

addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** William T. Flynn, Center for Veterinary Medicine (HVF-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9084, email: [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

In the **Federal Register** of April 13, 2012 (77 FR 22327), FDA published the notice of availability for a draft guidance entitled “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209,” giving interested persons until July 12, 2012, to comment on the draft guidance. FDA received numerous comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated April 13, 2012.

The purpose of this guidance document is to provide information to sponsors of certain antimicrobial new animal drug products who are interested in revising conditions of use for those products consistent with FDA’s Guidance for Industry (GFI) #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” and to set timelines for stakeholders wishing to comply voluntarily with this guidance. FDA intends to work with affected drug sponsors to help them to voluntarily implement the principles described above through modifications to the approved conditions of use of their new animal drug products. FDA believes a voluntary approach, conducted in a cooperative and timely manner, is the most effective approach to achieve the common goal of more judicious use of medically important antimicrobials in animal agriculture.

FDA recognizes that it is important to identify ways to assess the effect of GFI #209 and GFI #213 over time. FDA

currently collects data on the sale and distribution of antimicrobial drugs intended for use in food-producing animals, as well as data on antimicrobial resistance among foodborne pathogens as part of the National Antimicrobial Resistance Monitoring System. FDA is currently working in collaboration with other agencies, including United States Department of Agriculture and the Centers for Disease Control, to explore approaches for enhancing current data collection efforts in order to measure the effectiveness of the strategy. FDA anticipates seeking additional public input as it develops these enhancements.

##### **II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910-0032 and 0910-0669.

##### **IV. Comments**

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of 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 guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: December 9, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–29697 Filed 12–11–13; 8:45 am]

**BILLING CODE 4160-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2013–N–1504]

#### **Independent Assessment of the Process for the Review of Device Submissions; High Priority Recommendations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is presenting Booz Allen Hamilton’s high priority recommendations submitted as part of their independent assessment of the process for the review of medical device submissions. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013 to 2017. The assessment is described in section V, “Independent Assessment of Review Process Management”, of the commitment letter entitled “MDUFA Performance Goals and Procedures”<sup>1</sup> (MDUFA III Commitment Letter). The assessment is being conducted in two phases. The high priority recommendations are the first of a series of deliverables, as outlined in the contract statement of work,<sup>2</sup> to be published as part of Phase 1 of the assessment.

**FOR FURTHER INFORMATION CONTACT:** Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3291, Silver Spring, MD 20993–0002, 301–796–9384, [Amber.Sligar@fda.hhs.gov](mailto:Amber.Sligar@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).<sup>3</sup> Title

<sup>1</sup> [www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf).

<sup>2</sup> <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm>.

<sup>3</sup> <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>.

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.<sup>4</sup>

## 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.*

[FR Doc. 2013-29612 Filed 12-6-13; 8:45 am]

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## 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](mailto: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](mailto: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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<sup>4</sup> [www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf](http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf).