.e., name and address of the firm and the manufacturing plant; name, telephone number, and e-mail address (if available) of contact person; list of products presently shipped and expected to be shipped in the next 3 years; identities of agencies that inspect the plant and date of last inspection plant number and copy of last inspection notice; and, if other than an FDA inspection, copy of last inspection report. The term ''dairy products,'' for purposes of this list, is not intended to cover the raw agricultural commodity raw milk. The guidance can be found at *http://www.cfsan.fda.gov/guidance.html*.

The burden estimates presented in the following paragraphs considered the number of U.S. firms that FDA believes produce dairy products and that will be interested in exporting to Chile, which is estimated to total 75. After the first year, FDA believes that approximately eight new firms each year will be interested in exporting dairy products to Chile, and thus, being placed on the list. In the **Federal Register** of April 10, 2003 (68 FR 17655), FDA published an emergency notice requesting public comment on the information collection provisions that had been submitted to OMB for emergency processing under the PRA. Four comments were received from trade associations and private industry.

Those comments were answered in the 60-day notice.

In the **Federal Register** of July 10, 2003 (68 FR 41157), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Mail questionnaire	1,000	1	1,000	3	3,000
Phone Survey	1,000	1	1,000	.5	500
Internet or Cable Survey	3,000	1	3,000	1	3,000
Total					6,500

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

The estimate of the number of firms is based on the actual number of U.S. firms that applied to be placed on the list as a result of the **Federal Register** of May 23, 2003 (68 FR 28237), publication of the availability of a guidance entitled ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors With Interest in Exporting to Chile.'' The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms. We (FDA) estimate that for the first year a firm will require 1.5 hours to read the **Federal Register**, gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list. We estimate the recurring burden in subsequent years to be 1.5 hours for a new firm to be placed on the list and 0.5 hours for reporting changes to FDA for firms already on the list.

Dated: September 30, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25448 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Anesthetic and Life Support 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 November 18, 2003, from 8 a.m. to 5 p.m. and on November 19, 2003, from 8 a.m. to 12 noon.

Location: Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, 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, FAX: 301–827–6776, or e-mail: *cliffordj@cder.fda.gov*, or FDA Advisory Committee Information Line: 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 18, 2003, the committee will discuss the assessment and management of risk related to QTc prolongation by Droperidol (Inapsine) Akorn, Inc., indicated for nausea and vomiting in surgical and diagnostic

procedures, premedication, and neuroleptanalgesia.

Procedure: On November 18, 2003, the meeting is open to the public. 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 November 10, 2003. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 10, 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.

Closed Committee Deliberations: On November 19, 2003, from 8 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 John Lauttman 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: September 29, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25445 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Subcommittee of the Anti-Infective 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: Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee.

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

Date and Time: The meeting will be held on October 29, 2003, from 8 a.m. to 5:30 p.m. and October 30, 2003, from 8 a.m. to 3:30 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD, 301–556–2046.

Contact Person: Thomas H. Perez, 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: *perezt@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 29, 2003, the subcommittee will meet between 8 a.m. and 3:30 p.m., to discuss the risk assessment and possible risk management strategies for hypothalamic pituitary adrenal (HPA) axis suppression in children who are treated for skin disorders with topical corticosteroids. Following this, from approximately 3:45 p.m. to 5:30 p.m., the agency will report to the subcommittee on Adverse Event Reporting as mandated in section 17 of the Best Pharmaceuticals for Children Act (BPCA). The products to be discussed during this portion of the meeting include ZYRTEC (cetirizine), BUSULFEX (busulfan), COZAAR (losartan), NOLVADEX (tamoxifen), ACCUPRIL (quinapril), and SERZONE (nefazodone).

On October 30, 2003, the subcommittee will meet between 8 a.m. and 3:30 p.m., to discuss how to approach long-term monitoring for cancer occurrence among patients treated for atopic dermatitis with topical immunosuppressants.

The background material for this meeting will be posted on the Internet when available or 1 working day before the meeting at *http:// www.fda.gov/ohrms/dockets/ac/menu.htm.*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 21, 2003. On October 29, 2003, oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. for issues related to atopic dermatitis, and between approximately 4:30 p.m. and 5 p.m. for issues related to section 17 of the BPCA. On October 30, 2003, oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by October 21, 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 notify Thomas Perez 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: October 2, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–25443 Filed 10–7–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Postponement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Drug Safety and Risk Management Advisory Committee scheduled for September 19, 2003, due to Hurricane Isabel. The future date of this meeting is to be determined. This meeting was announced in the **Federal Register** of August 5, 2003 (68 FR 46199).

FOR FURTHER INFORMATION CONTACT: Shalini Jain, Center for Drug Evaluation and Research (HFD–21), Food and Drug