

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

In accordance with FDA's good guidance practices (GGPs) regulation (21 CFR 10.115), this document is being called a guidance, rather than a guideline.

To facilitate the process of making ICH guidances available to the public, the agency has changed its procedures for publishing ICH guidances. As of April 2000, FDA no longer include the text of ICH guidances in the **Federal Register**. Instead, we publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance is placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). Draft ICH guidances are left in the original ICH format. Final guidances are reformatted to conform to the GGP style before publication.

In the **Federal Register** of April 21, 2000 (65 FR 21446), FDA published a draft revised tripartite guidance entitled "Q1A(R) Stability Testing of New Drug Substances and Products." The notice gave interested persons an opportunity to submit comments by June 5, 2000. The draft revised guidance was a revision of an ICH guidance on the same topic published in the **Federal Register** of September 22, 1994 (59 FR 48754).

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies on November 9, 2000.

ICH Q1A provides guidance on the information to be submitted in the stability data package for a new drug substance or drug product for a registration application within the three regions: The EU, Japan, and the United States. The purpose of the ICH Q1A revision is to add information to certain sections and to provide clarification to other sections of the guidance. The following sections are the most important sections that have been revised:

- The section on stress testing of the active substance has been moved from the glossary to the main text.
- The text on test procedures has been brought in line with the ICH Q6A guidance. Relevant cross-references to other ICH guidances have been introduced.

- The text on testing frequency has been amended for accelerated testing conditions.

- Storage conditions have been described in more detail. Testing at low temperature and testing of aqueous liquids in semipermeable containers have been specifically addressed.

- The postapproval commitment is now clearly described.

The guidance has also been revised to remove several editorial inconsistencies, including some revision of the glossary.

This guidance represents the agency's current thinking on stability testing of new drug substances and products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals can submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ohrms/dockets/default.htm>, <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/cber/publications.htm>.

Dated: October 30, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-27958 Filed 11-6-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization Functions and Delegations of Authority of the Department of Health and Human Services (DHHS), Health Resources and Services Administration (HRSA) (60 FR

56605, as amended November 6, 1995 as last amended at 66 FR 52421-29, dated October 15, 2001).

This notice announces the title change only for the Division of Health Careers Development (RPD) in the Bureau of Health Professions (BHP), the functions remain the same. Make the following change in the title:

Division of Health Careers Diversity and Development (RPD)

Serves as the focal point for the Health Professions and Nursing Student Loan and Scholarship Programs, the Exceptional Financial Need Scholarship Program, the Federal Assistance to Disadvantaged Health Professions Scholarship Program, the Health Educational Assistance Loan Program, the Health Professions and Nursing Educational Loan Repayment and Loan Cancellation Programs by providing leadership to assure equity in access to health resources and health careers for diverse and disadvantaged populations. Specifically: (1) Provides technical assistance to groups that represent and seek to improve the health status of diverse and disadvantaged populations, and facilitates the access of such groups to Bureau and other Federal programs and resources; (2) provides leadership and direction for the development and implementation of Bureau objectives as they relate to diverse and disadvantaged populations; (3) develops and recommends health resources and health career opportunities for diverse and disadvantaged populations; (4) initiates, stimulates, supports, coordinates, and evaluates Bureau programs for improving the availability and accessibility of health careers for diverse and disadvantaged populations; (5) initiates, stimulates, supports, coordinates, and evaluates in conjunction with other Bureau units, comprehensive data systems and analyses on requirements, resources, accessibility, and accountability of the health delivery system for diverse and disadvantaged populations; (6) conducts special studies and collects baseline data to identify specific factors contributing to the health and health-related problems of diverse and disadvantaged populations, and to develop strategies for improving health services and career opportunities for diverse and disadvantaged populations; (7) conducts extramural programs, including the use of grants and contracts, specifically designed to promote equity in access to health careers; (8) assures contract compliance and implementation of the Policy Statement on Civil Rights in the Bureau; (9) in coordination with the Bureau's

divisions and in collaboration with other HRSA entities, provides leadership for and assures implementation of Presidential, Departmental, and other special initiatives addressing the needs of diverse and disadvantaged populations; (10) conducts and coordinates Bureau programs in health careers for women; (11) provides leadership to develop and coordinate Bureau program support to student health organizations; (12) provides advice and consultation on policy and other matters related to assuring equity in access to health resources and health careers for diverse and disadvantaged populations; (13) plans, develops, implements and promotes special initiatives and projects; (14) coordinates all necessary Federal, state and/or private sector involvement to insure the success of the initiative; (15) takes appropriate steps to institutionalize initiatives which successfully promote the mission of the Bureau; (16) directs and administers the Health Professions and Nursing Student Loan and Scholarship Programs, the Exceptional Financial Need Scholarship Program, the Federal Assistance to Disadvantaged Health Professions Scholarship Program, the Health Educational Assistance Loan Program, the Health Professions and Nursing Educational Loan Repayment and Loan Cancellation Programs including the awarding of loan and scholarship funds; (17) develops and implements program plans and policies and operating and evaluation plans and procedures in coordination with the Office of Policy and Planning; (18) monitors and assesses educational and financial institutions with respect to capabilities and management of Federal support for students; (19) develops and conducts training activities for staff of educational and financial institutions; (20) maintains liaison with and provides assistance to program-related public and private professional organizations and institutions; (21) maintains liaison with the Office of the General Counsel, and the Office of the Inspector General, DHHS, components of the Department of Education and the Department of Defense, and State agencies concerning student assistance; (22) coordinates financial aspects of programs with educational institutions; and (23) develops program data needs, formats, and reporting requirements, including collection, collation, analysis and dissemination of data.

Section RA-30 Delegation of Authority

All delegations of authority which were in effect immediately prior to the effective date hereof have been

continued in effect in them or their successors pending further redelegation. I hereby ratify and affirm all actions taken by any DHHS official which involved the exercise of these authorities prior to the effective date of this delegation.

This reorganization is effective upon the date of signature.

Dated: October 30, 2001.

Elizabeth M. Duke,
Acting Administrator.

[FR Doc. 01-27899 Filed 11-6-01; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4407-N-02]

The Performance Review Board

AGENCY: Office of the Deputy Secretary, HUD.

ACTION: Notice of Appointments.

SUMMARY: The Department of Housing and Urban Development announces the appointments of Alphonso Jackson, Frank L. Davis, Marcella E. Belt, Paula O. Blunt, Nelson R. Bregon, Kathleen D. Koch, Floyd O. May, Michael J. Najjum Jr., Lawrence L. Thompson, Margaret E. White, and Margaret Young as members; and Sam E. Hutchinson and Pamela H. Patenaude as alternate members to the Departmental Performance Review Board. The address is: Department of Housing and Urban Development, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT:

Persons desiring any further information about the Performance Review Board and its members may contact Earnestine Pruitt, Director, Executive Personnel Management Division, Department of Housing and Urban Development, Washington, DC 20410, telephone (202) 708-1381. (This is not a toll-free number.)

Dated: October 25, 2001.

Alphonso Jackson,
Deputy Secretary, Department of Housing and Urban Development.

[FR Doc. 01-27902 Filed 11-6-01; 8:45 am]

BILLING CODE 4201-32-M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Meeting of the Exxon Valdez Oil Spill Public Advisory Group

AGENCY: Department of the Interior, Office of the Secretary.

ACTION: Notice of meeting.

SUMMARY: The Department of the Interior, Office of the Secretary is announcing a public meeting of the Exxon Valdez Oil Spill Public Advisory Group.

DATES: December 10, 2001, at 9:00 a.m.

ADDRESSES: Fifth floor conference room, 441 West 5th Avenue, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT:

Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 "C" Street, Suite 119, Anchorage, Alaska, (907) 271-5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States District Court for the District of Alaska in settlement of *United States of America v. State of Alaska*, Civil Action No. A91-081 CV. The meeting agenda will feature discussions about the fiscal year 2002 restoration work plan, the habitat program, the 2002 annual workshop, and the proposed Gulf of Alaska Ecosystem Monitoring and Research program.

Willie R. Taylor,

Director, Office of Environmental Policy and Compliance.

[FR Doc. 01-27937 Filed 11-6-01; 8:45 am]

BILLING CODE 4310-RG-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Issuance of Permit for Marine Mammals

On April 18, 2001, a notice was published in the **Federal Register** (66 FR 19979), that an application had been filed with the Fish and Wildlife Service by National Biological Services, Alaska Biological Science Center, Anchorage, Alaska, for renewal of a permit (PRT-801652). The applicant requested renewal of their permit to capture, immobilize, tag, implant transmitters, collect blood, tissue and whisker samples, biopsy, and release walrus from the wild to continue scientific research to develop reliable methods for anesthetizing and holding walrus, develop methods for attaching transmitters and testing these devices in determining walrus movements, diving and haulout patterns, and collect data on physiological status and life history parameters of walrus. The applicant also intends to import biological samples