Dated: June 20, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–18456 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0268]

Draft Guidance for Industry; Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics.'' This draft guidance was prepared by FDA's Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). The draft guidance discusses information on container closure systems used in packaging drugs that manufacturers should provide to CDER in meeting regulatory requirements for new drug applications (NDA's), abbreviated new drug applications (ANDA's), investigational new drug applications (IND's), abbreviated antibiotic applications (AADA's), and supplements to these applications, and to CBER in meeting requirements for biologics license applications (BLA's) and product license applications (PLA's). The draft guidance, when completed, will supersede the agency's ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics,'' issued February 1987. The agency requests comments on the draft guidance.

DATE: Written comments by September 15, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for the Packaging of Human Drugs and Biologics'' 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Alan C. Schroeder, Center for Drug Evaluation and Research (HFD–570), 5600 Fishers Lane, Rockville MD 20857, 301–827–1050.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for Packaging of Human Drugs and Biologics.'' The guidance discusses information on container closure systems used in packaging drugs that manufacturers should provide to CDER and CBER in meeting regulatory requirements for initial applications, amendments, and supplements.

The Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA to establish standards for drug product packaging, including containers and closures. According to section 501(a)(3) of the act (21 U.S.C. 351(a)(3)), a drug is deemed to be adulterated if its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health * * *. Under section 505(b)(1)(D) of the act (21 U.S.C. 355(b)(1)(D)), an application for approval to market a new drug must include ''a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.'' FDA's regulations on current good manufacturing practices for the control of drug product containers and closures are set forth in subpart E of part 211 (21 CFR part 211). In particular, § 211.94 states that finished drug manufacturers must establish and follow ''[s]tandards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties * * * for drug product containers and closures.''

In February 1987, FDA issued a ''Guideline for Submitting Documentation for Packaging for Human Drugs and Biologics.'' The guideline was intended to provide drug manufacturers with guidance on preparing information on the fabrication and quality of containers and container components for use in the submission of NDA's, ANDA's, IND's, or PLA's.

The draft ''Guidance for Industry: Submission of Documentation in Drug Applications for Container Closure Systems Used for Packaging of Human Drugs and Biologics'' revises and updates the February 1987 guideline to reflect innovations in drug product container closure systems that have occurred in the past decade. In addition, the document provides more extensive guidance on qualification and quality control of packaging components used with drug products having particular dosage forms and routes of administration, including the following: Inhalation drug products, drug products for injection and ophthalmic drug products, liquid-based oral and topical drug products and topical delivery systems, solid oral dosage forms and powders for reconstitution, and other dosage forms. The draft guidance also addresses post-approval packaging changes, Type III drug master files, and bulk containers. The draft guidance, when completed, will supersede the 1987 guideline.

This draft guidance represents the agency's current thinking on submitting information in drug applications on container closure systems used in packaging human drugs and biologics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. A regulated entity may adopt an alternative approach to submitting information on container closure systems if such approach satisfies the applicable statutory and regulatory requirements.

Interested persons may, on or before September 15, 1997, submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments should 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. An electronic version of this draft guidance is available via Internet using the World Wide Web (WWW) at http://www.fda.gov/cder/guidance.htm.

Dated: July 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–18460 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on August 6, 1997, 10 a.m. to 5 p.m., and August 7, 1997, 9:30 a.m. to 2 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Agenda: On August 6, 1997, the committee will hear a presentation of the basic concepts of FDA's Product Development Protocol Process. The committee will discuss issues relating to a premarket approval application (PMA) for an implanted neuromuscular stimulator for the management of urinary urge incontinence. On August 7, 1997, the committee will discuss and advise FDA on the classification of External Penile Rigidity Devices and an update of the Triage list of gastroenterology and urology devices will be presented and discussed.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 30, 1997. Oral presentations from the public will be scheduled between approximately 10 a.m. and 11 a.m. on August 6, 1997, and between approximately 9 a.m. and 10 a.m. on August 7, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 30, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 9, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–18524 Filed 7–14–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

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–831781

Applicant: Herbert M. Jones, South Bend, IN.

The applicant requests a permit to take (capture, handle, band and release) peregrine falcons (*Falco peregrinus*) in Minnesota, Wisconsin, and Michigan for enhancement of the species in the wild through scientific research.

PRT–831774

Applicant: Biological Resources Division, U.S. Geological Survey, North Central Forest Experiment Station, St. Paul, Minnesota, L. David Mech, Principle Investigator.

The applicant requests a permit to take gray wolves (*Canis lupus*) throughout the lower 48 states to continue research, restoration and public education efforts previously conducted under the authority of the U.S. Fish and Wildlife Service. Activities are proposed for survival, enhancement and recovery of the species in the wild.

Written data or comments should be submitted to the Regional Director, U.S. Fish and Wildlife Service, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056, and must be received within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review 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, Ecological Services Operations, 1 Federal Drive, Fort Snelling, Minnesota 55111–4056. Telephone: (612/725–3536 x250); FAX: (612/725–3526).

Dated: July 8, 1997.

John A. Blankenship,

Assistant Regional Director, IL, IN, MO (Ecological Services), Region 3, Fort Snelling, Minnesota.

[FR Doc. 97–18530 Filed 7–14–97; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Resighini Rancheria Liquor Licensing Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8, and in accordance with the Act of August 15, 1953, 67 Stat. 586, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983). I certify that the Resighini Rancheria Liquor Licensing Ordinance was duly adopted by Resolution 96–09 of the Coast Indian Community of the Resighini Rancheria of California on December 11, 1996. The ordinance provides for the control of distribution, sale and possession of liquor on lands within the Tribe's jurisdiction.

DATES: This ordinance is effective as of July 15, 1997.

FOR FURTHER INFORMATION CONTACT: Jerry Cordova, Office of Tribal Services, 1849 C Street, NW., MS 4641 MIB, Washington, DC 20240–4001; telephone (202) 208–4401.

SUPPLEMENTARY INFORMATION: The Resighini Rancheria Liquor Licensing Ordinance shall read as follows: