TABLE 2.—TOTAL ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Devices and Radiological Health	6,091	1	6,091	2	12,182
Center for Veterinary Medicine	664	1	664	1	664
Center for Food Safety and Applied Nutrition	1,794	5	8,876	2	17,752
Total	14,853		21,935		36,902

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 10, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29897 Filed 12–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0623]

Draft Guidance for Industry on Anesthetics for Companion Animals; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #192 entitled ''Anesthetics for Companion Animals.''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: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 2, 2009.

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 draft 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 draft 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*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 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.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent 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 draft 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 number 0910–0032.

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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management

System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

V. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cvm* or *http://www.regulations.gov*.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29953 Filed 12–16–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–08–8003]

Memorandum of Understanding Between the Office of the Assistant Secretary of Defense (Health Affairs), the Veterans Health Administration, and the U.S. Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Office of the Assistant Secretary of Defense (Health Affairs), the Veterans Health Administration, and the U.S. Food and Drug Administration. The purpose of the MOU is to enhance knowledge and efficiency by providing for the sharing of information and expertise between the Federal partners. The goals of the collaboration are to explore ways to: Further enhance information sharing efforts through more efficient and robust interagency activities; promote efficient utilization of tools and expertise for product risk identification, validation and analysis; and build infrastructure and processes that meet the common needs for evaluating the safety, efficacy, and utilization of drugs, biologics, and medical devices, as well as the safety and utilization of foods. The MOU is available on FDA's Web site at *www.fda.gov/oc/mous/domestic/domesticmous.htm*.

DATES: The agreement became effective November 25, 2008.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4324, Silver Spring, MD 20993, 301–796–4830.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.