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Determination That CECLOR CD (Cefaclor Extended-Release Tablets) 375 Milligrams and 500 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, Except the Indication of Secondary Bacterial Infections of AcuteBronchitis, Which Was Withdrawn From Sale for Reasons of Safety or Effectiveness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or we) has determined that CECLOR CD (cefaclor extended-release tablets) 375 milligrams (mg) and 500 mg were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication of secondary bacterial infections of acute bronchitis (SBIAB) that was withdrawn from sale for reasons of safety or effectiveness.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 20993–0022, 301–796–3363, 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 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.

This determination 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 of secondary bacterial infections of acute bronchitis (SBIAB), was made on July 20, 2021.

On June 28, 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.

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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.


SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounding 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 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. The non-payroll component of the annual inflation adjustment is calculated by taking the average change in per-FTE PC&B in the first 3 of the 4 previous fiscal years. These fees:

(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).

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

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>3-Year average</th>
</tr>
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<tbody>
<tr>
<td>Total PC&amp;B</td>
<td>$2,690,678,000</td>
<td>$2,620,052,000</td>
<td>$2,875,592,000</td>
<td>2.7383 percent</td>
</tr>
<tr>
<td>Total FTE</td>
<td>17,023</td>
<td>17,144</td>
<td>17,535</td>
<td>2.7383 percent</td>
</tr>
<tr>
<td>PC&amp;B per FTE</td>
<td>$158,061</td>
<td>$152,826</td>
<td>$163,992</td>
<td>2.7383 percent</td>
</tr>
<tr>
<td>Percent change from previous year</td>
<td>4.2206</td>
<td>–3.1210</td>
<td>7.3063</td>
<td>2.7383 percent</td>
</tr>
</tbody>
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