

a notice announcing the availability of a draft guidance for industry entitled "Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)" that appeared in the **Federal Register** of January 5, 1998 (63 FR 236). FDA is taking this action because of the complexity and importance of the issues raised by this draft guidance and to allow interested parties additional time to prepare and submit comments.

DATES: Written comments by July 31, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of the draft guidance for industry "Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Regarding prescription drugs: Laurie B. Burke, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2828, or via Internet at burkel@cder.fda.gov;

Regarding prescription biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-200), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3028, or via Internet at stifano@cber.fda.gov;

Regarding restricted medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ-302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4639, or via Internet at bxt@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 1998 (63

FR 236), FDA published a notice announcing the availability of a draft guidance for industry entitled "Promoting Medical Products in a Changing Healthcare Environment; I. Medical Product Promotion by Healthcare Organizations or Pharmacy Benefits Management Companies (PBMs)." The draft guidance is intended to assist sponsors of regulated medical products (human drugs, biologics, and medical devices) by describing circumstances in which they may be held responsible for promotional activities performed by a healthcare organization/PBM subsidiary or by a nonsubsidiary healthcare organization/PBM that violate the Federal Food, Drug, and Cosmetic Act and regulations issued thereunder. The draft guidance also reminds medical product sponsors of their responsibility to submit or, in the case of some devices, maintain historical files of promotional labeling and advertising. Following the review of all comments received between January 5 and July 31, 1998, the agency intends to solicit public comment on a new draft guidance document.

Interested persons may, on or before July 31, 1998, submit to the Dockets Management Branch (address above) written comments on this subject. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 25, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98-17413 Filed 6-30-98; 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 63 FR 33379-80 dated June 18, 1998). This notice reflects the changes in the Bureau of Primary Health

Care (BPHC), Division of National Health Service Corps.

I. Under Division of National Health Service Corps (RC5) delete the current functional statement in its entirety and replace with the following:

Provides (1) strategic planning and overall policy guidance, and program oversight to the National Health Service Corps (NHSC); (2) initiates national program and policy changes, including regulatory and statutory amendments, as necessary, to ensure NHSC consistency with evolving national health care policy; (3) supports the NHSC National Advisory Council (NAC), which advises the Secretary, DHHS, on national health care policy, particularly as it affects health manpower issues and the NHSC; (4) works with the Office of the Administrator and the Office of the Secretary to ensure that the NAC membership are nationally recognized leaders in national health care policy issues, and in their respective primary health care disciplines; (5) provides national NHSC leadership, integration and coordination with BPHC, HRSA and other Departmental programs serving or impacting the Nation's underserved communities and populations; (6) works directly with Bureau, Agency and intra-Agency, Departmental, and inter-Departmental organizations and staffs, as appropriate, on national policies and strategies affecting underserved populations and development and distribution of primary care clinical personnel; (7) coordinates with the Bureau of Health Professions regarding health professionals education and training, as appropriate; (8) speaks for NHSC with national, regional, State, and local public and private health care professional associations, universities and other health professions training institutions and other groups whose public policy interests relate to primary health care manpower and access issues; (9) articulates NHSC policy interests and issues to a variety of national forums, including universities, foundations, think tanks, and other organizations whose interests in primary and other health care public policy issues have potential for affecting the NHSC; (10) provides policy guidance and support to HRSA field offices, and to State and Regional Primary Care Offices and Primary Care Associations; and (11) coordinates NHSC and Bureau policy on primary and other health care manpower issues, and works with a wide variety of national, regional, State and local constituencies in ensuring their effective implementation.

II. Delegations of Authority

All delegations and redelegations 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 officials which involved the exercise of these authorities prior to the effective date of this delegation.

This reorganization is effective upon date of signature.

Dated: June 19, 1998.

Claude Earl Fox,

Administrator.

[FR Doc. 98-17472 Filed 6-30-98; 8:45 am]

BILLING CODE 4160-15-U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

PRT-843092

Applicants: San Antonio Zoological Gardens and Aquarium, San Antonio, TX.

The applicant requests a permit to import 4.4 live Japanese Giant Salamanders (*Andrias japonicus*), bred in captivity by the Asa Zoological Park, Hiroshima, Japan, for the purpose of enhancement of the species through captive breeding and exhibition.

PRT-841435

Applicant: Panamerican Marketing, San Antonio, TX.

The applicant requests a permit to export 1.2 live ring-tailed lemurs (*Lemur catta*) to Promotora Zoofari, Morelos, Mexico for the purpose of enhancement of the propagation and survival of the species through captive breeding.

PRT-831689

Applicant: University of Wisconsin, Dept. of Zoology, Madison, WI.

The applicant requests a permit to import blood and feather samples taken from captive-held and wild caught Andean condors (*Vultur gryphus*) in South America, for the purpose of scientific research.

PRT-844311

Applicant: Geraldine Mr. Stallman, Salem, WI.

The applicant requests a permit to import the sport-hunted trophy of one male bonetebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Writtend data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice. U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358-2104); FAX: (703/358-2281).

Dated: June 26, 1998.

MaryEllen Amtower,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 98-17524 Filed 6-30-98; 8:45 am]

BILLING CODE 4310-55-U

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Intent To Issue 2 Draft Comprehensive Conservation Plans and Associated Environmental Assessments for 2 National Wildlife Refuges in the Southwest Region

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service (Service) has prepared draft Comprehensive Conservation Plans (CCP) and associated Environmental Assessments for the Bitter Lake National Wildlife Refuge, Roswell, New Mexico, and San Andres National Wildlife Refuge, Las Cruces, New Mexico pursuant to the National Wildlife Refuge System Improvement Act of 1997, and National Environmental Policy Act of 1969, and its implementing regulations.

DATES: The Service will be open to written comments through July 30, 1998.

ADDRESSES: Copies may be obtained by writing to: Mr. Tom Baca, Natural

Resource Planner, Division of Refuge, U.S. Fish and Wildlife Service, P.O. Box 1306, Albuquerque, NM 87103-1306. Comments should be submitted to: Lou Bridges, Project Coordinator, Research Management Consultants, Inc., 1746 Cole Blvd., Bldg. 21, Suite 300, Golden, CO 80401.

SUPPLEMENTARY INFORMATION: It is Service policy to have all lands within the National Wildlife Refuge System managed in accordance with an approved CCP. The CCP guides management decisions and identifies refuge goals, long-range objectives, and strategies for achieving refuge purposes. The planning process has considered many elements, including habitat and wildlife management, habitat protection and acquisition, public and recreational uses, and cultural resources. Public input into this planning process has assisted in the development of the draft documents. The CCP will provide other agencies and the public with a clear understanding of the desired conditions for the Refuges and how the Service will implement management strategies.

The Service intends to consider comments and advice generated in response to the draft documents prior to the preparation of a final CCP. The Service is furnishing this notice in compliance with Service CCP policy: (1) To advise other agencies and the public of the availability of the draft documents, and (2) to obtain suggestions and advice for consideration in preparation of final documents.

The Service anticipates that final CCP documents and any associated NEPA documents will be available by September 15, 1998.

Dated: June 26, 1998.

Renne Lohefner,

Acting Regional Director.

[FR Doc. 98-17460 Filed 6-30-98; 8:45 am]

BILLING CODE 4310-55-U

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Notice of Intent To Prepare an Environmental Impact Statement for the White River Amphitheatre, Muckleshoot Indian Reservation, King County, WA

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of intent and public scoping notice.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs, with the cooperation of the U.S. Army Corps of Engineers, U.S. Environmental