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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]

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## 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In the **Federal Register** of April 14, 2006 (71 FR 19526), FDA published a notice of availability of a draft guidance entitled "Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims." The notice gave interested persons until June 28, 2006, to comment on the draft guidance.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]

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## 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