



ANDA 76-168

Food and Drug Administration  
Rockville MD 20857

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

MAR 23 2004

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<sup>®</sup> 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:



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