the samples from the original bioequivalence study. FDA recommended to Watson that the results of the requested bioequivalence studies or re-assays be submitted to ANDA 078394 within 6 months of the date of the August 9, 2011, letter.

In its October 28, 2019, notice of opportunity for a hearing, CDER provided Watson with an opportunity to request a hearing to show why approval of ANDA 078394 should not be withdrawn. No request for a hearing on this matter was received following publication of the notice for an opportunity for a hearing in the **Federal Register**. Failure to file a written notice of participation and request for a hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by Watson not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of ANDA 078394 and a waiver of any contentions concerning the legal status of the drug product. We note that in correspondence dated November 1, 2019, Watson requested withdrawal of the approval of ANDA 078394 under § 314.150(c) (21 CFR 314.150(c)). Because this application withdrawal is effectuated through the notice-of-opportunity-for-a-hearing process (see 84 FR 57739), Watson's request to withdraw approval under § 314.150(c) is moot.

FDA finds that Watson has repeatedly failed to submit the required data to support a finding of bioequivalence for ANDA 078394. In addition, under § 314.200, FDA finds that Watson has waived any contentions concerning the legal status of the drug product. Therefore, under section 505(e) of the FD&C Act, approval of ANDA 078394, and all amendments and supplements thereto, is withdrawn (see **DATES**). Introduction or delivery for introduction of this drug product into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a), 331(d))).

Dated: July 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16784 Filed 7–31–20; 8:45 am]

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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 September 2, 2020 to ensure that the Agency considers your comment on this report.

ADDRESSES: You may submit comments on this report at any time prior to September 2, 2020 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 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.

[FR Doc. 2020–16794 Filed 7–31–20; 8:45 am]

BILLING CODE 4164–01–P

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2021 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

DATES: This fee is effective October 1, 2020.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2021 third-party certification program user fee rate announced in this notice is effective on October 1, 2020, and will remain in effect through September 30, 2021.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2021

FDA must estimate its costs for each activity in order to establish fee rates for FY 2021. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2021

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.