Dated: April 1, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7130 Filed 4–8–05; 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 May 3 and 4, 2005, from 8:30 a.m. to 5 p.m.

Location: Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, 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, 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 3014512539. Please call the Information Line for up-to-date information on this meeting.

Agenda: On May 3, 2005, the committee will: (1) Receive an update from the Clinical Pharmacology Subcommittee and (2) discuss and provide comments on the general topic of establishing drug release or dissolution specifications. On May 4, 2005, the committee will: (1) Receive an update on current activities of the Parametric Tolerance Interval Test Workgroup, (2) discuss and provide comments on the general topic of considerations for assessment of pharmaceutical equivalence and product design, and (3) discuss criteria for establishing a working group for review and assessment of Office of Pharmaceutical Science research programs.

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 April 25, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 25, 2005, 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: April 1, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7129 Filed 4–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

SUMMARY: Pursuant to Pub. L. 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the eighth meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on May 9, 2005, and from 9 a.m. to 3 p.m. on May 10, 2005, at the Rockville DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. Section 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations from staff of the Centers for Medicare and Medicaid Services (CMS) on the CMS Organ Procurement Organization Notice of Proposed Rulemaking and the Transplant Center Notice of Proposed Rulemaking. The presentations may include a discussion and summary of the comments received during the 60-day public comment period which began February 4.

The draft meeting agenda will be available on April 15 on the Department's donation Web site at *http://www.organdonor.gov/acot.html*.

A registration form will be available on March 15 on the Department's donation Web site at *http://www.organdonor.gov/acot.html*. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Individuals without access to the Internet who wish to register may call Bryan Slattery with PSA at (703) 234–1734. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Director, Thomas E. Balbier, Jr., in advance of the meeting. Mr. Balbier may

be reached by telephone at 301–443–1896, e-mail: *Thom.Balbier@hrsa.hhs.gov*, or in writing at the address of the Division of Transplantation provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations from CMS and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting.

Dated: April 5, 2005.

Elizabeth M. Duke,

Administrator.

[FR Doc. 05–7160 Filed 4–8–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Galveston National Laboratory Record of Decision

ACTION: Notice.

SUMMARY: The Department of Health and Human Services, the National Institutes of Health (NIH), has decided, after completion of a Final Environmental Impact Statement (EIS) and a thorough consideration of the public comments on the Draft EIS to implement the Proposed Action, which is identified as the Preferred Alternative in the Final EIS. This action is to partially fund the construction of a state-of-the-art National Biocontainment Laboratory (NBL), which will be known as the Galveston National Laboratory (GNL), on the University of Texas Medical Branch (UTMB) Campus in Galveston, Texas.

FOR FURTHER INFORMATION CONTACT: Valerie Nottingham, Chief of the Environmental Quality Branch, Division of Environmental Protection, Office of Research Facilities Development and Operations, NIH, Building 13, Room 2W64, 9000 Rockville Pike, Bethesda, MD 20892, telephone 301–496–7775, Fax 301–480–8056, e-mail *nihnepa@mail.nih.gov.*

SUPPLEMENTARY INFORMATION:

Decision

After careful review of the environmental consequences in the Final Environmental Impact Statement for the Galveston National Laboratory for Biodefense and Emerging Infectious Diseases Research Facility in Galveston, TX (Final GNL EIS), and consideration of public comment throughout the NEPA process, the NIH has decided to implement the Proposed Action described below as the Selected Alternative.

Selected Alternative

The NIH plans to partially fund the construction of a state-of-the-art National Biocontainment Laboratory, which will be known as the Galveston National Laboratory (GNL), on the UTMB Campus in Galveston, Texas. The total cost of the proposed GNL project is estimated at approximately $147 million. NIH will fund approximately $110 million with UTMB providing the remaining approximately $37 million. The proposed GNL will enhance national security through the development and evaluation of improved diagnostics, therapeutics, and vaccines for protection against diseases, including those that have the potential for bioterrorism. The proposed GNL will not conduct research to develop biological weapons.

The proposed GNL facility will be a new reinforced concrete seven-story building that will be constructed within the footprint of a recently demolished building on the UTMB campus. The proposed GNL, with a total net area of approximately 82,411 square feet, will house Biosafety Level (BSL)–4, BSL–3, and BSL–2 facilities, BSL–4 and BSL–3 animal facilities, Arthropod Containment Level (ACL)–3 insectary, offices, conference rooms, and support facilities including an effluent treatment room, secure loading dock, and dedicated mechanical floors to enhance containment and minimize the risk of exposure.

The proposed GNL facility will be designed to safely support all of the superimposed loads applied to the building and to resist 140 mile-per-hour hurricane force winds. Also, as required by the National Earthquake Hazards Reduction Program, it will be designed and constructed to the highest building protection classification category of IV. Furthermore, the proposed GNL will be designed with regard to its location within a 100-year flood plain. For example, the BSL–4 laboratories will be located above the extreme 25-foot storm surge that might occur during a category 4 or 5 hurricane. In addition to standby generators to provide power in the event of a power outage, the proposed GNL facility will have a distributed on-line uninterruptible power supply module or a fuel cell power supply to power the BSL–4 biosafety cabinets, BSL–3 enhanced biosafety cabinets, critical building control panels and alarms.

In addition to designing for severe weather conditions, operating procedures will call for a lockdown of all infectious materials and decontamination of high-level biocontainment laboratories in the event of an approaching hurricane. Storm preparedness will be based on approximately 24-hour notice of probable landfall, taking into account the predicted strength of a storm. This allows sufficient time to close down high containment operations, should this be deemed necessary, including the management of animals.

The building also will be provided with an environmental monitoring system to assess room pressure differentials (to ensure negative pressure in the biocontainment areas), smoke detection, automatic watering system pressure and flow, and the condition of high efficiency particulate air (HEPA) filters. Visual indications (such as pressure gauges) and audible or strobic alarms will alert GNL personnel to an emergency or a situation that requires corrective action. The proposed GNL will have fire protection systems that meet or exceed requirements specified by the National Fire Protection Association and all applicable local, State, Federal, and UTMB requirements.

The design of the proposed GNL facility's BSL–4, –3, and –2 laboratories will comply with the recommendations and requirements of the Centers for Disease Control (CDC) and the NIH joint publication addressing biosafety in laboratories, the 4th Edition Biosafety in Microbiological and Biomedical Laboratories, as well as NIH's Design Policies and Guidelines for Biomedical Research Laboratories. The BSL–4, –3, –2 animal laboratories will further comply with the recommendations and requirements of the latest edition of Guide for Care and Use of Laboratory Animals published by the National Research Council. The four biosafety levels have increasingly stringent design, security, and containment requirements. The safety levels are determined based on the biological materials used in research and the ways they affect the human population. BSL–1 facilities have no requirements for safety equipment, while BSL–4 facilities have extensive and multiple requirements for safety equipment and facility design such as isolation, buffer