comments. Identify comments 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, and will be posted to the docket 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Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22772 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3106]

Animal Food; Export Certificates; Food and Drug Administration Food Safety Modernization Act of 2011; Certification Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fees we will assess for issuing export certificates for animal food. The FDA Food Safety Modernization Act (FSMA) of 2011 authorizes us to charge fees to cover our costs associated with issuing export certificates for regulated food including animal food. This notice provides the fee schedule for issuing these certificates and the basis for the fees. We have not previously collected fees to issue export certificates for animal food.

DATES: The fees described in this document for export certificates for animal food will be effective October 1, 2015.

FOR FURTHER INFORMATION CONTACT: Joanne Kla, Office of Surveillance and Compliance, Center for Veterinary Medicine (HFV–235), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5605, *CVMExportCertification@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In April 1996, a law entitled the ''FDA Export Reform and Enhancement Act of 1996'' (Pub. L. 104–134, amended by Pub. L. 104–180) amended sections 801(e) and 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FD&C Act provides that persons exporting certain FDA regulated products may request FDA to certify that the products meet the requirements of section 801(e)(1), section 802, or other applicable requirements of the FD&C Act. Section 801(e)(4) of the FD&C Act also requires FDA to issue certification within 20 days of receipt of the request and authorizes us to charge up to $175 for each certification issued within 20 days. In January 2011, section 801(e)(4)(A) of the FD&C Act was amended by FSMA (Pub. L. 111–353) to provide authorization for export certification fees for regulated food, including animal food (referred to as animal feed in section 107(b) of FSMA). Section 801(e)(4) of the FD&C Act authorizes FDA to issue export certificates for regulated food, drugs, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are legally exported under section 801(e) or 802 of the FD&C Act. The focus of this notice is on export certificates issued by the Center for Veterinary Medicine (CVM) for animal food.

II. Fees To Be Assessed for Export Certificates

CVM estimates the costs of the export certification program for animal food to be approximately $548,000 per year for payroll and operating expenses. There are four cost categories for preparing and issuing export certificates in general. They are: (1) Direct personnel for research, review, tracking, writing, and assembly; (2) purchase of equipment and supplies used for tracking, processing, printing, and packaging. Recovery of the cost of the equipment is calculated over its useful life; (3) billing and collection of fees; and (4) overhead and administrative support. In fiscal year (FY) 2014 CVM issued approximately 933 animal food export certificates. Because CVM has not been charging fees for issuing export certificates for animal food, the program has been covered by appropriated funds.

As mentioned previously in this document, FDA may charge up to $175 for each certificate. Certificates for some classes of products, including animal food, cost the Agency more than $175 to prepare. Subsequent certificates issued for the same product(s) in response to the same request generally cost FDA less than $175 to prepare. The fee for all subsequent certificates for the same product(s) issued in response to the same request reflects reduced FDA costs for preparing those certificates.

The following fees will be assessed starting October 1, 2015, for animal food export certificates:

TABLE 1—CVM FEES FOR FIRST, SECOND, AND SUBSEQUENT EXPORT CERTIFICATES

Type of certificate	Fee (dollars)
First certificate	175
Second certificate for the same product(s) issued in response to the same request	155
Subsequent certificates for the same product(s) issued in response to the same request	70

The fee for issuing the first export certificate for animal food will be at the maximum allowable amount and consistent with the export certification fees assessed since FY 1997 by other FDA Centers that provide export certification for drugs and devices. The fees for issuing subsequent certificates continue to differ among the Centers, based on varying costs.

Dated: September 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22795 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0481]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; New Animal Drugs for Investigational Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''New Animal Drugs for Investigational Use'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food

and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 14, 2015, the Agency submitted a proposed collection of information entitled, ''New Animal Drugs for Investigational Use'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0117. The approval expires on August 31, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22830 Filed 9–9–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental and Craniofacial Research; 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: National Institute of Dental and Craniofacial Research Special Emphasis Panel; NIDCR Clinical Trials SEP.

Date: October 8, 2015.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Crina Frincu, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, National Institutes of Health, 6701 Democracy Blvd., Suite 662, Bethesda, MD 20892, *cfrincu@mail.nih.gov.*

Name of Committee: NIDCR Special Grants Review Committee.

Date: October 22–23, 2015.

Time: 8:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, Conference Room #602, 6701 Democracy Boulevard, Bethesda, MD 20892.

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Dental and Craniofacial Research, 6701 Democracy Blvd., Rm. 676, Bethesda, MD 20892–4878, 301–594–4861, *mooremar@nidcr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: September 3, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–22769 Filed 9–9–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 on Aging Special Emphasis Panel; Thymic Aspects of T Cell Aging.

Date: November 6, 2015.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Isis S. Mikhail, MD, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7704, *MIKHAILI@MAIL.NIH.GOV.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 4, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–22801 Filed 9–9–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 section 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 Child Health and Human Development Special Emphasis Panel.

Date: November 18, 2015.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Peter Zelazowski, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6902, *peter.zelazowski@.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 3, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–22706 Filed 9–9–15; 8:45 am]

BILLING CODE 4140–01–P