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.

ADDRESSES: Submit written or electronic requests for single copies of this 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 or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (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 guidance document.

FOR FURTHER INFORMATION CONTACT:

Lawrence J. Lesko, Center for Drug Evaluation and Research (HFD–850), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5690, or

David Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Exposure-Response Relationships—Study Design, Data Analysis, and Regulatory Applications.'' This guidance provides recommendations on the use of exposure-response information in the development of drugs, including therapeutic biologics. The guidance describes: (1) The uses of exposure-response studies in regulatory decisionmaking; (2) the important considerations in exposure-response study designs to ensure valid information; (3) the strategy for prospective planning and data analyses in the exposure-response modeling process; (4) the integration of assessment of exposure-response relationships into all phases of drug development; and (5) the format and content of reports of exposure-response studies.

In the **Federal Register** of April 2, 2002 (67 FR 15576), FDA announced the availability of a draft guidance for industry. The April 2002 document gave interested persons an opportunity to submit comments through June 3, 2002. The agency received 12 comments on the draft guidance. All comments received during the comment period have been carefully reviewed and changes were made to this guidance, where appropriate.

This guidance is being issued consistent with FDA's good guidance practices (21 CFR 10.115). This guidance represents the agency's current thinking on study design, data analysis, and regulatory applications of exposure-response relationships. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two paper copies of mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: April 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–11074 Filed 5–5–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0165]

Draft Guidance for Industry on the Current Good Manufacturing Practices for Medical Gases; 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 ''Current Good Manufacturing Practice for Medical Gases.'' This draft guidance discusses how the requirements in Title 21, Code of Federal Regulations, parts 210 and 211, current good manufacturing practice (CGMP) regulations apply to medical gases. Medical gases are subject to these regulations because they are considered prescription drugs.

DATES: Submit written or electronic comments on the draft guidance by September 3, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Office 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 label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (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: Duane S. Sylvia, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., suite 272, Rockville, MD 20855, 301–594–0095 x 8, Sylviad@cder.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is intended to provide recommendations on how to comply with CGMPs for manufacturing, filling, transfilling, cascading, and transferring compressed and cryogenic medical gases. The guidance should help manufacturers and distributors comply with the CGMP requirements to ensure the identity, strength, quality, and purity of medical gases.

FDA's first guidance on compressed medical gases was issued in June of 1981 and revised in 1983. In February of 1989, FDA issued a revised guidance to address issues related to the home care area, including the delivery of oxygen to patients at home. Once finalized, this guidance will supersede those earlier versions. The guidance has been updated to reflect CGMPs in FDA's regulations, 21 CFR parts 210 and 211.

This level 1 draft guidance is being issued consistent with FDA's good guidance practice regulations (21 CFR