

Jeffery M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–16090 Filed 7–26–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)—Health Disparities Subcommittee (HDS)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC announces the following meeting for the Advisory Committee to the Director, Centers for Disease Control and Prevention—Health Disparities Subcommittee (ACD, CDC–HDS). This meeting is open to the public, limited only by the 50 audio phone lines. The public is also welcome to listen to the meeting by teleconference. Please dial (866) 918–8397 and enter code 9346283. There are 50 lines available. The public comment period is from 3:15 p.m.–3:20 p.m.

DATES: The meeting will be held on October 9, 2018, 1:30 p.m. to 3:30 p.m., EDT.

ADDRESSES: Teleconference phone (866) 918–8397 and enter code 9346283.

FOR FURTHER INFORMATION CONTACT: Leandris Liburd, Ph.D., M.P.H., M.A., Designated Federal Officer, Health Disparities Subcommittee, Advisory Committee to the Director, CDC, 1600 Clifton Road NE, M/S K–77, Atlanta, Georgia 30329. Telephone (404) 498–6482; Email: ACDDirector@cdc.gov.

SUPPLEMENTARY INFORMATION:

Purpose: The Subcommittee will provide counsel to the CDC Director through the ACD on strategic and other health disparities and health equity issues and provide guidance on opportunities for CDC.

Matters to be Considered: The agenda will include discussions on new member orientation. This meeting will provide information to new members regarding their role & duties on this subcommittee. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated

the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dia Taylor,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2018–16103 Filed 7–26–18; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–P–1283]

Determination That Metaxalone Tablets, 640 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that metaxalone tablets, 640 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for metaxalone tablets, 640 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Glen Cheng, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6217, Silver Spring, MD 20993–0002, 301–796–1494.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

355(j)(7)), which 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.

Metaxalone tablets, 640 mg, are the subject of NDA 22–503, held by Primus Pharmaceuticals, Inc., and initially approved on June 1, 2015. Metaxalone tablets, 640 mg, are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.

In a letter dated September 30, 2015, the previous NDA holder CorePharma, LLC notified FDA that metaxalone tablets, 640 mg, were discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Sovereign Pharmaceuticals, LLC submitted a citizen petition dated March 26, 2018 (Docket No. FDA–2018–P–1283), under 21 CFR 10.30, requesting that the Agency determine whether metaxalone tablets, 640 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that metaxalone tablets, 640 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that metaxalone tablets, 640 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of metaxalone tablets, 640 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that this drug product was

not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list metaxalone tablets, 640 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to metaxalone tablets, 640 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. 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, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16031 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0007]

Generic Drug User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes the Food and Drug Administration (FDA, Agency, or we) to

assess and collect fees for abbreviated new drug applications (ANDAs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, contract manufacturing organization (CMO) facilities, and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2019 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT:

Melissa Hurley, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202J, Silver Spring, MD 20993–0002, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain types of applications for human generic drug products; (2) certain facilities where APIs and FDFs are produced; (3) certain DMFs associated with human generic drug products; and (4) generic drug applicants who have approved ANDAs (the program fee) (see section 744B(a)(2)–(5) of the FD&C Act).

GDUFA II stipulates that user fees should total \$493,600,000 annually adjusted each year for inflation. For FY 2019, the generic drug fee rates are: ANDA (\$178,799), DMF (\$55,013), domestic API facility (\$44,226), foreign API facility (\$59,226), domestic FDF facility (\$211,305), foreign FDF facility (\$226,305), domestic CMO facility (\$70,435), foreign CMO facility (\$85,435), large size operation generic drug applicant program (\$1,862,167), medium size operation generic drug

applicant program (\$744,867), and small business generic drug applicant program (\$186,217). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019.

II. Fee Revenue Amount for FY 2019

The base revenue amount for FY 2019 is \$493,600,000, as set in the statute (see section 744B(b)(1) of the FD&C Act). GDUFA II directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA II, please refer to the FDA website (<https://www.fda.gov/gdufa>). The ANDA, DMF, API facility, FDF facility, CMO facility, and generic drug applicant program fee (GDUFA program fee) calculations for FY 2019 are described in this document.

GDUFA II specifies that the \$493,600,000 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see sections 744B(c)(1)(B) and (C) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of human generic drug activities for the first 3 of the preceding 4 fiscal years (see section 744B(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTE 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 2019. The 3-year average is 2.4152 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

| Fiscal year | 2015 | 2016 | 2017 | 3-Year average |
|---|-----------------|-----------------|-----------------|----------------|
| Total PC&B | \$2,232,304,000 | \$2,414,728,159 | \$2,581,551,000 | |
| Total FTE | 15,484 | 16,381 | 17,022 | |
| PC&B per FTE | \$144,168 | \$147,408 | \$151,660 | |
| Percent Change from Previous Year | 2.1136 | 2.2474 | 2.8845 | 2.4152 |

The statute specifies that this 2.4152 percent should be multiplied by the proportion of PC&B expended for

human generic drug activities for the first 3 of the preceding 4 fiscal years. Table 2 shows the amount of PC&B and

the total amount obligated for human generic drug activities from FY 2015 through FY 2017.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS

| Fiscal year | 2015 | 2016 | 2017 | 3-Year average |
|-------------------|---------------|---------------|---------------|----------------|
| PC&B | \$201,116,305 | \$242,963,571 | \$271,748,229 | |
| Non-PC&B | \$251,589,013 | \$250,987,599 | \$262,058,852 | |
| Total Costs | \$452,705,318 | \$493,951,170 | \$533,807,081 | |