will not be collected again. We have reduced the number of questions from 16 to 5. Collection(s) of information will be electronically and/or telephonically obtained thus, providing respondents with data already in the database to further the ease of response and lower the burden.

In the **Federal Register** of April 17, 2003 (68 FR 18989), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received in response to that notice.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Food Code Survey	150	4	600	1	600

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Experience in the initial survey has more clearly identified the respondents for updating the information in the database. For example, FDA will obtain information from the IHS, relative to the tribal nations' adoption of the Food Code that IHS maintains, using the information categories in the revised followup survey form for which this extension is requested. Seventy-three State and Territorial agencies were identified as respondents for Food Code adoption, and it appears that initially, only 30 local agencies in cities of 500,000 or more will need to be contacted because most local jurisdictions are under State requirements. This further reduces the total burden on respondents. Quarterly updates from respondents under active rulemaking, will be requested by AFDO to keep the database current and accurate. Respondents that have concluded rulemaking will likely need only annual contact. Estimated response time is about 1 hour or less because most reporting will be done telephonically or electronically.

Dated: September 24, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–24929 Filed 10–1–03; 8:45 am]

BILLING CODE 4160–0–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anti-Infective 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). At least one portion of the meeting will be closed to the public.

Name of Committee: Anti-Infective 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 October 28, 2003, from 8 a.m. to 5:30 p.m., and on October 29, 2003, from 8:30 a.m. to 4:30 p.m.

Location: Holiday Inn, The Ballrooms, 2 Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Tara P. Turner, 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, e-mail: *TurnerT@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12530. Please call the Information Line for up to date information on this meeting.

Agenda: On October 28, 2003, the committee will begin with a closed session from 8 a.m. to 12 noon. Following the closed session, from 1 p.m. to 5:30 p.m., the committee will discuss clinical trial design issues for demonstrating the safety and efficacy of antimicrobials in the treatment of diabetic foot infections. On October 29, 2003, the committee will discuss clinical trial design issues for demonstrating the safety and efficacy of antimicrobials in the treatment of acute bacterial sinusitis.

Procedure: On October 28, 2003, from 1 p.m. to 5:30 p.m., and on October 29, 2003, from 8:30 a.m. to 4:30 p.m., the meeting is open to the public. 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 21, 2003. Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 3:45 p.m. on October 28, 2003, and between approximately 1 p.m. and 1:30 p.m. on October 29, 2003. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 21, 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.

Closed Committee Deliberations: On October 28, 2003, from 8 a.m. to 12 noon, the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

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 Tara Turner 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. 03–24926 Filed 10–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Drug Safety and Risk Management Advisory Committee; Notice of Postponement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Drug Safety and Risk Management Advisory Committee scheduled for September 18, 2003, due to Hurricane Isabel. This meeting was announced in the **Federal Register** of June 30, 2003 (68 FR 38713). An amendment to the notice of meeting was announced in the **Federal Register** of July 23, 2003 (68 FR 43534). The future date for this meeting is to be determined.

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