ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SMR Form	Care Provider Program Staff	250	1.38	.08	27.6	9

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 6 U.S.C 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al.,* v. *Janet Reno*, Attorney General of the United States, et al., Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–19795 Filed 9–12–23; 8:45 am]

BILLING CODE 4184–45–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Determination That Oxandrin (Oxandrolone) Tablets, 2.5 Milligrams and 10 Milligrams, Were Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) has determined that Oxandrin (oxandrolone) tablets, 2.5 milligrams (mg) and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg.

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: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 (§ 314.162 (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.

The anabolic steroid Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, is the subject of NDA 013718, held by Gemini Laboratories LLC (Gemini), and initially approved on July 21, 1964 (for the 2.5 mg strength) and November 5, 2001 (for the 10 mg strength). Oxandrin 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]

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 that the Agency believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug product should be removed from the market, and to enable withdrawal of approval of its application under § 314.150(d). 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 for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg under § 314.150(d). In the **Federal Register** of June 28, 2023 (88 FR 41970), FDA announced that it was withdrawing approval of NDA 013718, effective June 28, 2023.

Novitium Pharma LLC submitted a citizen petition dated April 6, 2022 (Docket No. FDA–2022–P–0558), under 21 CFR 10.30, requesting that the Agency determine whether Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg,

[1] See Oxandrin (oxandrolone) tablets product labeling (NDA 013718, supplement 023), approved on June 20, 2005, available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/013718s023lbl.pdf.*

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 Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

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

As communicated in the product labeling for Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, multiple safety warnings and precautions are associated with the use of this product 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 product 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] Considering the safety concerns associated with the use of oxandrolone noted in the labeling, the Agency concluded that the benefit-risk profile of the drug product is unfavorable without substantial evidence to support effectiveness.

Based on a thorough evaluation of the information we have available to us and an evaluation of the latest version of the drug products' approved labeling, we have determined that the drug products would not be considered safe and effective if they were reintroduced to the market today. New clinical studies would first need to be conducted to address the concerns described above. Thus, 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 Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, were withdrawn for reasons of safety or effectiveness. Accordingly, the Agency will remove Oxandrin (oxandrolone) tablets, 2.5 mg and 10 mg, from the list of drug products published in the Orange Book per § 314.162. FDA will not accept or approve ANDAs that refer to this drug product.

Dated: September 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19796 Filed 9–12–23; 8:45 am]

BILLING CODE 4164–01–P

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

[3] See footnote 1.

[4] See footnote 1.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Kotha Subbaramaiah, Ph.D. (Respondent), who was a Professor of Biochemistry Research in Medicine, Department of Medicine, Weill Cornell Medical College (WCMC). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants P01 CA077839, P01 CA106451, R01 CA108773, R01 CA154481, T32 CA009685, R25 CA105012, and N01 CN43302, National Institute on Deafness and Other Communication Disorders (NIDCD), NIH, grant T32 DC000027, and National Center for Advancing Translational Sciences (NCATS), NIH, grant UL1 TR000457. The administrative actions, including debarment for a period of seven (7) years, were implemented beginning on August 16, 2023, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, JD, MPH, MBA, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Kotha Subbaramaiah, Ph.D., Weill Cornell Medical College: Based on the report of an investigation conducted by WCMC and additional analysis conducted by ORI in its oversight review, ORI found that Kotha Subbaramaiah, Ph.D., former Weill Cornell Medical College, WCMC, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P01 CA077839, P01 CA106451, R01 CA108773, R01 CA154481, T32 CA009685, R25 CA105012, and N01 CN43302, NIDCD, NIH, grant T32 DC000027, and NCATS, NIH, grant UL1 TR000457.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating data included in the following twelve (12) published papers:

- Increased levels of COX–2 and prostaglandin E2 contribute to elevated aromatase expression in inflamed breast tissue of obese women. *Cancer Discov.* 2012 Apr;2(4):356–65. doi: 10.1158/2159–8290.CD–11–0241 (hereafter referred to as ''*Cancer Discov.* 2012''). Retraction in: *Cancer Discov.* 2021 May;11(5):1306. doi: 10.1158/2159–8290.CD–21–0224.
- EP2 and EP4 receptors regulate aromatase expression in human adipocytes and breast cancer cells. Evidence of a BRCA1 and p300 exchange. *J Biol Chem.* 2008 Feb 8;283(6):3433–44. doi: 10.1074/jbc.M705409200 (hereafter referred to as ''*J Biol Chem.* 2008''). Retraction in: *J Biol Chem.* 2020 Jan 3; 295(1):295. doi: 10.1074/jbc.W119.012140.
- HDAC6 modulates Hsp90 chaperone activity and regulates activation of aryl hydrocarbon receptor signaling. *J Biol Chem.* 2009 Mar 20; 284(12):7436–45. doi: 10.1074/jbc.M808999200 (hereafter referred to as ''*J Biol Chem.* 2009''). Retraction in: *J Biol Chem.* 2020 Jan 3; 295(1):297. doi: 10.1074/jbc.W119.012142.
- p53 protein regulates Hsp90 ATPase activity and thereby Wnt signaling by modulating Aha1 expression. *J Biol Chem.* 2014 Mar 7;289(10):6513–25. doi: 10.1074/jbc.M113.532523 (hereafter referred to as ''*J Biol Chem.* 2014''). Retraction in: *J Biol Chem.* 2020 Jan 3; 295(1):289. doi: 10.1074/jbc.W119.012134.
- Hsp90 and PKM2 drive the expression of aromatase in Li-Fraumeni syndrome breast adipose stromal cells. *J Biol Chem.* 2016 Jul 29;291(31):16011–23. doi: 10.1074/jbc.M115.698902 (hereafter referred to as ''*J Biol Chem.* 2016''). Retraction in: *J Biol Chem.* 2020 Jan 3; 295(1):290. doi: 10.1074/jbc.W119.012135.
- Heat shock protein 90 inhibitors suppress aryl hydrocarbon receptor-mediated activation of CYP1A1 and CYP1B1 transcription and DNA adduct formation. *Cancer Prev Res* (Phila). 2008