access to target populations, and successful collaborations with a variety of organizations such as government, non-government, private, non-profit, academic, and evidence of existing quality assurance mechanisms to ensure appropriate and culturally sensitive health educational services as recommended for the proposed audiences (*i.e.*, MSM, IDUS, inmates of correctional facilities, health professionals and other populations at high-risk for viral hepatitis infections).

3. Background and Understanding (20 points)

Extent to which the applicant demonstrates a clear understanding of the subject area and responds to the purpose and objectives of this cooperative agreement, including collaboration in all aspects of the agreement with CDC program staff and other relevant organizations.

4. Measures of Effectiveness (5 points)

Does the applicant provide Measures of Effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant? Are the measures objective/quantitative and do they adequately measure the intended outcome?

5. Budget (not scored)

The budget will be reviewed to determine the extent to which it is reasonable, clearly justified, and consistent with the intended use of funds.

a. Submit line item itemized budget with narrative justification for personnel, travel, supplies, and other services related to the project.

b. Funding levels for years two, three, four and five should be estimated for Parts A and D and for years two and three for Parts B and C.

6. Human Subjects (not scored)

Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? An application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Interim progress report, no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application and must include the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Detailed Line-Item Budget and Justification.

e. Additional Requested Information.

2. Financial status report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where To Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this application. For a complete description of each, *see* Attachment I of the program announcement as posted on the CDC Web page.

AR–1—Human Subjects Requirements
AR–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–7—Executive Order 12372
AR–9—Paperwork Reduction Act Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2010
AR–12—Lobbying Restrictions

J. Where To Obtain Additional Information

This and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov.*

Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Merlin Williams, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2765, E-mail address: *mqw6@cdc.gov.*

For business management and budget assistance in the Territories, contact: Steward Nichols, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2788, E-mail address: *shn8@cdc.gov.*

For program technical assistance, contact: Linda Moyer, Chief, Education and Communication Team, Division of Viral Hepatitis, Centers for Disease Control and Prevention, 1600 Clifton Road, MS G–37, Atlanta, GA 30333, Telephone: 404–371–5900, E-mail address: *lam1@cdc.gov.*

Dated: April 30, 2003.

Edward Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–11142 Filed 5–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Endocrinologic and Metabolic 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: Endocrinologic and Metabolic 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 10, 2003, from 8:30 a.m. to 5 p.m.

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

Contact Person: Dornette Spell-LeSane, 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, e-mail: spelllesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss supplemental new drug application (sNDA) 19–604/S–033, HUMATROPER (somatropin recombinant deoxyribonucleic acid (rDNA) origin) for injection), Eli Lilly and Co., for the proposed indication of treatment of nongrowth hormone deficiency short stature.

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, 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.