wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16039 Filed 7–27–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0649]

Determination That CECLOR CD (Cefaclor Extended-Release Tablets) 375 Milligrams and 500 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, Except the Indication of Secondary Bacterial Infections of Acute Bronchitis, Which Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that CECLOR CD (cefaclor extended-release tablets) 375 milligrams (mg) and 500 mg were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication of secondary bacterial infections of acute bronchitis (SBIAB) that was withdrawn for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to suspend approval of any abbreviated new drug application (ANDA) that refers to this drug product and has removed the indication for SBIAB. This determination also will allow FDA to continue to approve ANDAs that refer to these drug products as long as they meet relevant legal and regulatory requirements. However, the Agency will not accept or approve ANDAs for CECLOR CD (cefaclor extended-release tablets) 375 mg and 500 mg that include SBIAB as an indication.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and, with certain exceptions, labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Under § 314.161(a)(2), the Agency must also determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that referred to the listed drug have already been approved prior to its market withdrawal. If the Agency determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, and there are approved ANDAs that reference that listed drug, FDA will initiate a proceeding to determine whether the suspension of the ANDAs is also required (21 CFR 314.161(d)).

CECLOR CD (cefaclor extended-release tablets) 375 mg and 500 mg are the subject of NDA 050673 held by Eli Lilly and Co., and initially approved on June 28, 1996. CECLOR CD (cefaclor extended-release tablets) is indicated for the treatment of patients with the following mild to moderate infections when caused by susceptible strains of the designated microorganisms:

- Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae* (non-β-lactamase-producing strains only), *Moraxella catarrhalis* (including β-lactamase-producing strains) or *Streptococcus pneumoniae.*
- Secondary bacterial infections of acute bronchitis due to *H. influenzae* (non-β-lactamase-producing strains only), *M. catarrhalis* (including β-lactamase-producing strains), or *S. pneumoniae.*
- Pharyngitis and tonsillitis due to *Streptococcus pyogenes.*
- Uncomplicated skin and skin structure infections due to *Staphylococcus aureus* (methicillin-susceptible).

On June 13, 2005, Eli Lilly and Co. submitted a request to the Agency to withdraw approval of NDA 050673, CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, under 21 CFR 314.150(c). The Agency published a **Federal Register** notice on April 22, 2014, withdrawing approval of NDA 050673, effective May 22, 2014.[1]

After reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication for SBIAB.

Based on a review of relevant information, FDA has concluded that the SBIAB indication is not appropriate because most cases of SBIAB are considered to be viral or noninfectious. As an antibacterial drug, CECLOR CD (cefaclor extended-release tablets) is not considered to be effective to treat SBIAB. Such use of CECLOR CD (cefaclor extended-release tablets) would likely result in inappropriate antibacterial drug use. Accordingly, for the treatment of SBIAB, the benefit-risk profile of CECLOR CD (cefaclor extended-release tablets) is unfavorable and does not support approval of these products (or ANDAs referencing them) for this indication. For the remaining indications, the Agency has determined that CECLOR CD (cefaclor extended-release tablets) continues to have a favorable benefit-risk profile.

Accordingly, the Agency will continue to list CECLOR CD (cefaclor extended-release tablets), 375 mg and 500 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The approved ANDA has

[1] See 79 FR 22501 (April 22, 2014).

removed the SBIAB indication from its labeling, consistent with this decision. In addition, FDA will continue to accept and, where appropriate, approve ANDAs that refer to CECLOR CD (cefaclor extended-release tablets) as long as they meet relevant legal and regulatory requirements, but FDA will not accept or approve ANDAs that refer to this drug product and propose to include the SBIAB indication. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16050 Filed 7–27–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0698]

Outsourcing Facility Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2022 rates for the establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2022 rates for the small business establishment fee ($5,824), the non-small business establishment fee ($18,999), and the reinspection fee ($17,472) for outsourcing facilities; provides information on how the fees for FY 2022 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2021, and will remain in effect through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: *For more information on human drug compounding and outsourcing facility fees:* Visit FDAs website at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can become an ''outsourcing facility.'' Outsourcing facilities, as defined in section 503B(d)(4), are facilities that meet all the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs); and (3) section 582 (21 U.S.C. 360eee–1) concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) An annual establishment fee from each outsourcing facility and (2) a reinspection fee from each outsourcing facility subject to a reinspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, reinspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's website at: *https://www.fda.gov/media/136683/download.*

II. Fees for FY 2022

A. Methodology for Calculating FY 2022 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: One based on FDA's payroll costs and one based on FDA's non-payroll costs for the first 3 of the 4 previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first 3 of the 4 previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2022. The 3-year average is 2.7383 percent.

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	.....
Total FTE	17,023	17,144	17,535	.....
PC&B per FTE	$158,061	$152,826	$163,992	.....
Percent change from previous year	4.2206	−3.3120	7.3063	2.7383