4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-4508]

Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA) is seeking information and public comment, in anticipation of the passage of Generic Drug User Fee Amendments reauthorization (GDUFA II), relevant to FDA's planned approach for administering generic drug program fees under that legislation for fiscal year (FY) 2018. This includes requests for comment and information regarding FDA's initial inventory of approved abbreviated new drug application sponsors and application numbers. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA program fees in a timely manner.

DATES: Submit written or electronic comments and information by [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-4508 for "Generic Drug User Fee Amendments II Program Fee: List of Abbreviated New Drug Application Sponsors and Application Numbers; Request for Information and Comment." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper 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 and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristan Callahan, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20993, 301-796-7900, CDERCollections@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In anticipation of the enactment and implementation of GDUFA II, FDA has begun taking steps to ensure efficient administration of GDUFA for FY 2018. It is projected that the GDUFA II legislation will include an annual program fee for which holders of approved abbreviated new drug applications (ANDAs) will be responsible.

Under GDUFA II, it is anticipated that affiliated companies will be grouped together and counted as a single entity for purposes of assessing the program fee. The proposed legislation defines the term "affiliate" in the same way it was defined in GDUFA. An "affiliate" is defined as a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls, or has the power to control, the other business entity; or a third party controls, or has the power to control, both of the business entities. As set forth in the proposed legislation, the program fee will be allocated among three tiers of application holders:

- Large (companies with 20 or more approved ANDAs);
- Medium (companies with between 6 and 19 approved ANDAs); and,
- Small (companies with 5 or fewer approved ANDAs).

To assess program fees in an accurate and timely manner if these provisions are enacted, FDA seeks to identify how many approved ANDAs belong to each application holder, and which

application holders are affiliates for purposes of assessing GDUFA II program fees. In furtherance of this effort, FDA requests comments and information regarding FDA's initial inventory of approved ANDA sponsors and application numbers. The current spreadsheet containing this initial inventory and instructions on how to use it are available at http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm.

II. Request for Information and Comment

FDA is seeking information and public comment, in anticipation of the passage of GDUFA II, relevant to FDA's planned approach for administering generic drug program fees under that legislation for FY 2018. The information gathered from public comments will assist FDA in accurately assessing FY 2018 GDUFA Program Fees in a timely manner. Interested persons are invited to comment, in general, on any aspect of FDA's planned approach for administering these generic drug program fees under GDUFA II. FDA is particularly interested in comments and information addressing the accuracy and completeness of the information in the previously mentioned spreadsheet containing FDA's initial inventory of approved ANDA sponsors and application numbers. In addition, FDA is interested in any information that could be relevant to determining whether two or more companies that are currently listed separately in that spreadsheet should be considered to be affiliated for purposes of assessing the anticipated program fee. As a general matter, FDA does not consider affiliates to be confidential commercial information.

After receiving feedback and comments on the spreadsheet, FDA anticipates publishing a Federal Register notice and making available a revised spreadsheet that will incorporate information received in the comments on this notice. FDA plans to seek comment on the revised spreadsheet before compiling the final information regarding affiliated entities that will be used

as the basis for determining and assessing FY 2018 program fees in the event that GDUFA II is enacted.

Dated: January 3, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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