to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12351 Filed 5–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0622]

Draft Guidance for Industry on Best Practices in Developing Proprietary Names for Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Best Practices in Developing Proprietary Names for Drugs.'' The draft guidance focuses on the safety aspects in the development and selection of proposed proprietary names for all prescription and nonprescription human drug products and biological products. The draft guidance describes naming design practices to help avoid medication errors and provides a qualitative systematic framework for evaluating proprietary names before submitting them for FDA review. FDA is issuing this draft guidance to help drug and biologic product sponsors develop proprietary names that do not cause or contribute to medication errors or otherwise contribute to the misbranding of the drug.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 28, 2014.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: Kellie Taylor, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–0157, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Best Practices in Developing Proprietary Names for Drugs.'' FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors, and has addressed this issue repeatedly in recent decades. Our primary focus has been to develop and communicate to sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product review and approval process. As part of this initiative, FDA held public meetings in June and December 2003 to discuss the methods used for proprietary name evaluation. In 2007, FDA formally committed to certain performance goals (under the reauthorization of the Prescription Drug User Fee Act (PDUFA IV) (Public Law 110–85), including implementing measures to reduce medication errors related to look-alike and sound-alike proprietary names (PDUFA IV performance goals). In 2008, FDA held a public meeting to further discuss testing and evaluating proprietary names, and initiating a pilot project on proprietary name review. The 2008 meeting focused on advances and current limitations in the science of proprietary name evaluation, FDA's recommendations for best practices in the absence of a ''gold standard,'' and details of the proposed pilot project. The participating expert panel judged all the evaluation methods proposed by FDA to be complementary and of value in the proprietary name testing process. We are issuing this guidance in partial fulfillment of the PDUFA IV performance goals.

This draft guidance document, which addresses minimizing risks through the design of drug product naming, is the last in a series of three guidance documents that FDA is issuing to help sponsors minimize the potential for medication errors when designing and developing products. The first draft guidance, published in the **Federal Register** on December 13, 2012 (77 FR 74196), focuses on minimizing risks associated with the design of the drug product and its container closure system. The second draft guidance, published in the **Federal Register** on April 24, 2013 (78 FR 24211), focuses on safety aspects of the container label and carton labeling design.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on best practices for developing and selecting proposed proprietary names to minimize medication errors. 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.

II. 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.*

III. Paperwork Reduction Act of 1995

This draft 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). Proprietary name information submitted under 21 CFR part 314 has been approved under OMB control number 0910–0001, and proprietary name information submitted under 21 CFR part 601 has been

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.

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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.*