approved under OMB control number 0910–0338.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12348 Filed 5–28–14; 8:45 am]

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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; Final Comprehensive Findings and Recommendations and First Implementation Plan

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing Booz Allen Hamilton's final comprehensive findings and 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 (FYs) 2013–2017. The assessment is described in section V, Independent Assessment of Review Process Management, of the commitment letter entitled ''MDUFA Performance Goals and Procedures'' (MDUFA III Commitment Letter). The assessment is being conducted in two phases. The final comprehensive findings and recommendations are the last of a series of deliverables, as outlined in the contract statement of work, 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.*

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).[1] Title II of FDASIA is the Medical Device User Fee Amendments of 2012 (MDUFA III), which gives FDA the authority to collect device user fees from industry for FYs 2013–2017. 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.[2]

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 published in December 2013.[3] Final comprehensive findings and recommendations were scheduled to be published within 1 year of contract award and are included in the report available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.* FDA agreed to publish an implementation plan within 6 months of receipt of each set of recommendations. The first of these implementation plans has been completed and is also available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm.* 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:

- Identification of process improvements and best practices for conducting predictable, efficient, and consistent premarket reviews that meet regulatory review standards.
- Analysis of elements of the review process (including the Pre-Submission 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 and companion diagnostic products on the review process.
- Assessment of FDA methods and controls for collecting and reporting information on premarket review process resource use and performance.
- Assessment of effectiveness of FDA's Device Reviewer Training Program implementation.
- 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 for medical devices. FDA's implementation of the GRMP guidance will include initial and

[1] *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.*

[2] *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[3] *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/UCM378202.pdf.*

ongoing training of FDA staff, and periodic audits of compliance with the guidance.

The contractor's Phase 1 final comprehensive findings and recommendations along with FDA's implementation plan based on the contractor's high-priority recommendations issued December 11, 2013, are available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MDUFAIII/ucm314036.htm*.

Dated: May 22, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12403 Filed 5–28–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–E–0595]

Determination of Regulatory Review Period for Purposes of Patent Extension; ZACTRAN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZACTRAN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6257, Silver Spring, MD 20993–0002, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product ZACTRAN (gamithromycin). ZACTRAN, an animal drug product, is indicated for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in beef and non-lactating dairy cattle. ZACTRAN is also indicated for the control of respiratory disease in beef and non-lactating dairy cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.* Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ZACTRAN (U.S. Patent No. 5,985,844) from Merck Sharp & Dohme Corp., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 1, 2013, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of ZACTRAN represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ZACTRAN is 2,990 days. Of this time, 2,930 days occurred during the testing phase of the regulatory review period, while 60 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the FD&C Act (21 U.S.C. 355(i)) became effective:* April 11, 2003. The applicant claims September 11, 1997, as the date the investigational new animal drug application (INAD) became effective. However, FDA records indicate that the INAD effective date was April 11, 2003, which was the date a major health or environmental effects test is begun or the date on which the Agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* April 18, 2011. The applicant claims April 15, 2011, as the date the new animal drug application (NADA) for ZACTRAN (NADA 141–328) was initially submitted. However, FDA records indicate that NADA 141–328 was submitted on April 18, 2011.

3. *The date the application was approved:* June 16, 2011. FDA has verified the applicant's claim that NADA 141–328 was approved on June 16, 2011.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 28, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 25, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess.,