a clear direction in the inspection of these establishments, and provides logical stopping points, thus making the time it takes to complete an inspection more predictable. FDA concludes that pre-announcement of medical device inspections will remain standard procedure based on the defined criteria. For other establishments, pre-announcement of inspections remains voluntary at the discretion of the local FDA office. FDA will continue generally not to pre-announce inspections of food, blood bank, and plasmapheresis centers, but this, too, will be left to the district's discretion.

FDA investigators traditionally have discussed their observations with appropriate management at the establishment at the conclusion of the inspection. These discussions are reported in the Establishment Inspection Report. FDA will continue that practice, and will rely on the discretion of the investigator/team to determine whether to annotate the FDA 483. Since the medical device industry specifically asked FDA for annotations of the FDA 483, and since FDA has not found this practice to adversely affect the inspection process for medical devices, annotations will remain standard procedure for medical device inspections only.

In April 1997, FDA implemented a Field Management Directive (FMD 145) that requires FDA field offices to provide a copy of the EIR to the inspected establishment once the inspection is deemed closed. The copy of the EIR is provided along with a letter referred to as the ''FMD 145 letter.'' FDA has found that the issuance of both a post-inspection notification (PIN) letter and a FMD 145 letter is redundant. Because of this redundancy and the burden this puts on the field, the PIN letters will be discontinued in all program areas. FMD 145 will remain in place and these letters will continue to be issued. Establishments will receive a copy of their EIR when the inspection is deemed closed based on 21 CFR 20.64(d).

The 2001 IOM will be posted to FDA's website at www.fda.gov/ora under Inspection References/Investigations Operations Manual. The IOM sections that apply are: 510, 512.3, 516, 529 and 551.1. FMD 145 is posted to FDA's website at www.fda.gov/ora under Inspection References/Field Management Directives.

Dated: December 27, 2000.

John Marzilli,

Deputy Associate Commissioner for Regulatory Affairs.

[FR Doc. 01–141 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1681]

Draft Guidance on Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies; 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 ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.'' This draft guidance updates a notice of availability entitled ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use'' published in the **Federal Register** on June 29, 1982, concerning the prophylactic use of potassium iodide (KI) in the event of release of radioactive isotopes of iodine. In the draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified condition for use, and thus to obviate the risk of thyroid cancer in the event of a radiation emergency.

DATES: February 5, 2001.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of the draft guidance 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 requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rose E. Cunningham, Executive Operations (HFD–06), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies.''

The Federal Emergency Management Agency has established roles and responsibilities for Federal agencies in assisting State and local governments in their radiological emergency planning and preparedness activities. The Federal agencies, including the Department of Health and Human Services (DHHS), are expected to accomplish these roles and responsibilities as part of the Federal Radiological Preparedness Coordinating Committee. Among other responsibilities, the DHHS is to provide guidance on the use of radioprotective substances to reduce radiation doses to specific organs from the release into the environment of large quantities of radioactivity. FDA is specifically charged with providing guidance on the prophylactic use of KI in the event of release of radioactive isotopes of iodine.

FDA is announcing the availability of a draft guidance that updates the notice of availability, ''Potassium Iodide as a Thyroid-Blocking Agent In a Radiation Emergency: Final Recommendations On Use,'' published in the **Federal Register** of June 29, 1982 (47 FR 28158). In this draft guidance, FDA maintains its position that KI is a safe and effective means by which to prevent radioiodine uptake by the thyroid gland, under certain specified conditions of use, and thus to lessen the risk of thyroid cancer in the event of a radiation emergency. In this draft guidance, FDA proposes lower radioactive exposure thresholds for KI prophylaxis as well as lower doses of KI for neonates, infants, and children than previously recommended. FDA's revised recommendations are in general accordance with those of the World Health Organization (WHO), as expressed in its ''Guidelines for Iodine Phrophylaxis Following Nuclear Accidents'' (1999), though they differ from those of the WHO in two areas.

First, for the sake of logistical simplicity, FDA recommends the 65-milligram (mg) dose of KI for all school-age children while allowing for the full adult dose of 130 mg in adolescents approaching adult size. WHO recommends 130 mg KI for adults and adolescents (over 12 years of age). Second, FDA recommends that KI prophylaxis in those under age 19 and in pregnant or lactating women be triggered at a predicted thyroid radioiodine exposure of 5 centiGray (cGy), while WHO establishes 1 cGy as the threshold for intervention. FDA has concluded from the Chernobyl data that the most reliable evidence demonstrates

a significant increase in risk of childhood thyroid cancer at exposures of 5 cGy or greater.

The recommendations in the draft guidance were prepared by scientists from the Center for Drug Evaluation and Research and from the Center for Devices and Radiological Health of FDA in consultation with other governmental experts.

This draft guidance is being issued consistent with FDA's good guidance practices (65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on use of potassium iodide as a thyroid blocking agent in radiation emergencies. 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.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 26, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–189 Filed 1–3–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

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.*). Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division 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.

Applicant: Mitchel Kalmanson, Maitland, Florida, PRT–034041.

The applicant request a permit to export 4.8 captive born tigers (*Panthera tigris*) to Juan M. L. Salazar aka Johnny Lam, Mexico for the purpose of enhancement of the survival of the species through propagation.

Applicant: Institute for the Conservation of Tropical Environments, Stony Brook, NY, PRT–035632.

The applicant request a permit to import biological samples of diademed sifka (*Propithecus diadema*), lesser bamboo lemur (*Hapalemur griseus*), golden bamboo lemur (*Hapalemur aureus*), and greater bamboo lemur (*Hapalemur simus*) for the purpose of enhancement of the survival of the species through scientific research. This notification covers activities conducted by the applicant for a period of five years.

The U.S. Fish and Wildlife has information collection approval from OMB through February 28, 2001. OMB Control Number 1018–0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

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, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358–2104); Fax: (703/358–2281).

Dated: December 29, 2000.

Anna Barry,

Branch of Permits, Division of Management Authority.

[FR Doc. 01–226 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological survey

Request for Public Comments on Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

A request extending the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the USGS Clearance Officer at the phone number listed below. OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days; therefore, public comments should be submitted to OMB within 30 days in order to assure their maximum consideration. Comments and suggestions on the requirement should be made directly to the Desk Officer for the Interior Department, Office of Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 and to the USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192.

As required by OMB regulations at CFR 1320.8(d)(1), the U.S. Geological Survey solicits specific public comments regarding the proposed information collection as to:

1. Whether the collection of information is necessary for the proper performance of the functions of the USGS, including whether the information will have practical utility;

2. The accuracy of the USGS estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

3. The utility, quality, and clarity of the information to be collected; and,

4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: Production Estimate, Quarterly Construction Sand and Gravel and Crushed and Broken Stone.

Current OMB approval number: 1028–0065.

Abstract: The collection is required to provide data on mineral production for annual reports published by commodity for use by Government agencies, industry, education programs, and the general public. One publication is the ''Mineral Commodity Summaries,'' the first preliminary publication to furnish estimates covering the previous year's nonfuel mineral industry.

Bureau form numbers: 9–4042–A and 9–4124–A.

Frequency: Quarterly and Annual.

Description of respondents: Producers of industrial minerals and metals.

Annual Responses: 3,450.

Annual burden hours: 742.

Bureau clearance officer: John Cordyack, 703–648–7313.

John H. DeYoung, Jr.,

Chief Scientist, Minerals Information Team.

[FR Doc. 01–185 Filed 1–3–01; 8:45 am]

BILLING CODE 4310–Y7–M