

orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 3, 2003. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 3, 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 Dornette Spell-LeSane 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, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-11076 Filed 5-5-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0143]

Nonprescription 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: Nonprescription 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 12, 2003, from 8 a.m. to 5 p.m. Interested persons and organizations may submit written or

electronic comments until August 1, 2003, to the Dockets Management Branch (see *Addresses*).

Addresses: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select "03N-0143—Continued over-the-counter status of ipecac syrup" and follow the prompts to submit your statement. Written comments should be submitted to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, 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 e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area) code 12541. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will consider the safety and efficacy of ipecac syrup, indicated for emergency use to cause vomiting in poisoning, for continued over-the-counter (OTC) status under 21 CFR 201.308. The primary areas of consideration are: (1) The status of the role of ipecac syrup in gastrointestinal decontamination; (2) whether the literature clearly defines the risk/benefit ratio of ipecac syrup; (3) the role of ipecac syrup in poison treatment for populations with limited access to emergency medical treatment; (4) if there is significant abuse of ipecac syrup; and (5) alternative therapies to ipecac syrup.

The background material will become available no later than the day before the meeting and will be posted under the Nonprescription Drugs Advisory Committee (NDAC) docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2003 and scroll down to NDAC meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions for discussion or presentation at the meeting may be made to the contact person by June 5, 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 June 5, 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. However, until August 1, 2003, other submissions containing the docket number 03N-0143 and information relevant to the may be submitted for consideration to Dockets Management Branch (see *Addresses*).

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 Karen Templeton-Somers 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, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03-11075 Filed 5-5-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0095]

Guidance for Industry on Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications." The guidance provides recommendations for sponsors of investigational new drug applications (INDs) and applicants submitting new drug applications (NDAs) or biologics license applications (BLAs) on the use of exposure-response information in the development of drugs, including therapeutic biologics.

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