Any application that does not meet the above criteria will not be eligible for competition, and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the grant. Measures of effectiveness must relate to the performance goals stated in the purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

1. Scientific or Technical Approach (30 points)

a. Provide evidence of demonstrated scientific expertise involving programs for the promotion of public health in sub-Saharan Africa.

b. Provide evidence of demonstrated technical expertise in developing blood transfusion and blood safety systems to include methods that are culturally and technologically appropriate to sub-Saharan Africa.

2. Methodology and Approach (20 points)

a. Provide evidence of demonstrated expertise in methodology for evaluation and development of national blood safety and management systems.

b. Demonstrate experience in providing staff training, strategic planning, test kits, testing services, and operations planning in sub-Saharan Africa.

c. Provide evidence of demonstrated successful experience involving blood management services in developing nations of sub-Saharan Africa.

3. Staff Experience and Capability (20 points)

Provide evidence of demonstrated technical expertise and professional experience of staff in the evaluation, organization, and management of blood transfusion services in an African nation. Provide evidence that management staff has ample experience in blood banking in Africa. Provide assurance that the team will be headed by an MD from sub-Saharan Africa and that the staff includes physicians with expertise in hematology, blood transfusion, and infectious diseases.

4. Cultural Knowledge Requirements (20 points)

Provide evidence of demonstrated successful experience as a consultant in sub-Saharan African countries.

5. Understanding of the Project (10 points)

a. Demonstrated clarity, feasibility, and practicality of the proposed plan to accomplish this project.

b. Demonstrated recognition of the potential difficulties in performance and appropriateness and soundness of proposed solutions.

6. Budget Justification (not scored)

The extent to which the budget is clearly explained, adequately justified, and is reasonable and consistent with the stated objectives and planned activities.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of a final financial report and a final report of findings and recommendations. These reports are due 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.

Additional Requirements

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

AR–12—Lobbying Restrictions
AR–14—Accounting System Requirements
AR–15—Proof of Non-Profit Status

Executive Order 12372 does not apply to this program.

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 Road, Atlanta, GA 30341–4146, Telephone: 770–488–2700.

For business management and budget assistance, contact: Angelia Hill, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2785, E-mail address: *AHill@cdc.gov*.

For program technical assistance, contact: Mark Keim, MD, International Emergency and Refugee Health Branch, National Center for Environmental Health, Centers for Disease Control and Prevention, Mail Stop F–48, 4770 Buford Highway, Atlanta, GA 30341, Telephone: 770–488–4597, E-mail address: *MKeim@cdc.gov*.

Dated: April 30, 2003.

Sandra R. Manning,

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

[FR Doc. 03–11141 Filed 5–5–03; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 03099]

Cooperative Agreement to Develop, Implement, and Evaluate Viral Hepatitis Education and Training (VHET); Notice of Availability of Funds

Application Deadline: July 7, 2003.

A. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 301(a) and 317(k)(1) and 317(k)(2) of the Public Health Service Act, (42 U.S.C. 241(k) and 247b(k)(1) and 247(k)(2)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

B. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2003 funds for a cooperative agreement program to develop, implement and evaluate health education activities to prevent and control viral hepatitis and its consequences. This program addresses the ''Healthy People, 2010'' focus area of Immunization and Infectious Diseases.

The purpose of the program is to develop, implement and evaluate health educational activities that result in the prevention of infections with hepatitis viruses. The goals of these activities are to increase knowledge, change attitudes and practices (KAP) that should result in the prevention and control of viral

hepatitis among health professionals, high-risk populations, and the general public.

These activities are part of a comprehensive, national educational strategy to prevent and control viral hepatitis by changing behaviors that put persons at risk for acquiring these infections and increasing behaviors that prevent these infections. This comprehensive approach includes, but is not limited to, print, video and web-based health education tools, multi-media activities directed at populations at increased risk of infection, and curricula to train health care providers and counselors. Applicants should include formative, process and outcome evaluation methodologies in their comprehensive application.

This announcement has four distinct Parts. Applicants wishing to apply for more than one Part must submit a complete application for each Part.

The objective of Part A is to support up to six applicants to develop, implement and evaluate comprehensive communication strategies that target (1) men who have sex with men (MSM) who are at risk for hepatitis A and B; (2) injection drug users (IDUs) who are in or out of treatment and who are at risk for hepatitis A, B, and C; (3) men, women and juveniles who are incarcerated and who are at risk for hepatitis A, B, and C; (4) minority populations disproportionately infected with hepatitis A, B, and/or C viruses; and (5) other populations at increased risk for viral hepatitis. Applicants for Part A may apply to develop educational activities for more than one primary target population, but must include justification that the applicant has expertise in working with each primary target population(s). The applicant must provide a complete application that addresses development, implementation and evaluation for each target population and the specific viral hepatitis infection(s) that the applicant chooses to address.

The objective of Part B is to support one applicant to further develop, implement and evaluate an existing curriculum that could be used nationally to train health professionals, including those in training programs, in the prevention, management, and control of viral hepatitis. This curriculum should contain client-centered counseling as a major component.

The objective of Part C is to support up to two applicants to develop, implement and evaluate training programs or activities (*e.g.*, meetings, symposia, seminars, distance learning) for health professionals to prevent and control viral hepatitis. The training format must address the integration of all aspects of viral hepatitis prevention into existing public health (*e.g.*, STD, HIV/AIDS), substance abuse or clinical care (*e.g.*, corrections, primary care) programs.

The objective of Part D is to support one applicant to develop, implement, and evaluate educational tools that promote hepatitis A and hepatitis B vaccination. These tools might include, but are not limited to, brochures, newsletters, fact sheets, reports, Web site information, and manuals that provide public and provider education relative to the importance of hepatitis A and hepatitis B vaccination practices.

Measurable outcomes of the program will be in alignment with one or more of the following performance goals for the National Center for Infectious Diseases (NCID): Protect Americans from infectious diseases.

C. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is:

- Universities
- Colleges
- Technical schools
- Research Institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian Tribes
- Indian tribal organizations
- State and local governments or their bona fide agents (this includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Marianna Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau)
- Political subdivisions of States (in consultation with States)

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(C)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award.

D. Funding

Availability of Funds

Approximately $800,000 is available in FY 2003 for Part A to fund approximately six awards, approximately $300,000 is available in FY 2003 for Part B to fund one award, approximately $300,000 is available in FY 2003 for Part C to fund two awards, and approximately $300,000 is available in FY 2003 for Part D to fund one award. It is expected that the average award for Part A will be $130,000, ranging from $50,000 to $250,000 and it is expected that the average award for Part C will be $150,000, ranging from $100,000 to $200,000. It is expected that the awards will begin on or about September 15, 2003 and will be made for a 12-month budget period within a project of up to five years for Parts A and D and up to three years for Parts B and C. Funding estimates may change.

Continuation awards within an approved project period will be made on the basis of satisfactory progress toward stated goals and objectives and the availability of funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preferences

Preference will be given to applicants currently involved in devoting all or some of their activities and resources to educating the public, patients, and/or health professionals about the prevention and control of viral hepatitis and viral-hepatitis-related liver disease, or currently are devoting a major portion of their activities to educating the public, patients, and/or health professionals about the prevention and control of other blood-borne viral infections, vaccine-preventable diseases, or sexually transmitted diseases, and could readily expand to address viral hepatitis.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed in 1. Recipient Activities, and CDC will be responsible for the activities listed in 2. CDC Activities.

Applicants must indicate for which Part they intend to seek funding under this agreement and submit a complete application for each Part.

All educational activities developed through this cooperative agreement should incorporate information on viral hepatitis, which is consistent with current and future published CDC guidelines on prevention and control of hepatitis A, B, and C as contained in Attachment II (as posted on the CDC web site).

1. Recipient Activities

Part A

a. Develop, implement, and evaluate educational activities that target (1) men who have sex with men (MSM) who are

at risk for hepatitis A and B; (2) injection drug users (IDUs) who are in or out of treatment and who are at risk for hepatitis A, B, and C; (3) men, women and juveniles who are incarcerated and who are at risk for hepatitis A, B, and C; (4) minority populations disproportionately infected with hepatitis A, B, and/or C viruses; and (5) other populations at increased risk for viral hepatitis. In their application, applicants must show that they have expertise working with the population(s) they are addressing in their project proposal.

b. Indicate what type(s) of educational activities are considered to best reach the target audience. Based upon available data or data to be acquired by a needs assessment, develop, implement and evaluate a comprehensive approach to educational activities intended to reach the targeted audiences. This approach should have a strong KAP assessment component.

c. Describe what linkages with state or local hepatitis C and hepatitis B coordinators and STD, HIV, drug treatment, juvenile and adult corrections programs will be established and describe the best approaches for the delivery of viral hepatitis educational activities.

d. Describe how the activities developed in the proposal would incorporate information on viral hepatitis, which is consistent with published CDC guidelines on the prevention and control of hepatitis A, B, and C (see references in Attachment II).

e. Describe the plan for production and distribution of materials developed in the project.

f. Indicate the formative, process and outcome evaluations included for each educational activity.

Part B

a. Further develop an existing curriculum that could be used nationally to train health professionals, including those in training, in the prevention, management, and control of viral hepatitis.

b. Provide a curriculum that can be integrated into existing or ongoing training programs and that could be utilized in settings that provide services for patients who are at increased risk for viral hepatitis (*e.g.*, STD clinics, HIV counseling and testing sites, drug treatment centers, community health centers). This curriculum should address viral hepatitis A, B, and C prevention and highlight client-centered counseling messages.

c. Formative, process and outcome evaluation methodologies should be developed and applied to assess the utility and usability of the curriculum.

d. The curriculum should be produced and made available to governmental and non-governmental organizations nationwide.

Part C

a. Support education and training programs for health professionals who work with individuals at increased risk for viral hepatitis.

b. Develop and conduct training programs for health professionals related to the integration of viral hepatitis prevention and control into various public health and clinical settings that serve persons at increased risk of viral hepatitis.

c. Direct training programs to a wide range of health professionals (*e.g.*, physicians, nurses, counselors) from both governmental and private entities.

d. Conduct the training programs using several formats (*e.g.*, meetings, symposia, seminars, distance learning) and make the curriculum and training formats available nationwide through a Web site and/or through printed materials.

e. Evaluate the program(s) through formative, process and outcome measures.

Part D

a. Develop, implement and evaluate educational tools that promote hepatitis A and hepatitis B vaccination of children, adolescents and adults. These tools might include, but are not limited to, information brochures/booklets, newsletters, manuals, reports, videos, and Web site information. The educational tools should target health professionals and the general public.

b. Evaluate the tools using formative, process and outcome measures.

2. CDC Activities

a. Provide scientific and public health consultation and assistance in the development of educational activities related to the cooperative agreement.

b. Provide consultation and technical assistance regarding implementation of educational activities.

c. Provide technical assistance in the development and implementation of formative, process and outcome evaluation plans.

d. Assist in reporting and validating relevant information concerning viral hepatitis made available to Federal, State, local health agencies, health professionals, and volunteer organizations.

F. Content

Letter of Intent (LOI)

An LOI is optional for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than five pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font. Your letter of intent will be used to assist CDC in planning and executing the evaluation of applications submitted under this announcement, and should include the following information: name and address of institution; name, address, and telephone number of the contact person; and a brief description of intended effort. This description should include to which Part(s) the applicant is applying and which primary target population(s) the applicant is addressing. Each applicant must submit a separate LOI for each Part.

Applications

The Program Announcement title and number must appear in the application. Use the information in the Program Requirements, Other Requirements and Evaluation Criteria sections to develop the application content. Separate applications for each Part must be submitted. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 pages, double-spaced, printed on one side, with one-inch margins, and unreduced 12-point font.

The narrative should consist of, at a minimum, a description of the overall plan to achieve the objectives, methods, evaluation and budget. The plan should address activities to be conducted over the entire project period. A detailed index to application contents, including appendices, as well as a one-page executive summary should be included at the front of the application and included in the 25 page limit.

G. Submission and Deadline

Letter of Intent (LOI) Submission

On or before June 5, 2003, submit the LOI to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Application Forms

Submit the signed original and two copies of PHS 398 (OMB number 0925–0001). Adhere to the instructions on the Errata Instruction Sheet (posted on the CDC web site) for PHS 398. Forms are available at the following Internet

address: *http://www.cdc.gov/od/pgo/forminfo.htm.*

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) at: 770–488–2700. Application forms can be mailed to you.

Submission Date, Time, and Address

The application must be received by 4 p.m. Eastern Time July 7, 2003. Submit the application(s) to: Technical Information Management-PA#03099, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146.

Applications may not be submitted electronically.

CDC Acknowledgment of Application Receipt

A postcard will be mailed by PGO–TIM, notifying you that CDC has received your application.

Deadline

Letters of intent and applications will be considered as meeting the deadline if they are received before 4 p.m. Eastern Time on the deadline date. Any applicant who sends their application by the United States Postal Service or commercial delivery services must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If an application is received after closing due to (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, CDC will upon receipt of proper documentation, consider the application as having been received by the deadline.

Any application that does not meet the above criteria will not be eligible for competition and will be discarded. The applicant will be notified of their failure to meet the submission requirements.

H. Evaluation Criteria

Application

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goal as stated in purpose section of this announcement. Measures must be objective and quantitative and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

An independent review group appointed by CDC will evaluate each application against the following criteria:

1. Objectives and Technical Approach (45 points)

a. Extent to which the applicant describes objectives of the proposed activities which are (1) consistent with the purpose and goal of this cooperative agreement, (2) measurable and time-phased and (3) consistent with published CDC guidelines on prevention and control of hepatitis A, B, and C (see cited references in Attachment II).

b. Extent and quality of detailed plan proposed for designing, implementing, and evaluating the activities, which clearly and appropriately addresses all ''Recipient Activities'' in the application, and are appropriate and adequate to accomplish the objectives. These activities will be scored in four categories as follows:

(1) Methodologies used in the development of the activity. Methodologies should be based on established learning theories such as, but not limited to, adult learning theory, social learning theory, and/or behavioral change theory that include the health belief model and stages of change. The established objectives must be measurable and meet the broad goals of the application.

(2) The planning and development process. The process should include formative evaluation (*e.g.*, needs assessment) that clearly shows the need and structure of the plan for the specific educational activity.

(3) Implementation of educational activities. A complete description of implementation methodology should be included that describes the process evaluation throughout the implementation phase. Process evaluation during the development of the activity should directly address the planned activity and should be conducted (a) to assure that the educational activity is being implemented as intended and (b) to determine if the educational activity needs to be modified to better address the educational needs of the target population as outlined in the objectives.

(4) The expected outcome. Impact evaluation should be assessed to determine if the objectives (*e.g.*, change in KAPs) were met as a result of implementing the activity. A description of the standards (*e.g.*, scientific, historical, normative) to which the results will be compared should be included. Outcome evaluation should contain an assessment of the resultant policy changes or organizational practices (*e.g.*, extended/expanded use of the educational activity) after implementing the activity.

c. Extent to which the applicant clearly identifies specific assigned responsibilities of all key professional personnel, and describes collaboration with CDC and other relevant organizations.

d. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed activities. This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the plans for recruitment and outreach for participants include the process of establishing partnerships with communities and recognition of mutual benefits.

2. Capacity (30 points)

Extent to which the applicant provides evidence of adequate resources, facilities, experience (both technical and administrative), and access to target audiences for conducting the activities.

This should include:

a. Documentation that professional personnel involved are qualified and have past successful experience and achievements related to the proposed activities; this can include experience of either direct or collaborating personnel in providing viral hepatitis or other communicable disease (*e.g.*, HIV) education and/or training in prevention and control activities.

b. Inclusion of original letters of support from appropriate non-applicant organizations, individuals, institutions, academic institutions, public health departments, etc. needed to carry out proposed activities and the extent to which such letters clearly indicate the author's commitment to participate as described in the plan.

c. Evidence of past success in developing, disseminating and evaluating health education activities.

d. Extent of demonstrated experience in areas of viral hepatitis or other blood-borne virus prevention and control and education and demonstrated success in developing, implementing, and evaluating the impact of educational activities in disease prevention/health promotion at different levels (*e.g.*, community, high-risk populations, minority populations, patients, health professionals). Extent of demonstrated

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,