FDA announces decision to withdraw Oxandrin® (oxandrolone)

- On June 28, 2023, the FDA announced the final decision to withdraw approval of brand and generic Oxandrin (oxandrolone). The FDA believes a potential problem associated with oxandrolone tablets is sufficiently serious that the drug products should be removed from the market.

- Oxandrin is indicated 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.

- 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.

- 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.

- In March 2019, Gemini, the manufacturer of Oxandrin requested that FDA withdraw approval, stating the product was no longer being marketed. On December 2022, the FDA notified Gemini and other manufacturers that these products should be withdrawn from the market due to safety issues.