

the recommendation of the Circulatory System Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of September 30, 1994, of the approval of the application.

DATES: Petitions for administrative review by November 4, 1996.

ADDRESSES: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Rhona Shanker, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8262.

SUPPLEMENTARY INFORMATION: On March, 30 1992, Thermo Cardiosystems, Inc., Woburn, MA 01888, submitted to CDRH an application for premarket approval of the HeartMate® IP LVAS. The device is a left ventricular assist device and is indicated for use in patients, who are on the cardiac transplant list, as temporary mechanical circulatory support for nonreversible left ventricular failure as a bridge to cardiac transplantation. The patient should meet all of the following criteria: (1) Be an approved cardiac transplant candidate; (2) be on inotropes; (3) be on an intra-aortic balloon pump (if possible); and (4) have left atrial pressure or pulmonary capillary wedge pressure \geq 20 mmHg with either: a. systolic blood pressure \leq 80 mmHg, or b. cardiac index of \leq 2.0 l/min/m².

On December 13, 1993, the Circulatory Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On September 30, 1994, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in

brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under part 12 (21 CFR part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before November 4, 1996, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: September 20, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96-25260 Filed 10-2-96; 8:45 am]

BILLING CODE 4160-01-F

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, contact the SAMHSA Reports Clearance Officer on (301) 443-8005.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: 1997 Inventory of Mental Health Services in Juvenile Justice Facilities—New—This survey will gather information for the first time about the availability of mental health services in the universe of approximately 3,100 juvenile justice facilities nationwide. State and national information will be collected about the organization of mental health services, characteristics of youth receiving these services, and mental health staffing patterns and costs. Automated collection techniques are not cost-effective for this survey. The total annual burden estimate is shown below.

	No. of respondents	No. of responses per respondent	Average burden per response (hrs.)	Total annual burden (hrs.)
Juvenile Justice Facilities	3,100	1	1.5	4,650

Send comments to Beatrice Rouse, SAMHSA Reports Clearance Officer, Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 26, 1996.
Richard Kopanda,
Executive Officer, SAMHSA.
[FR Doc. 96-25312 Filed 10-2-96; 8:45 am]
BILLING CODE 4162-20-P

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meetings

Pursuant to Public Law 92-463, notice is hereby given of the meetings of the Substance Abuse and Mental Health Services Administration (SAMHSA) National Advisory Council and Center for Substance Abuse Treatment (CSAT) National Advisory Council in October 1996.

Substantive program information may be obtained from the individual listed below as Contact person by name and telephone number.

The SAMHSA National Advisory Council meeting will include an open portion to include discussions of SAMHSA's appropriation, budget and reorganization. There will also be a status report on the Agency's Knowledge Development and Application Programs and an update on the Agency's managed care activities. In addition, there will be a discussion on issues of funding for the National Household Survey on Drug Abuse and the Drug Abuse Warning Network. Public comments are welcome during the open session. Please communicate with the individual listed as contact below for guidance. Attendance by the public will be limited to space available.

The meeting will also include the presentation and discussion of information about the Agency's procurement plans. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(3) and 5 U.S.C., App. 2, § 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Ms. Susan E. Day, Program Assistant, SAMHSA National Advisory Council, 5600 Fishers Lane, Room 12C-15, Rockville, Maryland 20857. Telephone: (301) 443-4640.

Committee Name: Substance Abuse and Mental Health Services Administration, National Advisory Council.

Meeting Date: October 22, 1996.

Place: Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, Virginia.

Closed: October 22, 1996, 9:00 a.m. to 9:30 a.m.

Open: October 22, 1996, 10:00 a.m. to 4:30 p.m.

Contact: Toian Vaughn, Room 12C-15, Parklawn Building, Telephone: (301) 443-4640 and FAX: (301) 443-1450.

The CSAT National Advisory Council will hold a teleconference meeting. The meeting will include the review, discussion and evaluation of individual contract proposals. Therefore, the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c) (3), (4) and (6) and 5 U.S.C. App. 2, § 10(d).

A summary of the meeting and a roster of Council members may be obtained from Ms. Joann Exline, Rockwall II Building, Suite 618, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone: (301) 443-4946.

Committee Name: Center for Substance Abuse Treatment, National Advisory Council.

Meeting Date: October 22, 1996.

Place: Center for Substance Abuse Treatment, 5515 Security Lane, Rockwall II Building, Suite 615, Rockville, Maryland 20852.

Closed: October 22, 1996, 2:00 p.m.-3:00 p.m.

Contact: Marjorie M. Cashion, Rockwall II Building, Suite 840, Telephone: (301) 443-3821 or FAX: (301) 480-6077.

Dated: September 27, 1996.

Jeri Lipov,

Committee Management Officer Substance Abuse and Mental Health Services Administration.

[FR Doc. 96-25377 Filed 10-2-96; 8:45 am]

BILLING CODE 4162-20-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. FR-4150-N-01]

The Performance Review Board

AGENCY: Office of the Secretary, Department of Housing and Urban Development.

ACTION: Notice of appointments.

SUMMARY: The Department of Housing and Urban Development announces the appointments of Emelda P. Johnson, Lawrence L. Thompson, and Dominic A. Nessi as members of 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: September 25, 1996.

Henry G. Cisneros,

Secretary, Department of Housing and Urban Development.

[FR Doc. 96-25299 Filed 10-2-96; 8:45 am]

BILLING CODE 4210-32-M

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.*):

Applicant: Walter H. White, Cable, WI, PRT-820007

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*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.

Applicant: Megan Boulton, Mundelein, IL, PRT-820020

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*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.

Applicant: PanAmerican Marketing, San Antonio, TX, PRT-817540

The applicant requests a permit to export 3 male and 2 female captive-born tiger (*Panthera tigris*) and one pair of captive-born snow leopard (*Uncia uncia*) to Promotora Zoofari, Cuernavaca, Morelos, Mexico for the purpose of enhancement of the species through breeding and conservation education.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 430, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.