ANDA 75-347

NOV 16 2001

Andrx Pharmaceuticals, Inc.
Attention: Diane Servello
4955 Orange Drive
Fort Lauderdale, FL 33314

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 17, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Omeprazole Delayed-release Capsules, 10 mg, 20 mg and 40 mg.

Reference is also made to our tentative approval letter dated March 23, 2000, and to your amendments dated August 6, 1999, January 20, December 18, 2000, March 27, July 30, August 31, September 11, and November 9, 2001.

The listed drug product (RLD) referenced in your application, Prilosec Delayed-release Capsules of Astra Zeneca, L.P., is subject to periods of patent protection which expire on April 2, 2002 (U.S. Patent No. 4,508,905); January 30, 2006 (U.S. Patent No. 4,636,499); October 20, 2007 (U.S. Patent Nos. 4,853,230 and 4,786,505); August 2, 2010 (U.S. Patent No. 5,093,342); August 4, 2014 (U.S. Patent Nos. 5,599,794 and 5,629,305); April 9, 2019 (U.S. Patent Nos. 6,147,103, 6,191,148 and 6,166,213) May 10, 2019 (U.S. Patent No. 6,150,380). Your application originally contained Paragraph IV Certifications to the '342, '794, and '305 patents. These certifications were subsequently withdrawn pursuant to 21 CFR 314.94(a)(12)(iii) based upon your statement that they are "method of use" patents and that such uses are not included in your proposed labeling.

We note that although the '905 patent was issued on April 2, 1985, it was not listed with the Agency by the NDA holder until May 4, 2001. Your application was accepted for filing by the Office of Generic Drugs on March 17, 1998. Thus, pursuant to 21 CFR 314.94(a)(12)(vi), Andrx is not required to file an amended patent certification to address the '905 patent.

Your application also contains Paragraph IV Certifications to the '499, '230, '505, '103, '380, '213, and '148 patents under Section 505(j)(2)(A)(vii)(IV) of the Act.
Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Andrx Pharmaceuticals, Inc. (Andrx) has complied with the requirements of Section 505(j)(2)(B) of the Act and no action for patent infringement regarding the '103, '380, '213 and '148 patents was brought against Andrx within the statutory forty-five day period. You further informed the Agency that litigation is underway in the United States District Court for the Southern District of Florida involving a challenge to the '499, '505 and '230 patents (Astra Aktiebolag, Aktiebolaget Hassle, Astra Merck Enterprises Inc. and Astra Merck Inc. v. Andrx Pharmaceuticals, Inc., Civil Action No. 98-6521). With respect to this litigation, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

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 Omeprazole Delayed-release Capsules, 10 mg, 20 mg, and 40 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug, Prilosec® Delayed-release Capsules, 10 mg, 20 mg, and 40 mg, respectively.

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 0.1N HCl for 2 hours [Acid stage]; followed by 900 mL of 0.05M phosphate buffer, pH 6.8 [buffer stage] at 37° C using USP 24 Apparatus I (basket) at 100 rpm. The test product should meet the following specifications:

NMT _____of the drug in the capsule is dissolved in 2 hours [acid stage]; and

NLT ____ of the drug in the capsule is dissolved in 45 minutes [buffer stage]

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. 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 issue of 180-day generic drug exclusivity is addressed in a separate letter dated November 16, 2001.

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 proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-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 FD-2253 at the time of their initial use.

Sincerely yours,

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