

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of those portions of NDA 19-627 that provide for a formulation of Diprivan Injectable Emulsion that does not contain the antimicrobial additive disodium edetate is hereby withdrawn effective December 10, 1998.

Dated: November 16, 1998.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 98-32742 Filed 12-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Product, Establishment, and Biologics License Applications, Refusal to File; Meeting of Oversight Committee

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the 1999 meetings of its standing oversight committee in the Center for Biologics Evaluation and Research (CBER) that conducts a periodic review of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's), establishment license applications (ELA's), and biologics license applications (BLA's). CBER's RTF oversight committee examines all RTF decisions that occurred during the previous quarter to assess consistency across CBER offices and divisions in RTF decisions.

**DATES:** The meetings will be held on February, 9, 1999; May 11, 1999; August 10, 1999; and November 9, 1999.

**FOR FURTHER INFORMATION CONTACT:** Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 15, 1995 (60 FR 25920), FDA announced the establishment and first meeting of CBER's standing oversight committee. As explained in the notice, the importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority. CBER's managed review process focuses

on specific milestones or intermediate goals to ensure that a quality review is conducted within a specified time period. CBER's RTF oversight committee meetings continue CBER's effort to promote the timely, efficient, and consistent review of PLA's, ELA's, and BLA's.

FDA's regulations on filing PLA's, ELA's, and BLA's are found in 21 CFR 601.2 and 601.3. A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter may ask that the application be filed over protest, similar to the procedure for drugs described under 21 CFR 314.101(a)(3).

CBER's standing RTF oversight committee consists of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings, ordinarily, will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions. If there are no RTF decisions to review, however, the meeting may be cancelled. FDA intends to post any meeting cancellation on the CBER home page at "<http://www.fda.gov/cber/confmeet.htm>".

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all confidential commercial information omitted, may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. If, following the committee's review, an RTF decision changes, the appropriate division will notify the sponsor.

Dated: November 30, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-32743 Filed 12-9-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Veterinary Medicine Advisory Committee; Notice of Postponement of Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the meeting of the Veterinary Medicine Advisory Committee scheduled for December 10 and 11, 1998. The meeting was announced in the **Federal Register** of November 16, 1998 (63 FR 63740). FDA Center for Veterinary Medicine officials hope to reschedule the Committee meeting for early next year. The meeting will be announced in the **Federal Register** and on the Center for Veterinary Medicine Internet Home Page.

**FOR FURTHER INFORMATION CONTACT:** Jacquelyn L. Pace, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6650, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12546.

Additional information about the new time and dates for the meeting will be provided on the Center for Veterinary Medicine Internet Home Page (<http://www.fda.gov/cvm>) as soon as they are set.

Dated: December 8, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98-33006 Filed 12-8-98; 2:56 pm]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

[Document Identifier: HCFA-2088, and HCFA-2540]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed

collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Outpatient Rehabilitation Cost Report and Supporting Regulations in 42 CFR 413.20 and 413.24 *Form No.:* HCFA-2088 (0938-0037); *Use:* This form is used by Outpatient Rehabilitation Facilities to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. In addition, the fiscal intermediary uses the cost report to make settlement with the provider for the cost reporting period. *Frequency:* Annually; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Government; *Number of Respondents:* 4,298; *Total Annual Responses:* 4,298; *Total Annual Hours:* 429,800.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility (SNF) and Skilled Nursing Facility Health Care Complex Cost Report, 42 CFR 413.20 and 413.24; *Form No.:* HCFA-2540 (0938-0463); *Use:* The Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report is used by freestanding SNFs to submit annual information to achieve a settlement of costs for health care services rendered to Medicare beneficiaries. In addition, the fiscal intermediary uses the cost report to make settlement with the provider for the fiscal year. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local, or Tribal government; *Number of Respondents:* 7,000; *Total Annual Responses:* 7,000; *Total Annual Hours Requested:* 1,372,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your

request, including your address, phone number, OMB number, and HCFA document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: December 3, 1998.

**John P. Burke III,**

*HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*

[FR Doc. 98-32852 Filed 12-9-98; 8:45 am]

BILLING CODE 4120-03-P

## 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-005314

*Applicant:* Cornell University, Ithaca, NY

The applicant requests a permit to export and re-import non-living museum specimens of endangered and threatened species of insects previously accessioned into the permittee's collection for scientific research. This notification covers activities conducted by the applicant for a five year period.

PRT-005629

*Applicant:* The Elephant Sanctuary, Hohenwald, TN

The applicant requests a permit to buy one female Asian elephant (*Elephas maximus*) in interstate commerce for the purpose of enhancement of the survival of the species.

PRT-005532

*Applicant:* Omaha's Henry Doorly Zoo, Omaha, NE

The applicant requests a permit to export Western Lowland gorilla (*Gorilla gorilla gorilla*) semen to Johannesburg Zoo, South Africa for the purpose of captive propagation for the enhancement of the survival of the species.

PRT-004720

*Applicant:* American Museum of Natural History, New York, NY

The applicant requests a permit to import brown lemur subspecies (*Eulemur fulvus albocollaris, collaris, rufus, albifrons, and sanfordi*) blood samples from Madagascar for the purpose of enhancement of the survival of the species.

PRT-005708

*Applicant:* Praveen Karanth, Albany, NY

The applicant requests a permit to export samples taken from a captive-born gray langur (*Semnopithecus entellus*) for the purpose of scientific research.

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 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date 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: December 4, 1998.

**Mary Ellen Amtower,**

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

[FR Doc. 98-32816 Filed 12-9-98; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Emergency Exemption: Issuance

On November 26, 1998, the Fish and Wildlife Service (Service) issued a permit (PRT-005319) to Wildlife Conservation Society, Bronx, New York to import 33 angulated/plowshare tortoises (*Geochelone ynipora*) into the United States at the request of the Management Authority of the Netherlands. The 30-day public comment period required by section 10(c) of the Endangered Species Act was waived. The Service determined that an emergency affecting the survival of these tortoises existed and that no reasonable alternative was available to