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

Dated: September 23, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-19349 Filed 10-1-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006D-0138]

#### Guidance for Industry: Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#178) entitled "Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims." This guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims. **DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-

addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>.

#### FOR FURTHER INFORMATION CONTACT:

Michelle L. Stull, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5058, e-mail: [michelle.stull@fda.hhs.gov](mailto:michelle.stull@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 14, 2006 (71 FR 19526), FDA published a notice of availability of a draft guidance entitled "Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims." The notice gave interested persons until June 28, 2006, to comment on the draft guidance. FDA received a few comments on the draft guidance. We considered those comments as we finalized the guidance. The guidance, announced in this document, finalizes the draft guidance that we announced on April 14, 2006.

The purpose of the guidance is to provide the Center for Veterinary Medicine's (CVM's) current thinking regarding the recommended design and evaluation of effectiveness studies for swine respiratory disease (SRD) claims. This guidance identifies specific, detailed recommendations for sponsors of new animal drug applications to consider when they design and write protocols for SRD effectiveness studies.

##### II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 514.1 have been approved under OMB Control Number 0910-0032.

##### III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the topic. 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.

#### IV. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the full title of the guidance and the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Persons with access to the Internet may obtain the guidance from either the CVM home page (<http://www.fda.gov/cvm>) or the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: September 24, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-19412 Filed 10-1-07; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### Endangered Species Recovery Permit Applications

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

**ACTION:** Notice of receipt of permit applications; request for comment.

**SUMMARY:** We invite the public to comment on the following applications to conduct certain activities with endangered species.

**DATES:** Comments on these permit applications must be received on or before November 1, 2007.

**ADDRESSES:** Written data or comments should be submitted to the U.S. Fish and Wildlife Service, Endangered Species Program Manager, California/Nevada Operations Office (CNO), 2800 Cottage Way, Room W-2606, Sacramento, California, 95825 (telephone: (916) 414-6464; fax: (916) 414-6486). Please refer to the respective

permit number for each application when submitting comments. All comments received, including names and addresses, will become part of the official administrative record and may be made available to the public.

**FOR FURTHER INFORMATION CONTACT:**

Daniel Marquez, Fish and Wildlife Biologist, at the above CNO address, (telephone: (760) 431-9440; fax: (760) 431-9624).

**SUPPLEMENTARY INFORMATION:** The following applicants have applied for scientific research permits to conduct certain activities with endangered species pursuant to section 10(a)(1)(A) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*). The U.S. Fish and Wildlife Service (“we”) solicits review and comment from local, State, and Federal agencies, and the public on the following permit requests. Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

**Permit No. TE-163017**

*Applicant:* California Department of Fish and Game, Sacramento, California

The applicant requests a permit to take (survey, capture, handle, mark, collect biological samples, radio collar, translocate, and release) the Peninsular bighorn sheep (*Ovis canadensis nelsonii*) in conjunction with ecological research, population monitoring, and life history studies throughout the range of the species in San Diego, Imperial, and Riverside Counties, California for the purpose of enhancing its survival.

**Permit No. TE-163012**

*Applicant:* Aindrea Jensen, Petaluma, California

The applicant requests a permit to take (survey, capture, and release) the tidewater goby (*Eucyclogobius newberryi*) in conjunction with surveys for the purpose of enhancing their survival throughout the range of the species in California.

**Permit No. TE-163662**

*Applicant:* Coachella Valley Mosquito and Vector Control District, Indio, California

The applicant requests a permit to take (survey, collect, captive rear,

captive propagate, and release to the wild) the desert pupfish (*Cyprinodon macularius*) in conjunction with ecological and disease control research in Riverside County, California, for the purpose of enhancing its survival.

**Permit No. TE-163610**

*Applicant:* The Nature Conservancy, Ventura, California

The applicant requests a permit to take (survey, capture, collect, PIT tag, biological sample, radio collar, captive breed, perform veterinary examinations, and release) the Santa Cruz Island Fox (*Urocyon littoralis santacruzae*) in conjunction with ecological, genetic, and reproductive research on Santa Cruz Island, Santa Barbara County, California, for the purpose of enhancing its survival.

**Permit No. TE-815537**

*Applicant:* Swaim Biological, Livermore, California

The applicant request an amendment to take (harass by survey, capture, and release) the California tiger salamander (*Ambystoma californiense*) in conjunction with surveys for the purpose of enhancing their survival throughout the range of the species in California.

We solicit public review and comment on each of these recovery permit applications. Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent’s identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment, but you should be aware that we may be required to disclose your name and address pursuant to the Freedom of Information Act. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

Dated: September 26, 2007.

**Michael Fris,**

*Acting Manager, California/Nevada Operations Office, Sacramento, California.*  
[FR Doc. E7-19401 Filed 10-1-07; 8:45 am]

**BILLING CODE 4310-55-P**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**Endangered Species Recovery Permit Applications**

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**FOR FURTHER INFORMATION CONTACT:**

Daniel Marquez, Fish and Wildlife Biologist, at the above CNO address, (telephone: 760-431-9440; fax: 760-431-9624).

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