II of FDASIA is MDUFA III, which gives FDA the authority to collect device user fees from industry for fiscal years 2013 to 2017. MDUFA III took effect on October 1, 2012, and will continue through September 30, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the Agency, whenever they submit an application or a notification to market a new medical device in the United States, and for certain other types of submissions. Under MDUFA III, FDA is authorized to collect user fees that will total approximately $595 million (plus adjustments for inflation) over 5 years. With this additional funding, FDA will be able to hire more than 200 full-time-equivalent workers over the course of MDUFA III. In exchange, FDA has committed to meet certain performance goals outlined in the MDUFA III Commitment Letter.[4]

II. Assessment of FDA's Process for the Review of Device Submissions

Section V of the MDUFA III Commitment Letter states that FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment will be conducted in two phases by a private, independent consulting firm, under contract with FDA, that is capable of performing the technical analysis, management assessment, and program evaluation tasks required to address the assessment as described in the MDUFA III Commitment Letter.

FDA awarded the contract in June 2013 to the consulting firm Booz Allen Hamilton. Findings on high-priority recommendations (i.e., those likely to have a significant impact on review times) were scheduled to be published within 6 months of award and are included in the report available through the link near the end of this notice. Final comprehensive findings and recommendations are scheduled to be published within 1 year of contract award. FDA agreed to publish an implementation plan within 6 months of receipt of each set of recommendations. For Phase 2 of the independent assessment, the contractor will evaluate the implementation of recommendations and publish a written assessment no later than February 1, 2016.

The assessment includes, but is not limited to, the following areas:

1. Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.

2. Analysis of elements of the review process (including the presubmission process, and investigational device exemption, premarket notification (510(k)), and premarket approval application reviews) that consume or save time to facilitate a more efficient process. This includes analysis of root causes for inefficiencies that may affect review performance and total time to decision. This will also include recommended actions to correct any failures to meet MDUFA goals. Analysis of the review process will include the impact of combination products, companion diagnostic products, and laboratory developed tests on the review process.

3. Assessment of FDA methods and controls for collecting and reporting information on premarket review process resource use and performance.

4. Assessment of effectiveness of FDA's Reviewer Training Program implementation.

5. Recommendations for ongoing periodic assessments and any additional, more detailed, or focused assessments.

FDA will incorporate findings and recommendations, as appropriate, into its management of the premarket review program. FDA will analyze the recommendations for improvement opportunities identified in the assessment, develop and implement a corrective action plan, and assure its effectiveness. FDA also will incorporate the results of the assessment into a Good Review Management Practices (GRMP) guidance document. FDA's implementation of the GRMP guidance will include initial and ongoing training of FDA staff, and periodic audits of compliance with the guidance.

The contractor's Phase 1 findings on high priority recommendations are available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.*

Dated: December 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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[4] *www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

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; Obesity, Insulin Action, and Metabolic Dysfunction.

Date: January 9, 2014.

Time: 9:00 a.m. to 1:00 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: Reed A Graves, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6166, MSC 7892, Bethesda, MD 20892, (301) 402–6297, *gravesr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Immune and Radiotherapy.

Date: January 16, 2014.

Time: 9:30 a.m. to 12:30 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: Lawrence Ka-Yun Ng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301–435–1719, *ngkl@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: *December 6, 2013.*

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–29613 Filed 12–11–13; 8:45 am]

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