Medicine (CVM) (HFV–3), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9004, FAX: 240–276–9020, e-mail: *asindela@cvm.fda.gov*.

Transcripts: Meeting transcripts will be made available on CVM's Web site (*http://www.fda.gov/cvm/adufa.htm*) approximately 30 working days after the meeting. The transcript will also be available for public examination at the Division of Dockets Management (see **ADDRESSES**), between 9 a.m. and 4 p.m., Monday through Friday.

SUPPLEMENTARY INFORMATION:

I. Background

In the language authorizing the Animal Drug User Fee Act, Congress directed the Secretary of Health and Human Services (the Secretary) to consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor and Pensions of the Senate, appropriate scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry in developing recommendations to Congress for the reauthorization of ADUFA and for the goals and plans for meeting the goals associated with the process for review of animal drug applications. As directed by Congress, FDA is holding a public meeting to gather information on what features we should propose to include in the ADUFA program (*http://www.fda.gov/cvm/4218.htm*) and hear stakeholder views on this subject.

We are offering the following two general questions for consideration, and we are interested in responses to these questions and any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the ADUFA program thus far?

2. What suggestions or changes would you make relative to the reauthorization of ADUFA?

ADUFA, amended the Federal Food, Drug, and Cosmetic Act (the act) and authorized FDA to collect fees for certain animal drug applications, establishments, products, and sponsors in support of the review of animal drugs. These additional resources support FDA's responsibilities under the act to ensure that new animal drug products are safe and effective for animals as well as for the public with respect to animals intended for food consumption.

FDA's animal drug user fee program was authorized in 2003 and implemented in 2004. A significant part of the preparations for the program included determining the fee levels for fiscal year (FY) 2004. ADUFA provides for the following four fees: (1) A sponsor fee, (2) an establishment fee, (3) a product fee, and (4) an application fee. The act also provides for specific waivers and exemptions from fees. FDA prepared guidance for the industry regarding the fees, billings and submission of fees, and waivers and exemptions (*http://www.fda.gov/cvm/adufa.htm*).

The total amounts of monies expected for collection were as follows: $5 million for FY 2004; $8 million in FY 2005; and, $10 million in each FY 2006 through 2008. Each fee type was expected to be 25 percent of the total amount collected. Thus, in FY 2006, we expect to receive $2,500,000 from sponsor fees, establishment fees, product fees, and application fees, for a total of $10,000,000 dollars (figures are subject to inflation and workload adjustments). The user fees are used to achieve shorter, more predictable review times by increasing the review staff at FDA and building better management systems. As a result, we anticipate substantial savings to the industry in regulatory review and developmental expenses.

FDA's animal drug premarket review program is making continual and substantial improvements in the animal drug review process as a result of user fees. This helps ensure an adequate supply of safe and effective therapeutic and production animal drugs.

We have published a number of reports that may help inform the public about the ADUFA program. Key documents such as ADUFA-related guidance, legislation, performance reports, and financial reports, can be found at *http://www.fda.gov/cvm/adufa.htm*.

II. Meeting

FDA will conduct the meeting on February 24, 2006, at the DoubleTree Hotel (see *Location*). In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry). FDA and panel presentations are planned from 9 a.m. until 12 noon. The open public comment portion of the meeting for registered speakers is planned to begin at 1 p.m. An opportunity for public comments from meeting attendees will commence following the registered presentations, if time permits. The docket will remain open for written comments through March 26, 2006, 30 days following the meeting.

If you wish to reserve time to make a presentation at the meeting, please contact Aleta Sindelar (see **FOR FURTHER INFORMATION CONTACT**) by February 10, 2006. Your request to make a presentation should include the following information: Name, company, company address, company phone number, and e-mail address. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak.

If you require special accommodations due to a disability, please contact the DoubleTree Hotel (see *Location*) at least 7 days in advance of the meeting.

III. Comments

If you would like to submit written comments to the docket regarding ADUFA, please send your comments to the Division of Dockets Management (See **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any written comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E5–7876 Filed 12–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

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

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: February 13, 2006, 9 a.m. to 5 p.m.; February 14, 2006, 8:30 a.m. to 3 p.m.

Place: Ronald Reagan Building and International Trade Center, Rotunda Room,

1300 Pennsylvania Avenue, NW., Washington, DC 20004.

Status: The meeting will be open to the public with attendance limited to space availability.

Purpose: The Advisory Committee provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program and technical information to develop policies and priorities for this program. The Heritable Disorders Program was established to enhance the ability of State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders. The Committee was established specifically to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

Agenda: The first day will be devoted to a presentation on the National Coordination Center for the Regional Genetics and Newborn Screening Collaboratives, presentations on newborn screening projects of the Regional Collaboratives, and reports from the Committee's subcommittees on laboratory standards and procedures, follow-up and treatment and education and training. The second day will include discussions on the nomination process for candidate conditions on the Newborn Screening Panel and presentations by organizations representing policy makers and legislation. Proposed agenda items are subject to change.

Time will be provided each day for public comment. Individuals who wish to provide public comment or who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACHDGDNC Executive Secretary, Michele A. Lloyd-Puryear, M.D., Ph.D. (contact information provided below).

Contact Person: Anyone interested in obtaining a roster of members or other relevant information should write or contact Michele A. Lloyd-Puryear, M.D., Ph.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080. Information on the Advisory Committee is available at *http://mchb.hrsa.gov/programs/genetics/committee.*

Dated: December 20, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. E5–7934 Filed 12–27–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–23333]

Random Drug Testing Rate for Covered Crewmembers

AGENCY: Coast Guard, DHS.

ACTION: Notice of minimum random drug testing rate.

SUMMARY: The Coast Guard has set the calendar year 2006 minimum random drug testing rate at 50 percent of covered crewmembers. Based upon an evaluation of the 2004 Management Information System (MIS) data collection forms submitted by marine employers, we will maintain the minimum random drug testing at 50 percent of covered crewmembers for the calendar year 2006. The purpose of setting a minimum random drug testing rate is to establish a measure of deterrence for the illegal use of controlled substances.

DATES: The minimum random drug testing rate is effective January 1, 2006 through December 31, 2006. You must submit your 2005 MIS reports no later than March 15, 2006.

ADDRESSES: The annual MIS report may be submitted in writing to Commandant (G–MOA), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Room 2404, Washington, DC 20593–0001 or by electronic submission to the following Internet address: *http://www.uscg.mil/hq/g-m/moa/dapip.htm.*

FOR FURTHER INFORMATION CONTACT: For questions about this notice, please contact Mr. Robert C. Schoening, Drug and Alcohol Program Manager, Office of Investigations and Analysis (G–MOA), U.S. Coast Guard Headquarters, telephone 202–267–0684. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Dockets Operations, Department of Transportation, telephone 202–366–0402.

SUPPLEMENTARY INFORMATION: Under 46 CFR 16.230, the Coast Guard requires marine employers to establish random drug testing programs for covered crewmembers on inspected and uninspected vessels. All marine employers are required to collect and maintain a record of drug testing program data for each calendar year, January 1 through December 31. You must submit this data by 15 March of the following year to the Coast Guard in an annual MIS report.

You may either submit your own MIS report or have a consortium or other employer representative submit the data in a consolidated MIS report. The chemical drug testing data is essential to analyze our current approach for deterring and detecting illegal drug abuse in the maritime industry.

Since 2004 MIS data indicates that the positive random testing rate is greater than one percent industry-wide (1.53 percent), the Coast Guard announces that the minimum random drug testing rate is set at 50 percent of covered employees for the period of January 1, 2006 through December 31, 2006 in accordance with 46 CFR 16.230(e).

Each year we will publish a notice reporting the results of the previous calendar year's MIS data, and the minimum annual percentage rate for random drug testing for the next calendar year.

Dated: December 20, 2005.

T.H. Gilmour,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. E5–7897 Filed 12–27–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Change in Regional Partners for Southeast Alaska and the Kodiak Archipelago for the Alaska Migratory Bird Co-Management Council

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Fish and Wildlife Service (Service) is announcing a change in two regional partners, one representing Southeast Alaska and the other one representing the Kodiak Archipelago, both on the Alaska Migratory Bird Co-management Council (Co-management Council). For Southeast Alaska, the Central Council, Tlingit and Haida Indian Tribes of Alaska (Central Council), has elected to step down, and the Co-management Council has voted to replace that partner with the Southeast Alaska Inter-Tribal Fish and Wildlife Commission. For Kodiak, the Kodiak Area Native Association has elected to step down, and the Co-Management Council has voted to replace that partner with the Shoonaq' Tribe of Kodiak.

DATES: The decision described in this notice became effective December 2, 2005.

ADDRESSES: Regional Director, Alaska Region, U.S. Fish and Wildlife Service,