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://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993, 301–796–3100, *Dominic.Markwordt@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' This draft guidance describes FDA's interpretation of, and policies concerning, the prohibition on wholesaling in section 503B of the FD&C Act (21 U.S.C. 353b). This draft guidance also describes examples of how FDA intends to apply section 503B of the FD&C Act's wholesaling provision.

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drugs compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee-1) (concerning drug supply chain security requirements).

Pursuant to section 503B(a)(8) of the FD&C Act, one of the conditions that must be met for a drug compounded by an outsourcing facility to qualify for the exemptions in section 503B of the FD&C Act is that the drug will not be sold or transferred by an entity other than the outsourcing facility that compounded the drug. However, the wholesaling provision does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act. The statutory prohibition on wholesaling in section 503B(a)(8) of the FD&C Act helps to ensure that compounding is based on individual patient need, which, in turn, reduces the overall risk of patient harm and helps to preserve the integrity of the U.S. drug approval process. It also helps to preserve the integrity of the U.S. drug supply chain. This prohibition, like other conditions in section 503B of the FD&C Act, preserves important distinctions between outsourcing facilities, which are intended to compound drugs for patients whose medical needs cannot be met by approved drugs, from conventional manufacturers, which generally engage in mass manufacturing of FDA-approved drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the ''Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach than what is described in the guidance can be used if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 207 pertaining to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910–0045. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910–0139. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910–0230. The collections of information for adverse event reporting and human drug compounding under section 503B of the FD&C Act have been approved under OMB control number 0910–0800.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs* or *https://www.regulations.gov.*

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2226]

Gemini Laboratories, LLC, et al.; Withdrawal of Approval of One New Drug Application for OXANDRIN (Oxandrolone) Tablets and Four Abbreviated New Drug Applications for Oxandrolone Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for OXANDRIN (oxandrolone) tablets, 2.5 milligrams (mg) and 10 mg, held by Gemini Laboratories, LLC (Gemini). Gemini

voluntarily requested withdrawal of this application and waived its opportunity for a hearing. In addition, FDA is withdrawing approval of four abbreviated new drug applications (ANDAs) for oxandrolone tablets from multiple ANDA holders. Upsher-Smith Laboratories, LLC (Upsher-Smith), Par Pharmaceutical, Inc. (Par), and Sandoz Inc. (Sandoz) voluntarily requested withdrawal of their respective applications and waived their opportunity for a hearing.

DATES: Approval is withdrawn as of June 28, 2023.

FOR FURTHER INFORMATION CONTACT: Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993–0002, 301–796–3600, *Alexandria.Fujisaki@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The applicants and their respective drugs and applications are included in the following table.

Application No.	Drug	Applicant
NDA 013718	Oxandrin (oxandrolone) Tablets, 2.5 mg and 10 mg	Gemini, 400 Crossing Blvd., 5th Floor, Bridgewater, NJ 08807.
ANDA 076761	Oxandrolone Tablets, 2.5 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.
ANDA 076897	Oxandrolone Tablets, 2.5 mg and 10 mg	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 077827	Oxandrolone Tablets, 2.5 mg and 10 mg	Par Pharmaceutical, Inc., c/o Endo, 1400 Atwater Dr., Malvern, PA 19355.
ANDA 078033	Oxandrolone Tablets, 10 mg	Upsher-Smith Laboratories, LLC, 6701 Evenstad Dr., Maple Grove, MN 55369.

In a letter dated March 26, 2019, Gemini requested that FDA withdraw approval of NDA 013718 for OXANDRIN (oxandrolone) tablets, 2.5 mg and 10 mg, under § 314.150(c) (21 CFR 314.150(c)), stating that the product was no longer being marketed. Subsequently, on December 16, 2022, FDA notified Gemini and other holders of approved applications that the Agency believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug products should be removed from the market, and to enable withdrawal of approval of their applications under § 314.150(d).

The anabolic steroid OXANDRIN (oxandrolone) tablets, 2.5 mg and 10 mg, under NDA 013718, is indicated as follows: ''as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.'' [1] FDA initially approved NDA 013718 in 1964.

In January 1984, FDA's Endocrinologic and Metabolic Drugs Advisory Committee met and discussed anabolic steroids. The advisory committee unanimously concluded that there was no evidence of efficacy for oxandrolone.[2]

As communicated in the product labeling, multiple safety warnings and precautions are associated with the use of oxandrolone tablets including peliosis hepatis, sometimes associated with liver failure and intra-abdominal hemorrhage; liver cell tumors, sometimes fatal; and blood lipid changes that are known to be associated with increased risk of atherosclerosis.[3] Per the labeling, additional warnings with using this product include the risks associated with cholestatic hepatitis, hypercalcemia in patients with breast cancer, and increased risk for the development of prostatic hypertrophy and prostatic carcinoma in geriatric patients.[4]

Based on FDA's review of currently available data and information regarding the safety and effectiveness of oxandrolone tablets, the Agency believes that the potential problems associated with oxandrolone tablets are sufficiently serious that the drug should be removed from the market.

After FDA notified Gemini that it believes the potential problems associated with the drug are sufficiently serious that the drug should be removed from the market pursuant to § 314.150(d), Gemini requested in a letter dated December 19, 2022 that FDA withdraw approval of NDA 013718 under § 314.150(d). Gemini waived its opportunity for a hearing. In a letter dated December 23, 2022, Sandoz requested that FDA withdraw approval of ANDA 076897 under § 314.150(d). Sandoz waived its opportunity for a hearing. In a letter dated January 5, 2023, Par requested that FDA withdraw approval of ANDA 077827 under § 314.150(d). Par waived its opportunity for a hearing. In separate letters dated January 6, 2023, Upsher-Smith requested that FDA withdraw approval of ANDAs 078033 and 076761 under § 314.150(d). Upsher-Smith waived its opportunity for a hearing.

Therefore, for the reasons discussed above, which the applicants do not dispute in their letters requesting withdrawal of approval under § 314.150(d), FDA's approval of NDA 013718 and ANDAs 076897, 077827, 078033, and 076761, and all amendments and supplements thereto, are withdrawn (see DATES). Distribution of Gemini's OXANDRIN (oxandrolone) tablets, 2.5 mg and 10 mg; Sandoz's oxandrolone tablets 2.5 mg and 10 mg; Par's oxandrolone tablets, 2.5 mg and 10 mg; or Upsher-Smith's oxandrolone tablets, 2.5 mg and 10 mg, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–13733 Filed 6–27–23; 8:45 am]

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[1] See OXANDRIN (oxandrolone) tablets, NDA 013718, product labeling, (rev. June 2005), available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/013718s023lbl.pdf.*

[2] See minutes from the January 24 to 25, 1984, advisory committee meeting discussing anabolic steroids, at pg. 7.

[3] See OXANDRIN (oxandrolone) tablets, NDA 013718, product labeling, (rev. June 2005).

[4] Id.