Part I prohibits the respondent from making any representation about the braking benefits, performance, or efficacy of any covered product, including that such product: (1) Will stop a vehicle significantly sooner than competing brake pads; and (2) reduces the risk of collisions compared to competing brake pads, unless the representation is non-misleading, and, at the time of making such representation, the respondent possesses and relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the field of automotive braking, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

Part II requires the respondent to submit a signed acknowledgment that respondent received the order.

Part III requires the respondent to file compliance reports with the Commission, and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part IV contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. Part V contains other requirements related to the Commission's monitoring of the respondent's order compliance. Part VI provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to facilitate public comment on the order, and it is not intended to constitute an official interpretation of the complaint or order, or to modify the order's terms in any way.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

[FR Doc. 2020–07170 Filed 4–3–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0989]

Assessing the Resource Needs of the Prescription Drug User Fee Act and Biosimilar User Fee Act; Publication of Report; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a report providing options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug and biosimilar biologic review programs. FDA, in both the Prescription Drug User Fee Amendments of 2017 (PDUFA VI) and Biosimilar User Fee Amendments of 2017 (BsUFA II) committed to obtaining this report through a contract with an independent accounting or consulting firm and publishing it before September 30, 2020. This was also codified in the respective authorizing statutory language. FDA is announcing publication of this report and the opening of a docket to receive public comment on this report. Per the respective statutory sections, after review of this report and receipt and review of public comment thereon, FDA will establish a capacity planning methodology for adjusting the annual fee revenue amounts for the PDUFA and BsUFA programs.

DATES: Submit either electronic or written comments on the report by May 6, 2020, to ensure that the Agency considers your comment on this report before it implements the capacity planning adjustment methodology.

ADDRESSES: You may submit comments on this report at any time 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–0989 for ''Assessing the Resource Needs of the Prescription Drug User Fee Act, Biosimilar User Fee Act, Report Publication; Request for Comments.'' Received comments 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.

- 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.

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 providing options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug and biosimilar biologic review programs. FDA, in both the PDUFA VI and BsUFA II commitment letters, committed to obtaining this report and publishing it before September 30, 2020. These commitments were also codified in the statute authorizing these programs (sections 736(c)(2)(C) and 744H(c)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379h(c)(2)(C) and 379j–52(c)(2)(B)).

PDUFA and BsUFA, (referred to collectively here as ''UFA(s)'') each establish fee amounts for each fiscal year. Although the specifics for each UFA are different, the process for each generally involves the following: Taking an annual base revenue amount and adjusting that base revenue amount for inflation and other UFA-specific adjustments to establish a target revenue amount for the fiscal year for the UFA. The target revenue amount sets the total amount of fee revenue for the UFA that FDA expects to collect for that fiscal year. The target revenue amount is then divided up based on UFA-specific processes to set the individual fee amounts for the fiscal year.

While this process creates a relatively predictable source of UFA fee revenue for FDA, it also requires a method for adjustment to account for changes in workload. For example, without an adjustment for workload, during a period of growth in regulatory submissions the target revenue will remain fixed and a higher number of submissions results in the same total revenue collected; in other words, the Agency would have more work while fee revenue remains fixed and would not be able to afford hiring the additional staff required to maintain review timeline performance.

This issue was recognized by PDUFA-program stakeholders, and in 2003, the first year of PDUFA III, a Workload Adjustment was introduced. This adjustment created a means to adjust the annual PDUFA target revenue to account for long-term changes in the volume of certain regulatory submissions. Although an important mechanism to help ensure that the PDUFA target revenue keeps pace with regulatory submissions, the Workload Adjustment has been a topic in each PDUFA reauthorization negotiation since its inception. As such, it has undergone a number of changes, notably the addition and later removal of a factor to adjust revenue based on the complexity of submissions. It has also been the subject of a number of studies. A theme emerging from these studies identified the Workload Adjuster methodology as suboptimal, but the best method reasonably possible based on the data available to FDA at that time.

In PDUFA VI (fiscal years 2018 to 2022), FDA made commitments to help improve the available data and in turn the adjuster methodology. These commitments included establishing a Resource Capacity Planning capability and modernizing FDA's activity-based time reporting to provide better data to inform current and likely future resource needs. PDUFA VI changed the name of the adjustment to the *Capacity Planning Adjustment,* established an interim methodology for the early years of PDUFA VI, and outlined a process to implement a new fee adjustment methodology.

The process calls for FDA to obtain, through a contract with an independent accounting or consulting firm, an evaluation of options and recommendations for a new methodology to accurately assess changes in the resource and capacity needs of the human drug review program. Booz Allen Hamilton was commissioned 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,* and FDA will review public comments on the report. After review of the public comments, FDA can then implement a new robust methodology for assessing the resource needs of the program that results from sustained increases in PDUFA workload, as appropriate and warranted in light of comments we receive.

Within BsUFA II (fiscal years 2018 to 2022), FDA made a commitment to use this same study to also assess options and recommendations for a new methodology to assess changes in the resource and capacity needs of the biosimilar biological product review program. Whereas PDUFA has an interim Capacity Planning Adjustment in place now, BsUFA does not have and has not had an adjustment designed to accomplish similar goals for the BsUFA program. Like with the process outlined with PDUFA, FDA can also implement an adjustment methodology following the publication of the report and review of any public comments, as appropriate and warranted in light of comments we receive.

Dated: April 1, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–07175 Filed 4–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Council on Graduate Medical Education

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Council on Graduate Medical Education (COGME) meeting previously announced as in-person and webinar/conference call on Tuesday, April 28, 2020, and Wednesday, April 29, 2020, has changed its format, date, and time. The meeting will now be a one-day webinar and conference call only on Wednesday, April 29, 2020, from 12:00 p.m.–5:00 p.m. Eastern Time. The webinar link, conference dial-in number, meeting materials, and agenda will be available on the COGME website: *https://www.hrsa.gov/advisory-committees/graduate-medical-edu/meetings/index.html.*