

technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Molly Wagster, Ph.D., Division of Neuroscience, National Institute on Aging, NIH, DHHS, 7201 Wisconsin Avenue, Suite 350, Bethesda, Maryland 20892-9205 or call non-toll-free number 301-496-9350 or e-mail your request, including your address to: [wagsterm@nia.nih.gov](mailto:wagsterm@nia.nih.gov).

**Comments Due Date:** Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: April 23, 2010.

**Melissa Fraczkowski,**

National Institute on Aging Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2010-10015 Filed 4-28-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. Docket No. FDA-2009-N-0506]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 1, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0537. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Elizabeth Barbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, [Elizabeth.Barbakos@fda.hhs.gov](mailto:Elizabeth.Barbakos@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Bar Code Label Requirement for Human Drug and Biological Products—OMB Control Number 0910-0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), we issued new regulations that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the

product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Director, Center for Biologics Evaluation and Research as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately two exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

In the **Federal Register** of November 6, 2009 FR 74 57495, FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
201.25(d)	2	1	2	24	48

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-9902 Filed 4-28-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-D-0034]

#### Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Guidance for Industry on How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to the Center for Veterinary Medicine

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 1, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0453. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance for Industry on How to Submit a Notice of Final Disposition of Investigational Animals Not Intended for Immediate Slaughter in Electronic Format to the Center for Veterinary Medicine—(OMB Control Number 0910-0453)—Extension

The Center for Veterinary Medicine (CVM) monitors the final disposition of investigational animals where such

animals do not enter the human food chain immediately at the completion of an investigational study. CVM's monitoring of the final disposition of investigational food animals is intended to ensure that unsafe residues of new animal drugs do not get into the food supply. CVM issues a slaughter authorization letter to investigational new animal drug (INAD) sponsors that sets the terms under which investigational animals may be slaughtered (21 CFR 511.1(b)(5)). Also in the letter, CVM requests that sponsors submit a notice of final disposition of investigational animals (NFDA) not intended for immediate slaughter. NFDA's have historically been submitted to CVM on paper. CVM's guidance entitled "How to Submit a Notice of Final Disposition of Investigational Animals not Intended for Immediate Slaughter in Electronic Format to CVM" provides sponsors with an option to submit an NFDA as an e-mail attachment to CVM via the Internet.

The likely respondents are INAD sponsors.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section/ Form No. 3487	Number of Respondents	Annual Frequency per Response	Total Annual Responses <sup>2</sup>	Hours per Response	Total Hours
511.1(b)(5)	40	0.4	16	.08	1.3

<sup>1</sup> There are no capital or operating and maintenance costs associated with this collection of information.

<sup>2</sup> Electronic submissions received between January 1, 2008, and December 31, 2008.

The number of respondents in table 1 of this document are the number of sponsors registered to make electronic submissions (40). The number of total annual responses is based on a review of the actual number of such submissions made between January 1, 2008, and December 31, 2008. Thus, FDA estimates the total reporting burden at 1.3 hours (16 x .08= 1.3 total hours).

Dated: April 23, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-9901 Filed 4-28-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0055]

#### Agency Information Collection Activities; Submission for Office and Management and Budget Review; Comment Request; Guidance for Industry on How to Submit a Protocol Without Data in Electronic Format to the Center for Veterinary Medicine

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 1, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or e-mailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0524. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information