

**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**Determination That OPANA ER (Oxymorphone Hydrochloride) Drug Products Covered by New Drug Application 21-610 Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.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hydrochloride (HCl)) Extended-Release Tablet products approved under new drug application (NDA) 21-610 were not withdrawn from sale for reasons of safety or effectiveness.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 (Pub. L. 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approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 U.S.C. 355(j)(7)(C); 21 CFR 314.162).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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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2013-N-0010]

**Regulatory Systems Strengthening****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Office of International Programs. The goal of the Cooperative Agreement is to strengthen global regulatory capacity through activities that may include: Development of global norms and standards for product regulation; generation and analysis of evidence of regulatory systems performance; and provision of technical support to national regulatory systems strengthening efforts.

**DATES:** Important dates are as follows:

1. The application due date is August 9, 2013.
2. The anticipated start date is September 10, 2013.
3. The opening date is July 10, 2013.
4. The expiration date is August 10, 2013.

**ADDRESSES:** Submit electronic applications to: <http://www.grants.gov>. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

**FOR FURTHER INFORMATION CONTACT:** Charles Preston, Office of Science Policy Analysis/Office of International Programs, HFG-1, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 301-796-0654, [charles.preston@fda.hhs.gov](mailto:charles.preston@fda.hhs.gov); or Daniel Lukash, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2028, Rockville, MD 20857, 301-827-6771, [Daniel.Lukash@fda.hhs.gov](mailto:Daniel.Lukash@fda.hhs.gov).

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm>.

**SUPPLEMENTARY INFORMATION:****I. Funding Opportunity Description**RFA-FD-13-024  
93.103