

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The draft guidance for industry entitled "Stability Testing of Drug Substances and Drug Products" revises, updates, and is intended to supersede the guidance entitled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 This draft guidance relies on and incorporates the ICH Q1A guidance "Stability Testing of New Drug Substances and Products" (59 FR 48754, September 22, 1994) and its annexes.

This draft guidance represents the agency's current thinking on stability testing of human drugs and biologics regulated by CDER and CBER.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Interested persons may, on or before September 9, 1998, submit written comments on the draft guidance to the Dockets Management Branch (address above).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 The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.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 public 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

further isolate the habitat. Under this alternative, no contribution to the acquisition, preservation, and management of high-quality offsite Morro shoulderband snail habitat would occur.

The Alternate Site Alternative involves the use of a site for a commercial development project that does not support any listed species; therefore, the project would not result in the incidental take of a listed species. This alternative is considered to be unfeasible from a business and commercial standpoint given market, development, and private contractual constraints. Although this alternative would result in no impact at the proposed project site, it would not substantially benefit the Morro shoulderband snail. The project site contains marginal snail habitat, including non-native plants. Human disturbances to the project site would likely continue. Under this alternative, no contribution to the acquisition, preservation, and management of high-quality offsite Morro shoulderband snail habitat would occur.

This notice is provided pursuant to Section 10(c) of the Act and Service regulations for implementing the National Environmental Policy Act of 1969 (40 CFR 1506.6). The Service will evaluate the application, its associated documents, and submitted comments to determine whether the application meets the requirements of law. If the Service determines that the requirements are met, a permit will be issued for the incidental take of the Morro shoulderband snail. A final decision on permit issuance will be made no sooner than 30 days from the date of this notice.

Dated: June 1, 1998.

**Thomas Dwyer,**

*Acting Regional Director, Region 1, Portland, Oregon.*

[FR Doc. 98-15069 Filed 6-5-98; 8:45 am]

BILLING CODE 4310-55-P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### **Availability of a Revised Application for an Incidental Take Permit and Revised Environmental Assessment for Obyan Beach Resort Associates, Saipan, Commonwealth of the Northern Mariana Islands and the Commonwealth of the Northern Mariana Islands Department of Lands and Natural Resources**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability.

**SUMMARY:** This notice advises the public that the Obyan Beach Resort Associates and the Commonwealth of the Northern Mariana Islands (Commonwealth) Department of Lands and Natural Resources (Applicants) have applied to the Fish and Wildlife Service for an incidental take permit (PRT-824821) pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The application package includes a Habitat Conservation Plan (Plan), Implementation Agreement, and the Saipan Upland Mitigation Bank Agreement (Agreement). The Service also announces the availability of an Environmental Assessment for the proposed issuance of the incidental take permit. The proposed permit would authorize the incidental take of the federally listed endangered nightingale reed-warbler (*Acrocephalus luscini*) and Micronesian megapode (*Megapodius laperouse*), and/or their habitat during the construction of a proposed 36-hole golf course and resort. Green sea turtles (*Chelonia mydas*) may nest at the beach near the project site, but outside of the project boundaries, and are not expected to be impacted by the project. The permit would be in effect for 50 years.

The Plan, Implementation Agreement and Environmental Assessment were circulated for public review in February, 1997, in accordance with the Act and the National Environmental Policy Act (62 FR 7794). The original permit application proposed establishment of a mitigation bank on Saipan to compensate for impacts to nightingale reed-warblers. Since that time, the proposed Saipan Upland Mitigation Bank (Mitigation Bank) has been developed, and a Mitigation Bank Agreement has been prepared. This Agreement is now included in the permit application. Other than development of the Mitigation Bank and associated Agreement, no major revisions have been made to the permit application and Environmental Assessment. This notice advises the public that the revised Plan, Implementation Agreement and Environmental Assessment, and the Agreement are available for review and comment. All comments received, including names and addresses, will become part of the administrative record and may be made available to the public. This notice is provided pursuant to section 10(c) of the Act and National Environmental Policy Act regulations (40 CFR 1506.6).

**DATES:** Written comments on the permit application and Environmental

Assessment should be received on or before June 23, 1998.

**ADDRESSES:** Comments regarding the permit application, Plan, Agreement, or Environmental Assessment, or requests for these documents, should be addressed to Brooks Harper, Field Supervisor, Fish and Wildlife Service, P.O. Box 50088, Honolulu, Hawaii 96850; Fax (808) 541-3470. Please refer to permit number PRT-824821 when submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Brooks Harper or Gina Shultz, Pacific Islands Fish and Wildlife Office, telephone (808) 541-3441.

**SUPPLEMENTARY INFORMATION:** Section 9 of the Act prohibits the "taking" of a species listed as threatened or endangered. However, the Service, under limited circumstances, may issue permits to take listed species incidental to, and not the purpose of, otherwise lawful activities. 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.

### Background

The Applicants propose to construct a 36-hole golf course and resort on the southeastern part of Saipan, Commonwealth of the Northern Mariana Islands. The Applicants seek coverage for impacts to 814 acres that contain nightingale reed-warbler and Micronesian megapode habitat. To compensate for project impacts, the Applicants will: (1) Minimize on-site impacts and maintain habitat on-site for 10 pairs of nightingale reed-warblers, and (2) develop a Mitigation Bank and purchase 24 nightingale reed-warbler credits from the Mitigation Bank. Purchase of 24 credits from the Mitigation Bank will result in the permanent protection of 24 existing nightingale reed-warbler territories and permanent protection and enhancement of habitat to establish an additional 24 territories. Other measures are specified in the Plan to minimize potential for take during construction activities.

The Environmental Assessment considers the environmental consequences of three alternatives. Alternative 3, the proposed action, consists of the issuance of an incidental take permit, development of the Mitigation Bank, and implementation of the Plan and its implementation Agreement. This alternative is preferred because: (1) It satisfies the purpose and needs of the Service and Applicants; (2) impacts are minimized during construction; and (3) incidental take is