

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0623]

#### Guidance for Industry on Anesthetics for Companion Animals; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of Guidance for Industry #192 entitled "Anesthetics for Companion Animals." This guidance makes recommendations for the development of anesthetic new animal drug products for companion animals. The guidance discusses the contents of the target animal safety, effectiveness, and labeling technical sections of a new animal drug application (NADA) for general anesthetics.

**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.

Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Germaine Connolly, Center for Veterinary Medicine, (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8331, e-mail: [germaine.connolly@fda.hhs.gov](mailto:germaine.connolly@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a Guidance for Industry #192 entitled "Anesthetics for Companion Animals." This guidance document makes recommendations to assist developers of general anesthetic drugs (injectable or inhalational) for use in companion animals (dogs, cats, and horses). The guidance specifically describes what should be considered while planning and executing safety and field studies

for the proposed anesthetic. In addition, the guidance includes recommendations on how to analyze and package the collected data for submission to the Center for Veterinary Medicine (CVM).

In the **Federal Register** of December 17, 2008, (73 FR 76657), FDA published the notice of availability for a draft guidance entitled "Anesthetics for Companion Animals" which gave interested persons until March 2, 2009, to comment on the draft guidance. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. In addition to some of the changes based on the comments received, CVM made a few minor changes to the guidance to add clarity and accuracy. The guidance announced in this notice finalizes the draft guidance dated December 17, 2008.

##### II. 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 this 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.

##### III. 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 have been approved under OMB Control No. 0910-0032 (expiration date 04/30/2010).

##### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. 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 docket number found in brackets in the heading of this document. Received comments may be seen 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 at either <http://www.fda.gov/AnimalVeterinary/>

[default.htm](http://www.regulations.gov) or <http://www.regulations.gov>.

Dated: March 22, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel, GWAS of Arthritis, Osteoporosis and Lupus.

*Date:* March 31, 2010.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* David J. Remondini, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2210, MSC 7890, Bethesda, MD 20892, 301-435-1038, [remondid@csr.nih.gov](mailto:remondid@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 19, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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