

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—21 CFR 514.117(b)(2) and 21 CFR 511.1(b)(5); (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. NFDAs 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 BURDEN¹

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

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

² 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: January 29, 2010.

David Dorsey,
Acting Deputy Commissioner for Policy,
Planning and Budget.

[FR Doc. 2010-2527 Filed 2-4-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0057]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the

PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the Center for Veterinary Medicine's (CVM's) "Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Gateway."

DATES: Submit written or electronic comments on the collection of information by April 6, 2010.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of management and budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in

44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway—21 CFR 11.2 (OMB Control Number 0910-0454)—Extension)

CVM accepts certain types of submissions electronically with no

requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by 21 CFR 11.2. CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled

"Guidance for Industry: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any information by e-mail.

The likely respondents are sponsors for new animal drug applications.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section/FDA Form 3538	No. of Respondents	Annual Frequency per Response	Total Annual Responses ²	Hours per Response	Total Hours
11.2	40	1.3	52	.08	4.2

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

² Electronic submissions received between July 1, 2005, and June 30, 2006.

The number of respondents in table 1 of this document is 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, (52 x hours per response (.08) = 4.2 total hours).

Dated: January 29, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010-2523 Filed 2-4-10; 8:45 am]

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Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Peter Kozel, PhD, Scientific Review Officer, NCCAM, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892-5475, 301-496-8004, kozelp@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: January 29, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-2557 Filed 2-4-10; 8:45 am]

BILLING CODE 4140-01-P

Date: March 11, 2010.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaylord National Hotel & Convention Center, 201 Waterfront Street, National Harbor, MD 20745.

Contact Person: John K. Hayes, PhD, Scientific Review Officer, 6707 Democracy Boulevard, Suite 959, Democracy Two, Bethesda, MD 20892, 301-451-3398, hayesj@mail.nih.gov.

Dated: February 1, 2010

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-2562 Filed 2-4-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Alternative Medicine; 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: National Center for Complementary and Alternative Medicine Special Emphasis Panel Training.

Date: March 1, 2010.

Time: 8 a.m. to 5 p.m.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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: National Institute of Biomedical Imaging and Bioengineering Special; 2010/05 SBIR Review.

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, Member Conflict: Neurodevices, Bioengineering and Biomodeling.

Date: February 24, 2010.