4164-01-P

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DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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

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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.

§ 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.

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