DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0020]

SpecGX LLC, et al.; Withdrawal of Approval of 30 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of 30 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of April 29, 2024.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040163	Meperidine Hydrochloride (HCl) Preservative Free Injectable, 10 milligrams (mg)/milliliters (mL).	SpecGx LLC, 385 Marshall Ave., Webster Groves, MO 63119.
ANDA 040352	Meperidine HCl Tablets, 50 mg and 100 mg	Do.
ANDA 040680	Oxycodone and Acetaminophen Solution, 325 mg/5 mL; 5 mg/5 mL	Do.
ANDA 040773	Benzphetamine HCl Tablets, 50 mg	Do.
ANDA 063002	Ancef in Plastic Container (cefazolin sodium) Injectable, Equivalent to (EQ) 10 mg base/mL and EQ 20 mg base/mL.	Baxter Healthcare Corp., 1 Baxter Pkwy., Deerfield, IL 60015.
ANDA 076280	Tizanidine HCl Tablets, EQ 2 mg base and EQ 4 mg base	Target Health LLC, U.S. Agent for CASI Pharmaceuticals, Inc., 450 Commerce Boulevard, Carlstadt, NJ 07072.
ANDA 077021	Cilostazol Tablets, 100 mg	Do.
ANDA 077310	Cilostazol Tablets, 50 mg	Do.
ANDA 077517	Ondansetron HCl Tablets, EQ 4 mg base, EQ 8 mg base, and EQ 24 mg base.	Do.
ANDA 078319	Sumatriptan Succinate Injectable, EQ 4 mg base/0.5 mL (EQ 8 mg base/mL) and EQ 6 mg base/0.5 mL (EQ 12 mg base/mL).	Antares Pharma, Inc., 100 Princeton South Corporate Center, Suite 300, Ewing, NJ 08628.
ANDA 087748	Blephamide S.O.P (Prednisolone Acetate; Sulfacetamide Sodium) Ointment, 0.2%; 10%.	Allergan Sales, LLC, 2525 Dupont Dr., Irvine, CA 92612.
ANDA 087804	Butalbital, Acetaminophen, and Caffeine Tablets, 325 mg; 50 mg; 40 mg.	SpecGx LLC.
ANDA 087846	Imipramine HCl Tablets, 10 mg, 25 mg, and 50 mg	Do.
ANDA 090623	Ranitidine HCl Syrup, EQ 15 mg base/mL	Aurobindo Pharma USA, Inc., U.S. Agent for Aurobindo Pharma Ltd., 279 Princeton-Hightstown Rd., East Windsor, NJ 08520.
ANDA 202321	Oxymorphone HCl Tablets, 5 mg, and 10 mg	SpecGx LLC.
ANDA 202946	Oxymorphone HCl Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.	Do.
ANDA 204823	Cyproheptadine HCl Syrup, 2 mg/5 mL	Patrin Pharma, Inc., P.O. Box 1481, Skokie, IL 60076.
ANDA 206672	Entecavir Tablets, 0.5 mg and 1 mg	Target Health LLC.
ANDA 206710	Paricalcitol Capsules, 1 microgram (mcg), 2 mcg, and 4 mcg	Alvogen PB Research and Development LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd., Nantou Plant, 44 Whippany Rd, Suite 300, Morristown, NJ 07960.
ANDA 207578	Ranitidine HCl Tablets, EQ 150 mg base	Aurobindo Pharma USA, Inc.
ANDA 207579	Ranitidine HCl Tablets, EQ 75 mg base	Do.
ANDA 209550	Tenofovir Disoproxil Fumarate Tablets, 300 mg	Target Health LLC.
ANDA 209787	Methotrexate Sodium Tablets, EQ 2.5 mg base	Alvogen PB Research and Development LLC.
ANDA 210228	Ranitidine HCl Tablets, EQ 150 mg base	PTS Consulting, LLC, U.S. Agent for THINQ Pharma-CRO Private Ltd., 6739 Vahalla Ct., Shawnee, KS 66217.
ANDA 210250	Ranitidine HCl Tablets, EQ 75 mg base	Do.
ANDA 211058	Ranitidine HCl Capsules, EQ 150 mg base and EQ 300 mg base	Aurobindo Pharma USA, Inc.
ANDA 212312	Sildenafil Citrate for Suspension, EQ 10 mg base/mL	Tris Pharma, Inc., 2033 Route 130, Suite D, Monmouth Junction, NJ 08852.
ANDA 212626	Vigabatrin for Solution, 500 mg/packet	SpecGx LLC.
ANDA 213456	Colesevelam HCl Tablets, 625 mg	SPH Phililab Inc., 5207 Militia Hill Rd., Suite 100, Plymouth Meeting, PA 19462.
ANDA 215343	Fluticasone Propionate Ointment, 0.005%	BF Suma Pharmaceuticals Inc., U.S. Agent for Bright Future Pharmaceutical Laboratories Ltd., 5001 Earle Ave., Rosemead, CA 91770.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 29, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on April 29, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06730 Filed 3–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1298]

Over-the-Counter Monograph Drug User Fee Program—Facility Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the over-the-counter (OTC) monograph drug facility (MDF) fee rates under the OTC monograph drug user fee program (OMUFA) for fiscal year (FY) 2024. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests (OMORs). This notice publishes the OMUFA facility fee rates for FY 2024.

DATES: These facility fees are effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo (Funmi) Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC OMORs. The OTC OMOR fee rates for FY 2024 were published on September 12, 2023.[1] These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC MDF is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act); and
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2024 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2023, through December 31, 2023.[2] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees for FY 2024 are due on June 3, 2024 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[3]

As discussed in greater detail below:

- OTC monograph drug facilities are exempt from FY 2024 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2022 (see section 744M(a)(1)(B)(i) of the FD&C Act).
- Entities that registered with FDA during the Coronavirus Disease 2019 (COVID–19) pandemic whose sole activity with respect to OTC monograph drugs during the pandemic consists (or had consisted) of manufacturing OTC hand sanitizer products[4] are not identified as OTC monograph drug facilities subject to OMUFA facility fees for FY 2024.[5]

For FY 2024, the OMUFA facility fee rates are: MDF facility fees ($34,166) and CMO facility fees ($22,777). These fees are effective for the period from October 1, 2023, through September 30, 2024.[6] This document is issued pursuant to section 744M(a)(4) and 744M(c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA facility fees for FY 2024 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2024

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year

[1] *https://www.federalregister.gov/documents/2023/09/12/2023-19609/over-the-counter-monograph-drug-user-fee-program-otc-monograph-order-requests-fee-rates-for-fiscal.*

[2] Under section 744M(a)(1) of the FD&C Act, ''Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility.'' For purposes of FY 2024 facility fees, that time period is January 1, 2023, through December 31, 2023.

[3] Assuming that, as we anticipate, the FY 2024 fee appropriation will occur prior to June 3, 2024. Under section 744M(a)(1)(D)(ii), the FY 2024 facility fees are due on the later of: (1) the first business day of June 2024 (*i.e.,* June 3, 2024) or (2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of FY 2024 OMUFA fees.

[4] The term ''hand sanitizer'' commonly refers to consumer antiseptic rubs. However, because the Department of Health and Human Services (HHS) notice published January 12, 2021, referred to ''persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID–19 Public Health Emergency'' (86 FR 2420 *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during*), we are using the same terminology—''hand sanitizer products''—to refer to OTC monograph drug products intended for use (without water) as antiseptic hand rubs or antiseptic hand wipes by consumers or healthcare personnel.

[5] See HHS **Federal Register** notice of January 12, 2021, 86 FR 2420, *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during.*

[6] These OMUFA fees are for FY 2024, per section 744M(a) of the FD&C Act.