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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-P-0558]

Determination That Oxandrin (Oxandrolone) Tablets, 2.5 Milligrams and 10 Milligrams, Were Withdrawn From Sale for Reasons of Safety or Effectiveness; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of September 13, 2023 (88 FR 62799). The notice announced the determination that Oxandrin (oxandrolone) tablets, 2.5 milligrams (mg) and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. The notice did not include the determination that the abbreviated new drug applications (ANDAs) referencing Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were also determined to be withdrawn from sale for reasons of safety or effectiveness and that these ANDAs would be removed from "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." This notice corrects that error.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 13, 2023, appearing on pages 62799 and 62800 in FR Doc. 2023-19796, the following corrections are made:

1. On page 62799, in the first column, before the last sentence in the SUMMARY section, the following sentence is added:

Additionally, FDA has determined that Par Pharmaceutical Inc.'s ANDA 077827 for oxandrolone tablets, 2.5 mg and 10 mg; Roxane Laboratories, Inc.'s ANDA 077249 for oxandrolone tablets, 2.5 mg and 10 mg; Sandoz Inc.'s ANDA 076897 for oxandrolone tablets, 2.5 mg and 10 mg; and Upsher Smith Laboratories LLC's ANDA 076761 for oxandrolone tablet, 2.5 mg, and ANDA 078033 for oxandrolone tablet, 10 mg, that all reference Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were also withdrawn for reasons of safety or effectiveness.

2. On page 62799 in the third column, the second paragraph is corrected to read as follows:

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 for oxandrolone tablets, 2.5 mg and 10 mg, 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). After FDA notified Gemini that it believes the potential problems associated with the drugs are sufficiently serious that the drugs 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 for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, under § 314.150(d). Similarly, after notification by FDA, the following holders of approved ANDAs requested withdrawal of their applications under § 314.150(d) and waived their opportunity for a hearing: Par Pharmaceutical Inc. for ANDA 077827 for oxandrolone tablets, 2.5 mg and 10 mg; Sandoz Inc. for ANDA 076897 for oxandrolone tablets, 2.5 mg and 10 mg; and Upsher Smith Laboratories LLC for ANDA 076761 for oxandrolone tablet, 2.5 mg, and ANDA 078033 for oxandrolone tablet, 10 mg. In the *Federal Register* of June 28, 2023 (88 FR 41970), FDA announced that it was withdrawing

approval of NDA 013718, ANDA 077827, ANDA 076897, ANDA 076761, and ANDA 078033, effective June 28, 2023. Additionally, Roxane Laboratories, Inc. previously requested withdrawal of its ANDA 077249 for oxandrolone tablets, 2.5 mg and 10 mg, and waived its opportunity for a hearing. In the *Federal Register* of May 19, 2009 (74 FR 23407), FDA announced that it was withdrawing approval of ANDA 077249, effective June 18, 2009.

3. On page 62800 at the top of the second column, at the end of the first paragraph, the following two sentences are added:

Likewise, FDA has determined under § 314.161 that those ANDAs that used Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, approved in NDA 013718 as their reference listed drug were withdrawn for reasons of safety or effectiveness. Accordingly, the Agency will remove Par Pharmaceutical Inc.'s ANDA 077827 for oxandrolone tablets, 2.5 mg and 10 mg; Roxane Laboratories, Inc.'s ANDA 077249 for oxandrolone tablets, 2.5 mg and 10 mg; Sandoz Inc.'s ANDA 076897 for oxandrolone tablets, 2.5 mg and 10 mg; and Upsher Smith Laboratories LLC's ANDA 076761 for oxandrolone tablet, 2.5 mg, and ANDA 078033 for oxandrolone tablet, 10 mg, from the list of drug products published in the Orange Book per § 314.162.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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