4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1576]

Assessing the Resource Needs of the Generic Drug User Fee Amendments; Publication of Report; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of report publication; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a report, entitled "Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology," providing options and recommendations for a new methodology to assess accurately changes in the resource needs of the generic drug review program. FDA, in the Generic Drug User Fee Amendments of 2017 (GDUFA II), committed to obtaining this report through a contract with an independent third party and publishing it before September 30, 2020. FDA is announcing publication of this report and the opening of a docket to receive public comment on this report.

DATES: Submit either electronic or written comments on the report by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this report.

ADDRESSES: You may submit comments on this report at any time prior to [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://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 https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2020-N-1576 for "Assessing the Resource Needs of the Generic Drug User Fee Amendments, Publication of

Report; Request for Comments." Comments filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- 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 https://www.regulations.gov. Submit both copies to the Dockets Management Staff. 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: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993-0002, 301-796-5003, Fax: 301-847-8443, Graham.Thompson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing the publication of a report, entitled "Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology," providing options and recommendations for a methodology to accurately assess changes in the resource needs of the generic drug review program. FDA, in the GDUFA II Commitment Letter[1] (entitled GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2018-2022), committed to obtaining this report and publishing it before September 30, 2020.

The third authorization of the Prescription Drug User Fee Act (PDUFA III), which began in fiscal year 2003, introduced the concept of a Workload Adjuster. This was a mechanism to ensure that the annual revenue for the program could be adjusted based on workload levels to ensure adequate staffing levels. Since its introduction, several updates have been made to the methodology, including its renaming as the Capacity Planning Adjustment (CPA).

GDUFA does not currently have a methodology analogous to the CPA to enable adjustment of the annual target revenue. The study announced by this notice posits options

[1] Available at: https://www.fda.gov/media/101052/download.

and recommendations to consider regarding the potential application of an adjustment methodology for the GDUFA program.

FDA commissioned Booz Allen Hamilton to produce this report. The report is publicly available on FDA's website at: https://www.fda.gov/industry/fda-user-fee-programs/resource-capacity-planning-and-modernized-time-reporting. FDA will review the public comments on the report.

Dated: July 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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