TABLE 13—FEE SCHEDULE FOR FY 2021

Fee Category	Fee rates for FY 2021
Application:	
Requiring clinical data	$2,875,842
Not requiring clinical data	$1,437,921
Program	$336,432

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA that is submitted on or after October 1, 2020. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (**Note**: only full payments are accepted. No partial payments can be made online). Once an invoice is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979107, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery). Please make sure that the FDA post office box number (P.O. Box 979107) is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in FDA not filing an application and other penalties. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2021 program fees under the new fee schedule in August 2020. Payment will be due on October 1, 2020. FDA will issue invoices in December 2020 for FY 2021 program fees that qualify for fee assessments after the August 2020 billing.

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16833 Filed 7–29–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3723]

Watson Laboratories, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Oxycodone Hydrochloride and Ibuprofen Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is withdrawing approval of an abbreviated new drug application (ANDA) for oxycodone hydrochloride and ibuprofen tablets. The basis for the withdrawal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA. The holder of the ANDA has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 3, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: FDA's Office of Generic Drugs (OGD) approved ANDA 078394, held by Watson Laboratories, Inc. (Watson),[1] for a generic version of oxycodone hydrochloride and ibuprofen tablets, 5 milligrams (mg)/400 mg, under the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and FDA's implementing regulations. The OGD approved ANDA 078394 on November 26, 2007. In a notice of opportunity for a hearing (NOOH) published in the **Federal Register** of October 28, 2019 (84 FR 57739), CDER notified Watson of CDER's proposal to issue an order, under section 505(e) of the FD&C Act and § 314.150 (21 CFR 314.150), withdrawing approval of ANDA 078394 and all amendments and supplements to it on the grounds that Watson has failed to submit the required bioequivalence data necessary to demonstrate the bioequivalence of its drug product.

As noted in the October 28, 2019, NOOH, FDA issued a letter to Watson on August 9, 2011, regarding ANDA 078394 because this drug product application was supported by bioequivalence studies with the bioanalytical analysis conducted by Cetero Research at the Houston, TX, site between April 1, 2005, and June 15, 2010. As FDA noted in its August 9, 2011 correspondence, inspection findings regarding Cetero Research's bioequivalence studies raised significant concerns about the validity of the reported results of the analytical studies conducted between April 2005 and June 2010 in support of drug applications. Accordingly, FDA informed Watson that ANDA 078394 needed to be supplemented by conducting new bioequivalence studies or re-assaying

[1] In correspondence dated February 23, 2017, Watson notified FDA that Watson is an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.

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]

BILLING CODE 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 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://*