DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science. This meeting was announced in the **Federal Register** of October 4, 2004 (69 FR 59238). The amendment is being made to reflect changes in the *Agenda* and *Location* portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Hilda Scharen, 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: *SCHARENh@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12539. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 4, 2004, FDA announced that a meeting of the Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science would be held on November 3 and 4, 2004. On page 59238, in the third column, the *Location* and *Agenda* portions of the meeting are amended to read as follows:

Location: Hilton Washington DC North, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Agenda: On November 3, 2004, the subcommittee will address the following issues: (1) Receive topic updates for ongoing FDA activities previously presented to the subcommittee; (2) discuss and provide comments on the evidence for updating labels of approved drugs to include integrating pharmacogenetic, pharmacokinetic, and prognostic biomarkers for the purpose of optimizing therapeutic response and reducing risks of toxicity, with CAMPTOSAR (irinotecan hydrochloride), by Pfizer Inc., as an example; and (3) discuss and provide comments on metabolism- and transporter-based drug-drug interactions included as recommendations in a draft guidance for industry being prepared by FDA. On November 4, 2004, the subcommittee will discuss and provide comments on a new critical path project related to general aspects of the transition of biomarkers to surrogate endpoints, with a focus on planning and process, rather than on specific biomarkers or surrogate endpoints.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: October 14, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–23626 Filed 10–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Science Board to the Food and Drug Administration; 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: Science Board to the Food and Drug Administration.

General Function of the Committee: The Board shall provide advice primarily to the agency's Senior Science Advisor and, as needed, to the Commissioner and other appropriate officials on specific complex and technical issues as well as emerging issues within the scientific community in industry and academia. Additionally, the Board will provide advice to the agency on keeping pace with technical and scientific evolutions in the fields of regulatory science, on formulating an appropriate research agenda, and on upgrading its scientific and research facilities to keep pace with these changes. It will also provide the means for critical review of agency-sponsored intramural and extramural scientific research programs.

Date and Time: The meeting will be held on November 5, 2004, 8 a.m. to 5 p.m.

Location: 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

Contact Person: Jan Johannessen, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6687, *jjohannessen@fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512603. Please call the Information Line for up-to-date information on this meeting.

Agenda: The Board will hear about and discuss: (1) An update on the FDA Critical Path Initiative (*http://www.fda.gov/oc/initiatives/criticalpath/*), including an overview of docket submissions, current status, reports on related activities (Medical Technology Innovation Task Force and Foods Critical Path White Paper), and future plans; (2) FDA's final report on pharmaceutical current good manufacturing practices (*http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm*); and (3) an internal peer review of the Office of Regulatory Affairs' pesticide program, including plans for the establishment of a Science Board subcommittee to conduct an external program peer review.

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 October 29, 2004. 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 October 29, 2004, 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 Jan Johannessen 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: October 14, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–23625 Filed 10–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Council on Nurse Education and Practice; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: National Advisory Council on Nurse Education and Practice (NACNEP).

Dates and Times: November 3, 2004, 8:30 a.m.–5 p.m.; November 4, 2004, 8:30 a.m.–5 p.m.; November 5, 2004, 8:30 a.m.–3 p.m.

Place: The St. Regis Hotel, 923 16th Street, NW., Washington, DC 20006.

Status: The meeting will be open to the public.

Agenda: Agency and Bureau administrative updates will be provided. The purpose of the meeting is to continue the April 2004 meeting focusing on geriatrics with implications for the nursing workforce, education and practice. While the April meeting focused on geriatric nursing workforce issues, geriatric nursing practice and education will be highlighted in this meeting. An opening presentation will provide a comprehensive view of patient safety in long-term care to be followed by a panel presentation of Health Resources and Services Administration, Bureau of Health Professions (BHPr), geriatric exemplars. Additional presentations will highlight culturally competent care from the consumers' perspective and geriatric nursing education addressing models, gaps and implications for the future. An update of BHPr's performance measures will also be presented. Work group discussions will take place on the first and second days to develop recommendations related to geriatrics. On the third day the Council will review a draft of the Fourth Report to the Secretary, HHS, and Congress and finalize all geriatrics recommendations from the April 2004 and the November 2004 meetings on nursing workforce, education and practice.

FOR FURTHER INFORMATION CONTACT: Anyone interested in obtaining a roster of members, minutes of the meeting, or other relevant information should write or contact Ms. Elaine G. Cohen, M.S., R.N., Executive Secretary, National Advisory Council on Nurse Education and Practice, Parklawn Building, Room 9–35, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–1405.

Dated: October 14, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–23627 Filed 10–21–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: (301) 496–7057; fax: (301) 402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Inhibitors of HIV Ribonuclease H Antiviral Properties

Drs. John Beutler, Stuart LeGrice, Scott Budihas, Antony Wamiru, Roberta Gardella, and Jennifer Wilson (all of NCI); Dr. Michael Parniak (EM)

U.S. Provisional Application filed 30 Aug 2004 (DHHS Reference No. E–256–2004/0–US–01)

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

The invention describes a class of compounds that inhibit HIV RNase H and the methods of using these compounds for the treatment of HIV infections. More specifically, these compounds are vinylogous urea derivative containing substituted thiophene core structures and these compounds were part of the 100,000 member library of compounds purchased by NCI from ChemBridge. The selectivity of the antiviral activity was demonstrated in their selective inhibition of HIV–1 and HIV–2 Rnase H enzymes 1 in the CEM cell line of CD4+ lymphoblast cells. Five members of this class of compounds were able to block the cytopathic effect of the virus at concentrations that did not inhibit cell growth. Thus, these compounds may be used in the development of therapeutics for the treatment of retroviral infections, such as AIDS. In addition, these compounds described in this invention may also have particular value when used in combination treatments with other antiviral therapies directed at other viral targets, such as protease and integrase.

Protozoan Derived Antagonist of CCR5

Drs. Alan Sher, Julio Aliberti, Jose Ribeiro, and John Andersen (all of NIAID); Dr. Hana Golding (FDA)

U.S. Provisional Application No. 60/586,884 filed 08 Jul 2004 (DHHS Reference No. E–272–2004/0–US–01)

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

The invention describes the anti-HIV properties of cyclophilin-18, a protein expressed by the protozoan parasite Toxoplasma gondii. The protein was found to bind to the chemokine receptor CCR5 which is also a co-receptor for the HIV virus. Both the native and recombinant molecules display inhibitory activity in HIV–1 fusion (syncitia formation) and infectivity assays with human T cells and macrophages. Thus, Toxoplasma gondii cyclophilin-18 or modified versions of the molecule may be used in the development of treatment for AIDS. In particular, the protein described in this invention may have particular value when used as a microbicide for blocking initial HIV infection. More details of this invention can be found in Golding et al., ''Inhibition of HIV–1 Infection by a CCR5 Binding Cyclophilin from Toxoplasma gondii'', Blood 1 Nov 2003 102(9): 3280–3286.

Treatment of Human Viral Infections (Resveratrol)

Drs. Steven Zeichner and Vyjayanthi Krishnan (NCI)

U.S. Provisional Application No. 60/588,013 filed 13 Jul 2004 (DHHS Reference No. E–279–2004/0–US–01)

Licensing Contact: Sally Hu; 301/435–5606; *hus@mail.nih.gov*.

This application describes the methods for treating or preventing an HIV infection by the administration of an Egr 1 activator called Resveratrol (3, 5, 4''-trihydroxystilbene) and its derivatives. It has been known that HIV, once it infects a cell, integrates into the cellular genome and can (1) rapidly undergo lytic infection, or (2) lay dormant for a period of time (latent infection). The existence of latent infected cells poses a great challenge to HIV therapy because (1) there are no good existing means that can separate the latent infected cells from the uninfected cells; (2) even when antiretroviral drugs are able to completely suppress detectable HIV replication, these latent infected cells will remain and HIV can subsequently complete the viral replication cycle to produce more virus. Since Resveratrol and its derivatives can activate lytic replication from latent infected cells via its effects on Erk1/2 signaling, Resveratrol and its derivatives may lead to therapies in which Resveratrol and/or its derivatives is given together with highly active antiretroviral therapy in an