4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-P-0895]

Determination That OPANA ER (Oxymorphone Hydrochloride) Drug Products Covered by New Drug Application 21-610 Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that OPANA ER (oxymorphone hydrochloride (HCl)) Extended-Release Tablet products approved under new drug application (NDA) 21-610 were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs for oxymorphone HCl extended-release tablets if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Patrick Raulerson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6368, Silver Spring, MD 20993-0002, 301-796-3522.

SUPPLEMENTARY INFORMATION:

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with

certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 U.S.C. 355(j)(7)(C); 21 CFR 314.162).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 before 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.

Endo submitted a citizen petition dated August 10, 2012 (Docket No. FDA-2012-P-0895), under 21 CFR 10.30, requesting that the Agency: (1) Determine that OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets approved under NDA 21-610 were discontinued for reasons of safety, (2) refuse to approve any pending ANDA for a generic

version of OPANA ER approved under NDA 21-610, and (3) suspend and withdraw the approval of any ANDA referencing OPANA ER approved under NDA 21-610 as the reference listed drug (Petition at 1).

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 the original OPANA ER was not withdrawn for reasons of safety or effectiveness. We describe the basis for this determination in our letter response to Endo's citizen petition (available on http://www.regulations.gov under Docket No. FDA-2012-P-0895).

Accordingly, the Agency will continue to list OPANA ER (oxymorphone HCl) Extended-Release Tablets approved under NDA 21-610 in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" includes drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of ANDAs that refer to these drug products. Additional ANDAs that refer to OPANA ER (oxymorphone HCl) Extended-Release Tablets may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs.

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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