establishment size. The product types are vitamins and minerals, herbals and botanicals, herbal and botanical extracts, amino acids, proteins, animal extracts, tea-like products, concentrates/metabolites/constituents, and other dietary supplements. The survey is designed to determine the extent to which firm's operations use written procedures and maintain records to ensure that: (1) Personnel have the proper education, training and experience and are knowledgeable in disease control and other safety concerns; (2) buildings and facilities are maintained against contamination; (3) equipment is cleaned and sanitized; (4) quality control and laboratory operations determine that certificates of analysis are reliable and that identity and adulteration tests are conducted on raw materials and in-process formulations; (5) production and process controls use master and batch records as well as other records; (6) warehousing and distribution operations maintain records for forward and backward tracing of product; and (7) consumer complaints are handled and documented.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Computer Assisted Telephone Interview (CATI)	400	1	400	1.13	452

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

These estimates are based on FDA's experience with conducting industry surveys.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25899 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

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). The meeting will be open 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 20 and 21, 1999, 8 a.m. to 5 p.m.

Location: Holiday Inn, Kennedy Grand Ballroom, 8777 Georgia Ave., Silver Spring, MD.

Contact: Rhonda W. Stover, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, 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 12530. Please call the Information Line for up-to-date information on this meeting.

Agenda: On the morning of October 20, 1999, the committee will discuss the development of antimicrobial drugs for the treatment of catheter-related bloodstream infections.

On the afternoon of October 20, 1999, the committee will discuss new drug applications (NDA's) 20–634 and 20–635, levofloxacin (Levaquin™, The R.W. Johnson Pharmaceutical Research Institute) for the treatment of community-acquired pneumonia due to penicillin-resistant *Streptococcal pneumoniae*.

On October 21, 1999, the committee will discuss NDA 21–085, moxifloxacin (Avelox™, Bayer Corp. Pharmaceutical Division), for the treatment of community-acquired pneumonia, acute bacterial exacerbations of chronic bronchitis, skin and skin-structure infections, and acute sinusitis.

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 13, 1999. Oral presentations from the public will be scheduled between approximately 9 a.m. and 9:30 a.m. and between approximately 1 p.m. and 1:30 p.m. on October 20, 1999, and between approximately 8 a.m. and 8:30 a.m. on October 21, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 13, 1999, 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.

FDA regrets that it was unable to publish this notice 15 days prior to the October 20, 1999, Anti-Infective Drugs Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Anti-Infective Drugs Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 29, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–25970 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Round Table; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: ''Consumer Round Table—Risk Management in a Diverse Society.'' This meeting will provide an opportunity for consumers to engage in an open dialogue with senior officials on how FDA ensures drug safety and manages and communicates the risks and benefits of drug products.

Date and Time: The meeting will be held on Tuesday, October 26, 1999, from 8 a.m. to 3:30 p.m.

Location: The meeting will be held at the Hilton-Houston Southwest, Regency Ballroom, 6780 Southwest Freeway, Houston, TX 77074, 713–977–7911, FAX 713–974–5808.

Contact: Sheryl Lunnon-Baylor, Dallas District Office (HFR–SW1580), Food and Drug Administration, 1445 North Loop West, suite 420, Houston, TX 77008, 713–802–9095, ext. 115, FAX 713–802–0906.

Registration: Send registration information (including name, title, organization title, mailing address, telephone number, and fax number) to the contact person by October 15, 1999.

If you need special accommodations due to a disability, please contact Sheryl Lunnon-Baylor (address above) at least 7 days in advance.

Executive Summary: An executive summary of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Room 12A–16, Rockville, MD 20852, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 30, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–25969 Filed 10–5–99; 8:45 am]

BILLING CODE 4160–01–F

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 invention listed below is owned by an agency of the U.S. Government and is 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.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J.R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056, ext. 206; fax 301/402–0220; E-Mail: jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

SUPPLEMENTARY INFORMATION:

Title: ''Diagnostic and Therapeutic Methods of Detecting and Treating Cancers of Reproductive Tissues.''

Inventors: Drs. Ira H. Pastan (NCI), Ulrich Brinkmann (NCI), George Vasmatzis (NCI) and Byungkook Lee (NCI).

DHHS Ref. No. E–028–99/0—Filed with the U.S.P.T.O. September 1, 1998.

Background

The basis of cancer immunotherapy as a viable option of treatment rests on the supposition that tumor-specific antigens are expressed by the tumor cells, and that immune effector mechanisms can be induced selectively to destroy these tumor cells. Although a variety of host immune effector cells have been shown to participate in the killing of tumor cells, tumor-specific CD8+ Cytotoxic T Lymphocytes (''CTL'') are highly specific and effective in mediating tumor cell killing. CTLs that recognize tumor cells have been isolated from melanoma, breast, ovarian, renal, lung, colorectal and prostrate cancer patients. Their existence suggests that there is an immune response to cancer in these patients and that its augmentation might be therapeutically beneficial. Thus, approaches based on induction of tumor-specific CTLs by therapeutic vaccines may provide an attractive alternative for treating cancer patients.

Technology

PAGE–4 is a human X-linked gene that is strongly expressed in prostate and prostate cancer, and is also expressed in other male and female reproductive tissue (*e.g.*, testis, fallopian tube, placenta, uterus, and uterine cancer). PAGE–4 shows similarity with the GAGE protein family, but it diverges significantly from members of the family so that it appears to belong to a separate family. This, and the existence of another gene, PAGE–2, that share more homology with PAGE–4 than with members of the GAGE family indicates that the PAGE–4 protein belongs to a separate protein family.

The specific detection of PAGE–4 might be valuable for the diagnosis of prostate and testicular tumors, as well as uterine tumors. There are sufficient differences between PAGE–4 and other members of the PAGE and MAGE proteins to produce specific antibodies. Analyses with such antibodies are needed to confirm by immunohistology the expression specificity that is seen in database and mRNA analyses, and to evaluate whether anti-PAGE–4 immunotherapy could be a promising therapeutic approach. One possibility of eliminating PAGE–4 expressing cells could be to use it as cancer vaccine. Among the many possible approaches to vaccination, one method is direct vaccination with plasmid DNA. In fact, Dr. Pastan's laboratory has been able to obtain good expression of the PAGE–4 protein with mammalian expression plasmids, and has demonstrated that DNA-immunization with such expression constructs leads to good immune responses. Hence, this method may generate anti-PAGE–4 responses, and allow us to analyze if ''PAGE–4-vaccination'' can eliminate PAGE–4 expressing cells, as a therapeutic approach towards neoplasms of the prostate, testis, and uterus.

Prostate Cancer

Prostate Cancer is a disease affecting approximately 1 million men in the U.S.A., with an annual incidence of around 300,000 and approximately 40,000 deaths per year. Control of primary tumor by surgical resection and/or radiation has proven effective in a number of cases, however, metastatic spread, primarily to the bone, especially at late hormone independent stages of the disease, has been more difficult to control and monitor.

The above mentioned invention is available, including any available foreign intellectual property rights, for licensing on an exclusive or non-exclusive basis.

Dated: September 28, 1999.

Jack Spiegel, Ph.D.,

Director, Division of Technology Development & Transfer, Office of Technology Transfer.

[FR Doc. 99–25950 Filed 10–5–99; 8:45 am]

BILLING CODE 4140–01–M

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