



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-2267]

Endo Pharmaceuticals, Inc.; Withdrawal of Approval of a New Drug Application for OPANA (Oxymorphone Hydrochloride) Extended-Release Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of the new drug application (NDA) for OPANA (oxymorphone hydrochloride) extended-release (ER) tablets (NDA 201655), held by Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355 (Endo). Endo requested that the approval of this application be withdrawn and has waived its opportunity for a hearing.

DATES: Withdrawal of approval is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: On June 22, 2006, FDA approved NDA 021610 for OPANA ER (oxymorphone hydrochloride). On December 9, 2011, FDA approved a new formulation of OPANA ER (oxymorphone hydrochloride) tablets, 5 milligrams (mg), 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg, under NDA 201655 (“reformulated OPANA ER”) for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Over the course of 2011 and 2012, Endo removed the original formulation from the market.

Reformulated OPANA ER was intended by the sponsor to be resistant to physical and chemical manipulation for abuse by snorting or injecting. Although the reformulated product met the regulatory standards for approval, FDA determined that the data did not show that product could be expected to meaningfully reduce abuse and declined the company's request to include labeling describing potentially abuse-deterrent properties for OPANA ER.

Based on postmarketing data, FDA later observed that there was a significant shift in the route of abuse from nasal to injection following the product's reformulation. Injection abuse of reformulated OPANA ER has been associated with a serious outbreak of HIV and hepatitis C, as well as cases of a serious blood disorder (thrombotic microangiopathy). On June 8, 2017, FDA requested that Endo remove reformulated OPANA ER from the market based on its concern that the benefits of the drug may no longer outweigh its risks due to the public health consequences of abuse (see <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-opana-er-risks-related-abuse>). On July 6, 2017, Endo announced it would voluntarily remove reformulated OPANA ER from the market.

On October 3, 2017, Endo requested withdrawal of NDA 201655 for reformulated OPANA ER under § 314.150(d) (21 CFR 314.150(d)) and waived its opportunity for a hearing. For the reasons discussed above, and pursuant to the applicant's request, approval of NDA 201655 for reformulated OPANA ER (oxymorphone hydrochloride) extended-release tablets, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of reformulated OPANA ER 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: December 16, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.