

preamendments class III devices into class II and to establish special controls for these devices. FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received one request to reopen the comment period for six devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through FDA's good guidance practices (GGP's) (65 FR 56468, September 19, 2000). The request further noted that it

was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the requester asked that FDA extend the comment period until at least 90 days after the guidance documents are publicly available. FDA agreed with the request. FDA also identified three additional devices for which the agency had not issued the guidance documents proposed as special controls in accordance with the GGP policy. These three devices are the Indwelling Blood Carbon Dioxide Partial Pressure (P_{CO_2})

Analyzer (21 CFR 868.1150), the Indwelling Blood Hydrogen Ion Concentration (pH) Analyzer (21 CFR 868.1170), and the Indwelling Blood Oxygen Partial Pressure (P_{O_2}) Analyzer (21 CFR 868.1200).

The agency is announcing the availability of the two guidance documents (with separate docket numbers) for these three additional devices; the guidance documents, with their docket numbers, and Facts-on-Demand (FOD) numbers are as follows:

TABLE 1.

Name of Guidance	Docket Number	Facts-on-Demand Number
Guidance for Indwelling Blood Gas Analyzer 510(k) Submissions	00D-1557	1126
Guidance for Electrical Safety, Electromagnetic Compatibility and Mechanical Testing for Indwelling Blood Gas Analyzer Premarket Notification Submissions	00D-1558	1161

II. Significance of Guidance Documents

These guidance documents represent the agency's current thinking on premarket notifications for these devices. These guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both. Under FDA's GGP policy, each of these guidance documents is a Level 2 guidance.

III. Electronic Access

In order to receive these guidance documents via your fax machine, call the CDRH FOD system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number listed above followed by the pound sign (#). Follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of these guidance documents may do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes these guidance documents, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding these guidance documents by February 20, 2001. 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 for the guidance document as listed in table 1. If you wish to comment on more than one guidance document, please submit your comments separately for each guidance document. The guidance documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 31, 2000.

Linda S. Kahan,

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

[FR Doc. 00-29840 Filed 11-21-00; 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 (60 FR 56605 as amended November 6, 1995, as last amended at 65 FR 48007, dated August 4, 2000).

This notice reflects the change in the organizational structure of the Maternal and Child Health Bureau (RM).

Establish the Office of Communications (RM8)

The Office of Communications plans, designs, executes and evaluates national and international communication and information dissemination programs which include the development of written and broadcast materials conveying complex information about the Maternal and Child Health Bureau, the maintenance of effective working relationships with high-level public and private sector policy makers and development of recommendations to improve MCHB program effectiveness. Specifically: (1) From various public and private sources, collects, translates, interprets and distributes for public use, information on maternal and child health care legislation, innovations, research and data trends; (2) develops and provides information materials to MCHB health program planners, providers, consumers and others to assist in decision making and maintaining effective, efficient operations; (3) develops and produces in-house communications to help ensure the understanding of current maternal and child health issues and Bureau program objectives; (4) fosters and maintains relationships with and provides a referral service to Federal agencies, State and local governmental units, private health and medical organizations, and other organizations with which the Bureau has mutual interests; (5) provides technical assistance to Bureau program managers and project officers in identifying maternal and child health information

needs and developing information products; (6) provides technical assistance to Bureau program managers in information and communications product packaging, desktop publishing, and media relations; (7) produces reports, articles, briefings, speeches, exhibits and other multi-media communications on Bureau programs; (8) develops and implements new and innovative communication strategies including utilization of automated methods and electronic media in carrying out its responsibilities including managing and maintaining content of the Bureau's electronic web site, and liaison with the HRSA webmaster for technical support and design; and participation, coordination and content development in use of technologies such as satellite transmission and distance learning; (9) functions as media advisor to the Bureau Associate Administrator and other senior program staff; (10) reviews federal, state, and local legislation, issues, programs and policies and their impact on health care organization financing and service delivery to special populations served by Bureau programs; (11) identifies issues and problems and conducts appropriate analyses and studies in order to develop technical assistance products, presentations, seminars, and communications for the information and service needs of the intended audience; and (12) serves as principal liaison on behalf of MCHB in coordinating with HRSA's Office of Communications; through appropriate channels with other agency information, communications, and/or clearinghouses; with national constituency organizations such as the Association of Maternal and Child Health Programs, the American Academy of Pediatrics; with international organizations such as the World Health Organization and the Pan American Health Organization, and with health planners, service providers, and consumers, with respect to the development and dissemination of information on current and emerging health care issues, trends and problems affecting the services, program and populations served by the MCHB.

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 redelegations.

This reorganization is effective upon date of signature.

Dated: October 12, 2000.

Claude Earl Fox,

Administrator.

[FR Doc. 00-29843 Filed 11-21-00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Availability of a Draft Environmental Assessment and Receipt of an Application for an Incidental Take Permit for the Harding Property, Douglas County, CO

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and receipt of application.

SUMMARY: This notice advises the public that Susan K. Harding (Applicant) has applied to the Fish and Wildlife Service (Service) for an incidental take permit pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973 as amended. The Service proposes to issue a 3-year permit to the Applicant that would authorize the incidental take of the Preble's meadow jumping mouse (Preble's) (*Zapus hudsonius preblei*), federally listed as threatened, and loss and modification of its habitat associated with construction of a single-family residence in Douglas County, Colorado. Construction of the single family residence will result in the loss of up to 0.294 acres of grassland that provides potential foraging and hibernation habitat for the mouse. The permit application includes a combined Environmental Assessment/Habitat Conservation Plan (EA/HCP), which is available for public review and comment. The HCP fully describes the proposed project and the measures the Applicant would undertake to minimize and mitigate project impacts to the Preble's.

The Service requests comments on the EA/HCP for the proposed issuance of the incidental take permit. We provide this notice pursuant to section 10(a) of the Endangered Species Act and National Environmental Policy Act regulations (40 CFR 1506.6). All comments on the EA and permit application will become part of the administrative record and will be available to the public.

DATES: Written comments on the permit application and EA/HCP should be received on or before December 22, 2000.

ADDRESSES: Comments regarding the permit application or the EA/HCP, or

requests for the documents, should be addressed to LeRoy Carlson, Field Supervisor, Fish and Wildlife Service, Colorado Field Office, 755 Parfet Street, Suite 361, Lakewood, Colorado 80215. Comments may be sent by facsimile to (303) 275-2371. Please reference permit number PRT-TE035844-0 in any comments submitted.

FOR FURTHER INFORMATION CONTACT: Ms. Kathleen Linder, Fish and Wildlife Biologist, Colorado Field Office, telephone (303) 275-2370.

SUPPLEMENTARY INFORMATION:

Document Availability

Individuals wishing copies of the EA/HCP and associated documents for review should immediately contact the above office. Documents also will be available for public inspection, by appointment, during normal business hours at the above address.

Background

Section 9 of the Endangered Species Act and Federal regulation prohibit the "take" of a species listed as endangered or threatened (take is defined under the Endangered Species Act as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect, or to attempt to engage in any such conduct). However, the Service may issue permits to authorize "incidental take" (defined by the Endangered Species Act as take that is incidental to, and not the purpose of, the carrying out of an otherwise lawful activity) of listed species under limited circumstances. Regulations governing permits for threatened species are promulgated in 50 CFR 17.32. Regulations governing permits for endangered species are promulgated in 50 CFR 17.22.

The proposed action is the issuance of a permit under section 10(a)(1)(B) of the Endangered Species Act to allow the incidental take of Preble's during the construction of a single family residence at the site. The proposed project will directly affect approximately 0.294 acres of potential habitat for Preble's. An HCP has been developed as part of the preferred alternative. The proposed HCP will allow for the incidental take of the Preble's by permitting a single family residence to be constructed in an area that may be periodically used as foraging or hibernation habitat. Construction will result in about 0.12 acres of permanent habitat loss and another 0.18 acres of temporary effects to the habitat associated with this localized disturbance.

Alternatives considered in addition to the proposed action were; building at an alternate location, waiting for the