agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162) (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials are the subject of approved NDA 19–443 held by Abbott Laboratories. The drug products 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials are indicated for the treatment of metabolic acidosis, certain drug overdosage, and severe diarrhea. The holder of the application for 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials requested a voluntary withdrawal and the marketing of the drug products was discontinued (61 FR 40649, August 5, 1996). In a citizen petition dated March 18, 2004 (Docket No. 2004P–0141), submitted under 21 CFR 10.30 and 314.122, Abbott Laboratories requested that the agency determine whether 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were not withdrawn from sale for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports and has found no information that would indicate that these products were withdrawn for reasons of safety or effectiveness.

For the reasons outlined, FDA determines that Abbott Laboratories' 7.5% and 8.4% sodium bicarbonate injection in PET Abbject vials were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list 7.5% and 8.4% sodium bicarbonate injection in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to 7.5% and 8.4% sodium bicarbonate injection may be approved by the agency.

Dated: November 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26271 Filed 11–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0484]

Draft Guidance for Industry on the Role of Human Immunodeficiency Virus Drug Resistance Testing in Antiretroviral Drug Development; 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 ''Role of HIV Drug Resistance Testing in Antiretroviral Drug Development.'' This draft guidance is intended to assist sponsors in the clinical development of drugs for the treatment of human immunodeficiency virus (HIV) infection. Specifically, the draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is also intended to serve as a focus for continued discussions among the Division of Antiviral Drug Product (DAVDP) in FDA's Center for Drug Evaluation and Research, pharmaceutical sponsors, the academic community, and the public.

DATES: Submit written or electronic comments on the draft guidance by February 28, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft 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. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (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: Jeffrey S. Murray, or Kimberly A. Struble Center for Drug Evaluation and Research (HFD–530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Role of HIV Drug Resistance Testing in Antiretroviral Drug Development.'' This draft guidance addresses the role of HIV resistance testing during antiretroviral drug development and postmarketing. The draft guidance is based on the following: (1) A 2-day session of the Antiviral Drug Product advisory committee convened November 2 and 3, 1999, to address issues relating to HIV resistance testing; (2) the DAVDP's experience with reviewing resistance data for antiretroviral drugs; and (3) input from pharmaceutical sponsors and the HIV community.

The draft guidance discusses the nonclinical studies (mechanism of action; antiviral activity in vitro; cytotoxicity/therapeutic index; and the effects of serum protein binding on antiviral activity) we recommend be completed prior to the initiation of phase 1 clinical studies in HIV-infected patients. In addition, the draft guidance addresses the use of resistance testing in the clinical phases of drug development and recommends the type of information that should be collected and the types of analyses that should be conducted to characterize an antiretroviral's resistance profile. The draft guidance also reviews the role of resistance testing in initial activity and dose-finding, for study enrollment criteria, for background regimen selection, and to establish an indication. Included in this draft guidance are two appendices: (1) A template for submitting HIV resistance data and (2) information on the genetic threshold for resistance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the role of HIV resistance testing in antiretroviral drug development. 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 Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The collection of information in this guidance was approved under the OMB control number 0910–0014 (until January 31, 2006).

IV. Electronic Access

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

Dated: November 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26272 Filed 11–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Funding for the Pathways for Health Professions Program, HRSA–05–118

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of posting of availability of funds.

SUMMARY: This notice announces the posting of a funding opportunity (Guidance HRSA–05–118) for the Pathways to Health Professions Program (PHPP) on the Health Resources and Services Administration (HRSA) Guidance and Fedgrants.gov Web sites. Funding is being made available for a competitive grant program that supports the continuation and development of innovative, culturally competent approaches that encourage underrepresented minority and disadvantaged students in colleges and universities, community colleges, elementary, middle, and high schools to pursue a career in a health or allied health field. This program consists of two distinct grants: (1) Primary Pathways—Promotes academic achievement and exposes students in grades K–12 to health and allied health professions through innovative, non-traditional methods, with an emphasis on health professions that are experiencing severe shortages across the country; and (2) Advanced Pathways—Promotes academic achievement and exposes and prepares high school and undergraduate students to pursue careers in health and allied health professions, including faculty membership and research.

Name of Grant Program: Pathways to Health Professions Program.

Program Authorization: Section 739 of the Public Health Service Act, 42 U.S.C. 293.

Amount of Funding Available: $400,000. We expect that fiscal year 2005 funding for the Primary Pathways Program will be approximately $200,000 and approximately $200,000 for the Advanced Pathways grant program. It is anticipated that four awards will be made.

Eligible Applicants: Eligible applicants are elementary, middle, and high schools, community colleges, colleges and universities, and institutions of higher education, non-profit community-based organizations, including faith-based organizations, Tribes, Tribal organizations, and health or educational professional organizations. Eligible participants include underrepresented minorities, educationally and economically disadvantaged elementary, middle, high school, community college, and undergraduate students. They must be U.S. citizens, non-citizen nationals, or those foreign nationals who possess a visa permitting permanent residence in the U.S.

Guidance Availability: Guidance availability is currently posted on the HRSA Web site at: *http://www.hrsa.gov/grants/preview/guidanceprofessions/hrsa05118.htm* and on Fedgrants.gov at: *http://fedgrants.gov/Applicants/HHS/HRSA/GAC/HRSA–05–118/listing.html.*

Application Deadline: December 17, 2004.

Dated: November 22, 2004.

Elizabeth M. Duke,

Administrator.

[FR Doc. 04–26274 Filed 11–26–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Udall Center Review.

Date: December 2, 2004.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Joann McConnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5324, *mcconnej@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, NINDS T32 Review.

Date: December 7, 2004.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Joann McConnell, PhD, Scientific Review Administrator, Scientific Review Branch, NIH/NINDS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 496–5324, *mcconnej@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel, Neural Control of Motor Systems.

Date: December 16, 2004.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).