IV. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2016. The initial BPD fee for a product is due when the sponsor submits an IND that FDA determines is intended to support a biosimilar biological product application for the product or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product, or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (*http://www.fda.gov/bsufa*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay*. Once you search for your invoice, click ''Pay Now'' to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use *http://www.pay.gov,* a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If you prefer to send a check by a courier such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, ATTN: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314–418–4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002.

The tax identification number of FDA is 53–0196965.

B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2016. Payment instructions will be included in the invoices. Payment will be due on October 1, 2016. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2016, FDA will issue invoices in November 2016 to firms subject to fees for FY 2017 that qualify for the annual BPD fee after the August 2016 billing. FDA will issue invoices in November 2017 for any annual products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–17800 Filed 7–27–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute 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 Cancer Institute Special Emphasis Panel; NCI SPORE Review Meeting.

Date: October 7, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Rockville, 1750 Rockville Pike, Rockville, MD 20892.

Contact Person: Majed M. Hamawy, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W120, Rockville, MD 20892–9750, 240–276–6457, *mh101v@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project Review III (P01).

Date: October 13–14, 2016.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Klaus B. Piontek, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W612, Rockville, MD 20892–9750, 240–276–5413, *klaus.piontek@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Questions in Cancer Systems Biology.

Date: October 13, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Caterina Bianco, MD, Ph.D., Scientific Review Officer, Research Programs Review, Branch Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room

7W610, Rockville, MD 20892–9750, 240–276–6459, *biancoc@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Provocative Question #10.

Date: November 3, 2016.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Denise L. Stredrick, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W640, Rockville, MD 20892–9750, 240–276–5053, *stredrid@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: July 22, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–17810 Filed 7–27–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Center of Excellence for Infant and Early Childhood Mental Health Consultation—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services, in partnership with the Health Resources and Services Administration (HRSA) and the Administration for Children and Families (ACF), announces the establishment of the National Center of Excellence (CoE) for Infant and Early Childhood Mental Health Consultation (IECMHC), a new program to advance the implementation of high-quality infant and early childhood mental health consultation across the nation through the development of tools, resources, training, technical assistance, and collaborative public and private partnerships. Its primary goals will be to promote the healthy social and emotional development of infants and young children and to prevent mental, emotional and behavioral disorders within this age group. Major activities for the CoE include convening a national expert workgroup and to lead the workgroup in developing a state-of-the-art Toolkit of the latest research and best practices for IECMHC (*e.g.,* training, implementation, evaluation and financing) for early childhood settings, including early care and education and home visiting programs. The CoE will also create a dissemination and training plan for the Toolkit, and provide intensive training and technical assistance to states and tribes to help them build their capacity to implement, fund and evaluate IECMHC efforts successfully.

To monitor the reach, implementation and impact of the CoE's multiple efforts, learn which practices work for which populations, and gauge overall applicability and utility of the Toolkit to infant and early childhood mental health consultation, the CoE intends to employ a variety of standardized process and outcome measures that have been specifically designed to reduce participant burden. Measures will explore the related professional background and experience of IECMHC participants, degree of satisfaction with IECMHC trainings and technical assistance (TTA), usefulness of the TTA, areas for improvement, scope of IECMHC implementation across the State or Tribe, and IECMHC impact on childcare and pre-K expulsion rates.

Data-collection efforts will focus on two types of respondents: (1) Mental health consultants employed at maternal and child health, behavioral health, child care, Head Start, education and child welfare agencies, and (2) State or tribal representatives who have been selected to lead the implementation, expansion and sustainability of IECMHC in their state or tribal community.

The mental health consultants will be asked to provide background information on their prior experience in the IECMHC field, feedback immediately following the trainings, and follow-up feedback approximately two months after receiving training and/or technical assistance. Specific sample questions will include level of satisfaction with the training/technical assistance, perceptions of knowledge acquired, intentions to use training content, extent of implementation of content, and opinions regarding the training's cultural appropriateness for its audience.

State/tribal representatives will be asked to report on the reach and impact of the IECMHC program in the past year, level of satisfaction with IECMHC, suggested improvements for the program, and emerging state/tribal needs that the program could address. IECMHC mentors, whose primary role will be to work with the state/tribal representatives to implement the IECMHC Toolkit, will gather specific information from the representatives, including recommended IECMHC professional standards for mental health consultants, state- or tribal-level evaluations of IECMHC impact, and financing for the continuation of IECMHC. For programs also receiving funding from the Maternal Infant and Early Childhood Home Visiting (MIECHV) program, representatives will be asked to report on selected MIECHV outcome measures relating to maternal and newborn health; school readiness and achievement; and coordination and referrals for other community resources and supports.

SAMHSA will use this data to determine whether funded activities are progressing as expected, provide guidance to improve how work is being conducted, assess the impact of IECMHC on child-serving systems, and inform subsequent national, state, tribal and community policy and planning decisions.