



NDA 021611/S-004

**SUPPLEMENT APPROVAL**

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

Attention: Tara Chapman  
Associate Director, Regulatory Affairs

Dear Ms. Chapman:

Please refer to your January 9, 2009, Supplemental New Drug Application (sNDA), received January 9, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for OPANA (Oxymorphone Hydrochloride) Tablets, 5 mg and 10 mg.

We acknowledge receipt of your submissions dated March 24 and April 2, 2010.

This "Prior Approval" supplemental new drug application provides for conversion of the content of the currently approved package insert into the Physicians Labeling Rule (PLR) format as set forth under 21 CFR 201.56 and 21 CFR 201.57.

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.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission, "**SPL for approved NDA 21-611/S-004**."

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.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

## **PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa Basham, Senior Regulatory Health Project Manager, at (301) 796-1175.

Sincerely,

*{See appended electronic signature page}*

Bob A. Rappaport, MD  
Director  
Division of Anesthesia and Analgesia Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

Enclosure:  
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21611	SUPPL-4	ENDO PHARMACEUTICA LS INC	OPANA (OXYMORPHONE HCL TABS 5/10 MG)

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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SHARON H HERTZ on behalf of BOB A RAPPAPORT  
04/15/2010  
Signing for Bob Rappaport, M.D.