CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

201655Orig1s000

Trade Name: OPANA, ER

Generic Name: Oxymorphone Hydrochloride Extended-Release Tablets, CII

Sponsor: Endo Pharmaceuticals, Inc.

Approval Date: 12/09/2011

Indications:

OPANA ER is an opioid agonist indicated for the relief of moderate to severe pain in patients requiring continuous around-the-clock opioid treatment for an extended period of time.
Not intended for use as an as needed analgesic. Not indicated in the immediate post-operative period or if the pain is mild or not expected to persist for an extended period of time.

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APPROVAL LETTER

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 201655

NDA APPROVAL

Endo Pharmaceuticals Inc.
100 Endo Boulevard
Chadds Ford, PA 19317

Attention: Tara Chapman, Pharm.D.
Director, Regulatory Affairs

Dear Dr. Chapman:

Please refer to your New Drug Application (NDA) dated July 7, 2010, received July 7, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 30 mg, and 40 mg.

We also refer to our approval letter dated December 9, 2011, which contained the following error: The statement granting an expiration dating period of (b) (4) months was incorrect.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 9, 2011, the date of the original approval letter.

We acknowledge receipt of your amendments dated July 23, August 27 and 30, September 9, 14, and 29, October 1, 6, 12, 13, and 27, November 4 and 12, and December, 6, 17, 27, 28, and 29, 2010, and January 3, 6, and 14, February 22, June 13, July 8, September 7 and 30, October 6, and November 9, 16, 21, and 30, 2011.

The June 13, 2011, submission constituted a complete response to our January 7, 2011, action letter.

This new drug application provides for the use of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets for the management of moderate to severe chronic pain in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling text for the package insert and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your November 9, 2011, submission containing final printed carton and container labels.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

On April 18, 2011, you were notified that in accordance with section 505-1 of the FDCA, we have determined that a risk evaluation and mitigation strategy (REMS) is necessary for certain long-acting and extended-release (LA/ER) opioid products, including OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets, to ensure that the benefits of the drugs continue to outweigh the risks of adverse outcomes (addiction, unintentional overdose, and death) resulting from inappropriate prescribing, abuse, and misuse, and we notified you of the elements of the REMS that would be required. You were also notified that, in the interest of public health and to minimize the burden on the healthcare delivery system of having multiple unique REMS programs, a single, shared system should be used to implement the REMS for all members of the class.

While the class-wide REMS, including the single shared system, is being developed, your proposed interim REMS, submitted on November 21, 2011, and appended to this letter, is approved. This interim REMS consists of a Medication Guide, elements to assure safe use, and a timetable for submission of assessments of the REMS. We believe this interim REMS provides for management of the risks of adverse outcomes (addiction, unintentional overdose, and death) that is comparable to the REMS that we have determined is necessary for the class of LA/ER opioid products and is designed to ensure that the benefits of OPANA ER (oxymorphone hydrochloride) Extended-Release Tablets continue to outweigh its risks while the single shared system, class-wide REMS is being developed.

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