DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

ANDA 76-168

MAR 2 3 2004

TEVA Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Rd.
P.O. Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated May 8, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxycodone Hydrochloride Extended-release Tablets, 80 mg.

Reference is also made to the tentative approval letter issued by this office on September 29, 2003, and to your amendments dated December 19, 2003, and January 14, and February 5, 2004. We also acknowledge your correspondence dated January 29, February 18, February 25, and March 4, 2004, addressing TEVA's Risk Management Plan (RMP) for this drug product.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Oxycodone Hydrochloride Extended-release Tablets, 80 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Oxycontin® Extended-release Tablets, 80mg, of Purdue Pharma LP.). 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:

Dissolution testing should be conducted in 900 mL of (b)(4) at 37°C using USP (b)(4). The test product should meet the following "interim" specifications:

Time	Percent Dissolved
1 hour	(b)(4)
4 hours	
12 hours	

The "interim" dissolution tests 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" if there are no revisions to be made to the "interim" specifications or if the final specifications are tighter than the "interim" specifications. In all other instances, the data should be submitted in the form of a Prior Approval Supplement.

The reference listed drug product in your application, Oxycontin® Extended-release Tablets, 80 mg, of Purdue Pharma LP, is subject to multiple periods of patent protection. The following United States patents and their expiration dates currently appear in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book":

Patent Number	Expiration Date
4,861,598	August 29, 2006
4,970,075	August 29, 2006
5,266,331	October 26, 2007
5,549,912	October 26, 2007
5,656,295	October 26, 2007
5,508,042	April 16, 2013

Your application contains patent certifications to each of these patents under Section 505 (j)(2)(A)(vii)(IV) of the Act stating that none of the claims of the 4,861,598, 5,266,331, 5,549,912, 5,508,042, 5,656,295 and 4,970,075 patents will be infringed by your commercial manufacture, use, or sale of Oxycodone Hydrochloride Extended-release Tablets 80 mg under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought against TEVA Pharmaceuticals USA (TEVA) for infringement of one or more of the patents which were the subjects of the paragraph IV certifications. This infringement action must be brought before the expiration of forty-five days from the date the notice(s) TEVA provided under paragraph (2)(B)(i) were received by the NDA and patent holders. You have notified the Agency that TEVA has complied with the requirements of Section

505(j)(2)(B) of the Act. As a result, litigation was filed against TEVA in the United States District Court for the Southern District of New York involving a challenge to the '042 patent, the '912 patent and the '295 patent (Purdue Pharma LP, The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company, v. TEVA Pharmaceuticals USA, Inc., Civil Action No. 01-CV-8507). The Agency recognizes that the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time the Agency was precluded from approving your product, has expired.

TEVA is eligible for 180-day generic drug exclusivity for Oxycodone Hydrochloride Extended-release Tablets, 80 mg, as provided for under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) in Section 505(j)(5)(B)(iv) of the Act. This is because the agency has concluded that TEVA was the first ANDA applicant to submit a substantially complete ANDA for Oxycodone Hydrochloride Extended-release Tablets, 80 mg, containing paragraph IV certifications to each patent listed in the "Orange Book". This exclusivity will begin to run from the date TEVA begins commercial marketing of the drug product, or upon the decision of a court holding the patents which were the subjects of the paragraph IV certifications to be invalid or not infringed; whichever event occurs first.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product, or the date of a decision of the court holding the relevant patents invalid, unenforceable or not infringed.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

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 (HFD-40) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

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