FOR FURTHER INFORMATION CONTACT: Shalini Jain, 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: *JAINS@CDER.FDA.GOV*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12535. Please call the Information Line for up-to-date information on this meeting.

Dated: September 26, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–24925 Filed 10–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee for Pharmaceutical Science; 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: Advisory Committee for Pharmaceutical Science.

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 October 21, 2003, from 8:30 a.m. to 4:30 p.m., and October 22, 2003, from 8:30 a.m. to 5 p.m.

Location: Best Western Washington Gateway Hotel, 1251 West Montgomery Ave., Rockville, MD.

Contact Person: 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, 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.

Agenda: On October 21, 2003, the committee will do the following: (1) Receive updates from the Manufacturing, Clinical Pharmacology, and Pharmacology/Toxicology Subcommittees, (2) discuss and provide comments on the FDA draft guidance for industry entitled ''Process Analytical Technologies (PAT), a Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance,'' (see the FDA Internet Web address *http://www.fda.gov/cder/guidance/5815dft.htm)*, and (3) discuss and provide comments on parametric tolerance interval test for dose content uniformity. On October 22, 2003, the committee will do the following: (1) Discuss and provide comments on risk based Chemistry Manufacturing and Control (CMC) review proposals, (2) discuss and provide comments on nomenclature, and (3) discuss and provide direction to the research plan for generics.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 10, 2003. Oral presentations from the public will be scheduled between approximately 11:30 a.m. and 12:30 p.m. on October 21, 2003, and between approximately 1 p.m. and 2 p.m. on October 22, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 10, 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 Hilda Scharen 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: September 25, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–24927 Filed 10–1–03; 8:45 am]

BILLING CODE 4160–01–S

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 agencies 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.

HLtat Cell Line

Barbara K. Felber and George Pavlakis (NCI).

DHHS Reference No. E–273–2003/0 (NIH AIDS Research & Reference Reagent Program catalog number 1293).

Licensing Contact: Susan Ano; 301/435–5515; *anos@mail.nih.gov.*

This cell line contains stably integrated copies of the HIV–1 LTR promoter linked to a synthetic one-exon tat gene. HLtat was generated by cotransfection of HeLa cells with pSV2neo and with pL3tat, which contains the HIV–1 LTR promoter, synthetic first tat exon, and the SV40 polyadenylation signal. Clone HLtat was selected in G418 on the basis of high-level production of the one-exon Tat. The cell line is stable and does not need to be routinely maintained under G418 selection. When transfected with HIV DNA or with any plasmid expressing the gene of interest driven by the HIV LTR promoter, high-level of gene expression is achieved. This cell line is further described in J. Virol 64:3734, 1990; AIDS Res. Ref. Reagent Program Courier 91–01:8, 1991; and J. Virol 64:2519, 1990. This cell line is available for licensing through a Biological Materials License Agreement.

Novel Anti-Tumor and Anti-Fungal Compounds Isolated From Plants of the Genus

Aniba

R. Shoemaker, E. Sausville, G. Cragg, D. Newman, M. Currens, T. McCloud, P. Klausmeyer, K. Tucker, M. Baseler, G. Chnurny, and W. Bancroft (NCI).

U.S. Provisional Application No. 60/433,489 filed 28 Jan 2003 (DHHS Reference No. E–224–2002/0–US–01).

Licensing Contact: Brenda Hefti; 301/435–4632; *heftib@mail.nih.gov.*

The invention describes separate and combined extracts from two plants of the genus Aniba, and a specific compound possessing and indolizinium

core. Both the purified extracts and the pure substituted inolizinium compound were found to inhibit the growth of the azone-resistant fungi C. albicans, certain bacteria, as well as demonstrating a differential response across the NCI human tumor cell line panel with a special sensitivity observed in several leukemia cell lines.

Cloning and Characterization of VIAF in Several Organisms

Colin S. Duckett, Bettina M. Richter (NCI).

U.S. Provisional Application No. 60/163,748 filed 05 Nov 1999 (DHHS Reference No. E–016–2000/0–US–01), PCT/US00/20576 filed 28 Jul 2000 (DHHS Reference No. E–016–2000/0–PCT–02), U.S. Patent Application No. 10/129,424 filed 03 May 2002 (DHHS Reference No. E–016–2000/0–US–03).

Licensing Contact: Matthew Kiser; 301/435–5236; e-mail: *kiserm@mail.nih.gov.*

The process of apoptosis, or programmed cell death, can be utilized to eliminate unwanted cells, and it can occur during embryogenesis, turnover of senescent cells or metamorphosis. It can also be part of a defense mechanism against pathogens, *e.g.*, viruses, by allowing the host organism to eliminate infected cells. In an attempt to circumvent this defense mechanism, pathogens can produce gene products that block these apoptotic pathways. For example, *O. pseudotsugata* expresses a family of inhibitors of apoptosis proteins (IAP), and experimental data suggests that these IAPs can play a role in the protection from cellular apoptosis. This application claims nucleic acid and amino acid sequences corresponding to a viral IAP-associated factor, or VIAF. The gene and its product may enhance the anti-apoptotic properties of IAPs although the exact mechanism of this interaction is not clear. This technology could be used to treat disease states where VIAF is under-expressed, *e.g.*, breast adenocarcinomas, where there is an over-expression of VIAF, *e.g.*, neurodegenerative diseases and where apoptosis is undesired, *e.g.*, AIDS and autoimmune diseases. Additional information may be found in Duckett, CS, ''Novel modulators of the apoptotic cell death pathway,'' Mol. Biol. Cell 12: 732 Suppl. S Nov 2001.

Dated: September 26, 2003.

Richard U. Rodriguez,

Acting Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 03–24969 Filed 10–1–03; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Extension of Existing Collection; Comment Request

ACTION: 60-Day notice of information collection under review; The Student and Exchange Visitor Information System (SEVIS); OMB–30.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (BCIS), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Commenters are encouraged and will be accepted for sixty days until December 1, 2003.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of and existing information collection.

(2) *Title of the Form/Collection:* The Student and Exchange Visitor Information System (SEVIS).

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (File No. 0MB–30). Bureau of Citizenship and Immigration Services, Department of Homeland Security.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. This system is used by institutions and sponsors to provide notification, reports, updates and data required by regulations and the institutions and programs, as well as on student and exchange visitors. Additionally, the BCIS and the Department of State will use SEVIS to adjudicate benefits and services, track student and exchange visitor data, and to monitor institution and program sponsor compliance with current regulations.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 625,135 applicant and 5 responses at 20 minutes (.333 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 1,040,850 annual burden hours:

If you have additional comments, suggestions, or need a coy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan 202–514–3291, Director, Regulations and Forms Services Division, Bureau of Citizenship and Immigration Services, Department of Homeland Security, 425 I Street, NW., Room 4034, Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Theresa O'Malley, Chief Information Officer, Department of Homeland Security, Regional Office Building 3, 7th and D Streets, SW., Suite 4636–26, Washington, DC 20202.