Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avgerage burden per response (in hrs)	Total burden (in hrs)
School food service personnel	SFSNS	738	1	15/60	185
Total					560

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–10130 Filed 4–29–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns Evaluation of Treatments and Services Provided to People with Duchenne Muscular Dystrophy (DMD), FOA DD13–002, initial review.

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 12:00 p.m.–2:00 p.m., May 30, 2013 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Evaluation of Treatments and Services Provided to People with Duchenne Muscular Dystrophy (DMD), FOA DD13–002, initial review.''

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F–46, Atlanta, Georgia 30341, Telephone: (770) 488–3585, *EEO6@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2013–10064 Filed 4–29–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0450]

Agency Information Collection Activities; Proposed Collection; Comment Request; Abbreviated New Animal Drug Applications

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 paperwork associated with abbreviated new animal drug applications submitted to the Center for Veterinary Medicine, FDA.

DATES: Submit either electronic or written comments on the collection of information by July 1, 2013.

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: JonnaLynn Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Drive, PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov.*

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.

Abbreviated New Animal Drug Applications—Sections 512(b)(2) and (n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(b)(2) and (n)(1)) (OMB Control Number 0910–0669))—Extension

On November 16, 1988, the President signed into law the Generic Animal Drug and Patent Restoration Act (GADPTRA) (Pub. L. 100–670). Under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by GADPTRA, any person may file an abbreviated new animal drug application (ANADA) seeking approval of a generic copy of an approved new animal drug. The information required to be submitted as part of an abbreviated application is described in section 512(n)(1) of the FD&C Act. Among other things, an abbreviated application is required to contain information to show that the proposed generic drug is bioequivalent to, and has the same labeling as, the approved drug referenced in the abbreviated application. FDA allows applicants to submit a complete ANADA or to submit information in support of an ANADA for phased review followed by the submission of an Administrative ANADA when FDA finds that all the applicable technical sections for an ANADA are complete. FDA requests that an applicant accompany ANADAs and requests for phased review of data to support ANADAs with the Form FDA 356v to ensure efficient and accurate processing of information to support approval of the generic new animal drug.

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

TABLE 1—ANADAS: ESTIMATED ANNUAL REPORTING BURDEN

FD&C act section 512(b)(2)	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
ANADA	356v	18	1	18	159	2,862
Phased Review With Administrative ANADA	356v	3	5	15	31.8	477
Total						3,339

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

ANADA paperwork burden (section 512(b)(2) of the FD&C Act). Over the past 5 fiscal years, from October 2007 through September 2012, FDA has received an average of 21 ANADAs per year. FDA estimates that preparing the paperwork required under 21 U.S.C. 360b(n)(1) to be contained in an ANADA, whether all of the information is submitted with the ANADA or the applicant submits information for phased review followed by an Administrative ANADA that references that information, will take approximately 159 hours. (FDA is estimating that each ANADA that uses the phased review process will have approximately five phased reviews per application. Therefore, assuming that three respondents will take advantage of the phased review option per year and an average of five phased reviews are submitted per application, times 31.8 hours per phased review, equals 477 total hours per year or 159 hours per application.)

Although over the last 5 fiscal years all sponsors chose to submit traditional ANADAs, some sponsors did indicate an interest in using the phased review option in the future. FDA believes that with time, more and more sponsors will take advantage of the phased review option, as it provides greater flexibility, and estimates that there will be three respondents for the phased review option. FDA also estimates that sponsors of ANADAs take approximately 25 percent less time to put together the information to support an ANADA than a new animal drug application (NADA) because they only need to provide evidence of bioequivalence and not the data required in an NADA to support a full demonstration of safety and effectiveness.

Form FDA 356v. FDA requests that an applicant fill out and send in with an ANADA and requests for phased review of data to support an ANADAs, a Form FDA 356v to ensure efficient and accurate processing of information to support the approval of a generic new animal drug. Records and reports that are required post approval are described in 21 CFR 514.80 and that paperwork is already covered by that rule in OMB control number 0910–0284.

Dated: April 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–10088 Filed 4–29–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Cancer Therapeutics.

Date: May 22, 2013.

Time: 1:00 p.m. to 4:00 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: Careen K Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301)435–3504, *tothct@csr.nih.gov.*

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group Basic Mechanisms of Cancer Therapeutics Study Section.

Date: May 24, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Four Season Hotel Washington DC, 2800 Pennsylvania Avenue, Washington, DC 20007.

Contact Person: Lambratu Rahman Sesay, Ph.D., Scientific Review Officer, Center for