DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 75-896

NOV 2 2004

Mutual Pharmaceutical Company, Inc.
Attention: Robert Dettery
1100 Orthodox Street
Philadelphia, PA 19124

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 6, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Felodipine Extended-release Tablets USP, 2.5 mg, 5 mg and 10 mg.

Reference is also made to the Tentative Approval letter issued by this office on February 6, 2004, and to your amendments dated April 30, and June 25, 2001; and October 1, October 4, October 5, and October 19, 2004. We acknowledge receipt of your correspondence dated October 1, and October 29, 2004, addressing the courts findings of non-infringement by Mutual of the '081 patent.

As noted in our tentative approval letter dated February 6, 2004, the listed drug product referenced in your application, Plendil Extended-release Tablets of AstraZeneca, is subject to a period of patent protection that is scheduled to expire on October 3, 2007, (U.S. Patent No. 4,803,081), the '081 patent. In response to your paragraph IV certification to this patent, you informed the agency that AstraZeneca Pharmaceuticals LP initiated a patent infringement action against you in the United States District Court for the Eastern District of Pennsylvania (AstraZeneca AB, Aktiebolaget Hassle, KBI-E Inc., KBI Inc. and AstraZeneca LP v. Mutual Pharmaceutical Company, Inc. (Mutual), Civil Action No. 00-CV-4731). Subsequently, you notified the Agency that on November 12, 2003, the District Court ruled in favor of AstraZeneca and concluded that Mutual did infringe upon the '081 patent. Mutual appealed the District Court's decision to the U.S. Court of Appeals for the Federal Circuit. On September 30, 2004, the U.S. Court of Appeals overturned the District Court's decision by ruling that Mutual did not infringe the '081 patent. On October 29, 2004, the District Court

officially vacated its earlier ruling and stated that Mutual did not infringe the '081 patent under this ANDA.

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 Felodipine Extended-release Tablets USP, 2.5 mg, 5 mg, and 10 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Plendil Extended-release Tablets USP, 2.5 mg, 5 mg and 10 mg, respectively, of AstraZeneca Pharmaceuticals 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 (b)(4) (b)(4) (b)(4) The test product should meet the following "interim" specifications:

Sampling Time (hours)	% Dissolved
1	(b)(4)
4	
8	

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. These data should be submitted as a "Special Supplement - Changes Being Effected" when there are no revisions to be made 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.

With this approval, Mutual is eligible for 180-day generic drug exclusivity for Felodipine Extended-release Tablets USP, 2.5 mg, 5 mg, and 10 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 determined that Mutual was the first ANDA applicant to submit a substantially complete ANDA for this drug product containing a paragraph IV certification to the '081 patent. This exclusivity began on October 29, 2004, the date

the District Court entered its judgment concluding that Mutual did not infringe the '081 patent.

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.

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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

(b)(6)

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