

ANDA 76-446

December 6, 2005

IMPAX Laboratories, Inc.
Attention: Mark C. Shaw
Vice President, Regulatory Affairs & compliance
30831 Huntwood Avenue
Hayward, CA 94544

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 26, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxycodone Hydrochloride Extended-release Tablets, 10 mg, 20 mg and 40 mg.

Reference is also made to the tentative approval letter issued by this office on December 23, 2003, and to your amendments dated June 3, 2004 and July 21, 2005. We also acknowledge your correspondence dated July 21, 2005, addressing your Risk Management Plan (RMP) for this drug product.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the ANDA is approved. The Division of Bioequivalence has determined your Oxycodone Hydrochloride Extended-release Tablets, 10 mg, 20 mg and 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Oxycontin[®] Extended-release Tablets, 10 mg, 20 mg, and 40 mg, respectively, of Purdue Pharma L.P. (Purdue).

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

The dissolution testing should be conducted in 900 mL of simulated gastric fluid (b)(4) but enzyme at 37°C using USP Apparatus 1 (basket) at (b)(4) rpm. The test product should meet the following "interim" specifications:

1 hour	
2 hours	
4 hours	
6 hours	
8 hours	

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

The listed drug product (RLD) referenced in your ANDA, Purdue's Oxycontin® Extended-release Tablets, 10 mg, 20 mg and 40 mg, is subject to periods of patent protection. The following patents are listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
4,861,598 (the '598 patent)	August 29, 2006
4,970,075 (the '075 patent)	August 29, 2006
5,266,331 (the '331 patent)	October 26, 2007
5,549,912 (the '912 patent)	October 26, 2007
5,656,295 (the '295 patent)	October 26, 2007
5,508,042 (the '042 patent)	April 16, 2013

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Oxycodone Hydrochloride Extended-release Tablets, 10 mg, 20 mg and 40 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against IMPAX Laboratories, Inc. (IMPAX) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications. This action must have been brought against IMPAX prior to the expiration of 45 days from the date the notice you provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the Agency that IMPAX complied with the requirements of section 505(j)(2)(B) of the Act, and that Purdue initiated a patent infringement action against you in the United States

District Court for the Southern District of New York involving the '912, '042 and '295 patents (Purdue Pharma L.P., et al. v. IMPAX Laboratories, Inc., Civil Action No. 02 CIV 7569, and Purdue Pharma L.P., et al. v. IMPAX Laboratories, Inc., Civil Action No. 02 CIV-8036).

You have notified the Agency of the district court's summary judgment dated January 5, 2005, in favor of Impax, dismissing the case on the grounds of unenforceability of the three patents. The Agency also is aware of the June 7, 2005 ruling by the U.S. Court of Appeals for the Federal Circuit, affirming the Opinion and Order of the same district court in a related case, issued in favor of Endo Pharmaceutical (Endo). The Federal Circuit ruling, among other things, permanently enjoins Purdue from enforcing the '912, '042 and '295 patents.

That decision on June 7, 2005, as well as the first commercial marketing of the product by Endo on the same day, triggered Endo's 180-day generic drug exclusivity period as provided for in section 505(j)(5)(B)(iv) of the Act. Endo's 180-day exclusivity for this drug product expired on December 4, 2005. Therefore, under section 505(j)(5)(B)(iii)(I), your ANDA is eligible for full approval.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

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

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research