human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaskan Native, Asian, Black or African American, Native Hawaiian or Other Pacific Islander, and Hispanic or Latino. Applicants shall ensure that women and racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is not feasible, this situation must be explained as part of the application. In conducting the review of applications for scientific merit, review groups will evaluate proposed plans for inclusion of minorities and both sexes as part of the scientific assessment and assigned score. This policy does not apply to research studies when the investigator cannot control the race, ethnicity and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, Friday, September 15, 1995, pages 47947–47951.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161–1 (Revised 5/96, OMB Number 0937–0189) must be submitted to Sharron P. Orum, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers For Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mailstop E–18, Atlanta, GA 30305, on or before July 1, 1998.

1. *Deadline:* Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be accepted as proof of timely mailing.)

2. *Late Applications:* Applications that do not meet the criteria in 1.(a) or 1.(b) above are considered late applications. Late applications will not be considered and will be returned to the applicant.

Where To Obtain Additional Information

To receive additional written information, call (888) 472–6874. You will be asked to leave your name, address, and telephone number. Please refer to Announcement 98079. You will receive a complete program description, information on application procedures, and application forms. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from Sheryl L. Heard, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E–18, Atlanta, GA 30305, telephone (404) 842–6802; electronic mail at slh3@cdc.gov.

Programmatic technical assistance may be obtained from Sarah Kuester, MS, RD, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE., Mail Stop K–26, Atlanta, GA 30341–3724, telephone (770) 488–6019, fax (770) 488–6000, or Internet or CDC WONDER electronic mail at sak2@cdc.gov.

You may obtain this announcement from CDC's homepage at http://www.cdc.gov.

Please refer to Program Announcement 98079 when requesting information and submitting an application.

Potential applicants may obtain a copy of Healthy People 2000 (Full Report; Stock No. 017–001–00474–0) or Healthy People 2000 (Summary Report; Stock No. 017–001–00473–1) referenced in the ''Introduction'' through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, telephone (202) 512–1800.

Dated: June 1, 1998.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–15122 Filed 6–5–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0362]

Draft Guidance for Industry on Stability Testing of Drug Substances and Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed to support new drug applications, abbreviated new drug applications, investigational new drug applications, biologics license applications, product license applications, and supplements to these applications.

DATES: Written comments on the draft guidance may be submitted by September 9, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm. Submit written requests for single copies of the draft guidance entitled ''Stability Testing of Drug Substances and Drug Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville MD 20852–1448. Send one self-addressed adhesive label to assist the 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:

Kenneth J. Furnkranz, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2737, 301–827–5848, or

Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed by pharmaceutical applicants to support applications submitted to the Center for

Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

The draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products'' revises, updates, and is intended to supersede the guidance entitled ''Submitting Documentation for the Stability of Human Drugs and Biologics'' (February 1987). This draft guidance relies on and incorporates the ICH Q1A guidance ''Stability Testing of New Drug Substances and Products'' (59 FR 48754, September 22, 1994) and its annexes.

This draft guidance represents the agency's current thinking on stability testing of human drugs and biologics regulated by CDER and CBER. 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 requirement of the applicable statute, regulations, or both.

Interested persons may, on or before September 9, 1998, submit written comments on the draft guidance to the Dockets Management Branch (address above). 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15148 Filed 6–5–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application for the Proposed Issuance of a Permit To Allow Incidental Take of an Endangered Species at the Los Osos Center, LLC, Proposed Commercial Development Project, in Los Osos, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of document availability; request for comments.

SUMMARY: This notice advises the public that Los Osos Center, LLC (Applicant), has applied for an incidental take permit from the Fish and Wildlife Service pursuant to Section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended. The Applicant is requesting the Service issue a 5-year permit to allow the incidental take of the federally listed as endangered Morro shoulderband snail (*Helminthoglypta walkeriana*) associated with a proposed 5.5-acre commercial development project in the community of Los Osos, San Luis Obispo County, California. The permit application includes a Habitat Conservation Plan and an Implementation Agreement, both of which are available for pubic review and comment. The Service also announces the availability of an Environmental Assessment for the proposed issuance of the incidental take permit. All comments received will become part of the administrative record and may be released to the public.

DATES: Written comments on the permit application and Environmental Assessment should be received on or before July 8, 1998.

ADDRESSES: Comments regarding the application or the Environmental Assessment, or requests for these documents, should be addressed to Diane Noda, Field Supervisor, Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, California 93003; facsimile (805) 644–3958.

FOR FURTHER INFORMATION CONTACT: Kate Symonds, Fish and Wildlife Biologist, at the above address or telephone (805) 644–1766.

SUPPLEMENTARY INFORMATION:

Document Availability

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

Background

Under Section 9 of the Act and its implementing regulations, ''taking'' of threatened and endangered species is prohibited. However, the Service, under limited circumstances, may issue permits to take threatened or endangered wildlife species if such taking is incidental to, and not the purpose of, otherwise lawful activities. Regulations governing permits for threatened and endangered species are found at 50 CFR part 13 and 50 CFR 17.22 and 17.32.

The incidental taking would occur as the result of the Applicant's proposed commercial development project, which would result in the permanent loss of 0.5 acres of Morro shoulderband snail habitat within the 5.5-acre project site. The permit application includes a Habitat Conservation Plan (Plan) and the Implementation Agreement which defines the responsibilities of all of the parties under the Plan. The Plan addresses impacts to the Morro shoulderband snail that are associated with the proposed commercial development project and provides for implementation of measures to minimize and mitigate adverse impacts to the Morro shoulderband snail.

The Applicant will pay a mitigation compensation fee to the Service's land acquisition and management designee to be used for the acquisition and management in perpetuity of 0.5 acres of high-quality offsite Morro shoulderband snail habitat, as part of a larger habitat acquisition program in Los Osos. The 0.5-acre land acquisition will compensate for the permanent loss of 0.5 acres of snail habitat that will result from project implementation and will benefit the long-term conservation of the snail.

The Plan and the Environmental Assessment consider three alternatives to the proposed commercial development project: the No-Development Project Alternative, the Reduced Intensity Alternative, and the Alternate Site Alternative.

Under the No-Development Project Alternative, no commercial development project would be conducted. The Service would not issue a Section 10(a)(1)(B) permit because there would be no take of Morro shoulderband snails. This alternative would not adversely affect biological resources occurring on this site; therefore, impacts would be less than those of the proposed project. This alternative assumes the continuation of the existing conditions (i.e., undeveloped area). However, the No-Development Project Alternative would not substantially benefit the Morro shoulderband snail. Non-native plants would continue to occupy the project site and human disturbances would likely continue. Under this alternative, no contribution to the acquisition, preservation, and management of high-quality offsite Morro shoulderband snail habitat would occur.

The Reduced Intensity Alternative involves proceeding with a commercial development on the proposed 5.5-acre project site, but with a smaller construction configuration so as to avoid physical disturbance to the areas of Morro shoulderband snail habitat within the project site. This alternative would involve not developing approximately 1.5 acres within the 5.5-acre parcel. A Reduced Intensity Alternative would not benefit the Morro shoulderband snail because it would