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: Charu Mullick, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6365, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Vaginal Microbicides: Development for the Prevention of HIV Infection.'' This guidance addresses nonclinical development, early phases of clinical development, phase 3 trial considerations, and safety considerations in vaginal microbicide development including safety considerations in adolescent and pregnant populations. The guidance also outlines development of combination microbicide products such as drug-drug combinations, drug-device combinations, or combination products that include microbicide and are intended for multiple indications. This guidance finalizes the draft guidance issued on November 23, 2012 (77 FR 70167). The majority of public comments submitted to the docket were related to clinical trial considerations and nonclinical pharmacology/toxicology issues. This guidance incorporates FDA responses to the public comments.

This 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 developing vaginal microbicides for preventing HIV transmission. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under 0910–0014, and the collections of information referred to in the guidance for clinical trial sponsors entitled ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under 0910–0581.

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. Electronic Access

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

Dated: November 13, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27287 Filed 11–18–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1741]

Proposed Criteria for ''First Generic'' Submissions for Purposes of Abbreviated New Drug Application Review Prioritization Under the Generic Drug User Fee Amendments; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the opening of a public docket and requesting comments on proposed criteria for ''first generic'' abbreviated new drug application (ANDA) submissions. The purpose is to facilitate FDA's establishment of review prioritization under the Generic Drug User Fee Amendments of 2012 (GDUFA). Establishing clear criteria for this review prioritization category will allow FDA to appropriately prioritize ANDA submissions and track them in a manner consistent with the review prioritization commitments FDA made under GDUFA. Clear criteria for this category will also lead to less industry confusion and more consistent identification of ''first generic'' submissions.

DATES: Submit either electronic or written comments by December 19, 2014.

ADDRESSES: You may submit comments by any of the following methods:

Electronic Submissions

Submit electronic comments as follows:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written comments as follows:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions must include the Docket No. found in brackets in the heading of this document. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Maryll Toufanian, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1682, Silver Spring, MD 20993–0002, 240–402–7944.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, GDUFA (Title III of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144)) was signed into law by the President. GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and to reduce costs to industry. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges. An attendant

commitment letter enumerates the performance efficiencies, metric goals, and procedures to which FDA agreed for the GDUFA program (Commitment Letter).[1] In a portion of the Commitment Letter relevant to this notice, FDA agreed to: (1) Expedite review of ANDAs in the year 1 and year 2 cohorts (i.e., those ANDAs submitted in fiscal year (FY) 2013 and FY2014, respectively) that are submitted on the first day that any valid paragraph IV application for the drug in question is submitted (first-to-file ANDA); (2) strive to review and act on all first-to-file ANDAs within 30 months of submission to avoid inadvertent forfeiture of 180-day exclusivity eligibility under section 505(j)(5)(D)(i)(IV) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)(D)(i)(IV)); and (3) expedite review of ''first generic'' ANDAs for which there are no blocking patents or exclusivities.

To help meet the goals in the Commitment Letter, FDA will prioritize ANDA reviews in conformance with the recently issued Manual of Policies and Procedures (MAPP) 5240.3 Rev. I: Prioritization of the Review of Original ANDAs, Amendments, and Supplements; and MAPP 5200.4: Criteria and Procedures for Managing the Review of Original ANDAs, Amendments and Supplements.[2] These MAPPs contemplate FDA prioritizing its ANDA reviews in a manner consistent with the provisions of the Commitment Letter, which identify certain types of submissions, including ''first generic'' ANDA submissions, as representing public health priorities that will receive expedited review. The MAPPs also expressly describe prioritization of the ANDA types described previously.

Subsequent to enactment of GDUFA, FDA has received informal comments on the Commitment Letter from several stakeholders that conveyed different understandings of the criteria for the ''first generic'' review prioritization category. For example, stakeholders have characterized a ''first generic'' as the first ANDA submitted, the first ANDA approved, the first ANDA marketed, all first-to-file ANDAs, and a company's ''top priority'' ANDA. Without clear criteria for this category, there is the potential for confusion and inconsistent review prioritization.

On September 17, 2014, FDA's Office of Generic Drugs held a public hearing to solicit public comment on certain topics related to implementation of GDUFA.[3] The hearing provided an opportunity for public input on future policy priorities. At that hearing, FDA solicited comment on the specific criteria FDA should apply to identify an ANDA as a ''first generic'' eligible for expedited review. FDA has considered comments provided at that hearing and submitted to the related public docket. Today, FDA is announcing proposed criteria for the review prioritization category of ''first generic'' ANDA submissions.

II. Request for Comments and Supporting Information

FDA is requesting comments and supporting information on the following criteria for a ''first generic'' ANDA for the purposes of review prioritization. A first generic application is any received ANDA[4]: (1) That is a first-to-file ANDA eligible for 180-day exclusivity, or for which there are no blocking patents or exclusivities; and (2) for which there is no previously-approved ANDA for the drug product.

FDA believes that these proposed criteria appropriately focus FDA's resources on approving as quickly as possible, new safe and effective generic drug products for patient use. The Agency also believes that these criteria are consistent with the broad scope of the Commitment Letter, and generally reflect industry intent. Finally, these criteria enable FDA to prioritize review of a *pending* ANDA when the date on which the ANDA can be approved alters due to changes in the patent or exclusivity landscape.

We note that under these proposed criteria, ''first generic'' status is predicated largely on circumstances outside Agency control, and ones that may change while the ANDA is pending, for example, developments related to the disposition of related patent litigation. Accordingly, FDA also is seeking comments and supporting information on mechanisms the Agency could put in place to facilitate ANDA sponsor submission of such relevant information in a timely manner, in addition to that already required under the regulations.

We also note that as a result of such developments, ANDA submissions that originally met the criteria for a ''first generic'' submission may no longer meet those criteria; for example, the validity of a patent may be upheld in litigation, thereby blocking approval until patent expiry.

We thus are seeking comment on whether FDA should change the review prioritization for an ANDA that no longer meets the ''first generic'' criteria during its review.

III. 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.*

Dated: November 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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[1] *http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf.*

[2] *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/.*

[3] *https://www.federalregister.gov/articles/2014/08/19/2014-19632/generic-drug-user-fee-amendments-of-2012-public-hearing-on-policy-development-request-for-comments#footnote-4.*

[4] FDA evaluates each submitted ANDA individually to determine whether the ANDA can be received. The *receipt* of an ANDA means that FDA made a threshold determination that the ANDA is sufficiently complete to permit a substantive review.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Amprion, Inc. located in Houston Texas, USA, to practice the inventions embodied in the following Patents and Patent Applications, each entitled ''Detection of Infectious Prion Protein by Seeded Conversion of Recombinant Prion Protein'':

1. US provisional Application 60/961,364 filed July 20, 2007 [HHS Ref. No. E–109–2007/0–US–01]

2. PCT/US2008/070656, filed July 21, 2008; [HHS Ref. No E–109–2007/1–PCT–01]

3. EPC application No 08796382.3 filed July 21, 2008 [HHS Ref. No E–109–2007/1–EP–03]