DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-648

Food and Drug Administration
Rockville MD 20857

MAR 22 2004

Mylan Pharmaceuticals, Inc.
Attention: S. Wayne Talton
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 28, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Nitrofurantoin (Monohydrate/Macrocrystals) Capsules, 100 mg.

Reference is also made to your amendment dated August 13, and to your two amendments dated December 12, 2003; and your amendment dated February 12, 2004. We also acknowledge receipt of your correspondence dated May 27, 2003 addressing the patent issues noted below.

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 Nitrofurantoin (Monohydrate/Macrocrystals) Capsules, 100 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Macrobid® Capsules, 100 mg, of Procter and Gamble Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, Macrobid® Capsules of Procter and Gamble Pharmaceuticals, Inc., is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent No. 4,772,473 (the '473 patent) and U.S. Patent No. 4,798,725 (the '725 patent), are scheduled to expire on June 16, 2006. Your application contains a paragraph IV patent certification to each patent under section 505(j)(2)(A)(vii)(IV)

of the Act stating that the '473 and '725 patents are invalid, unenforceable, or will not be infringed by your manufacture, use, sale, offer for sale, or importation of Nitrofurantoin (Monohydrate/Macrocrystals) Capsules, 100 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 is brought against Mylan Pharmaceuticals, Inc. (Mylan) for infringement of the '473 or '725 patents which were the subjects of the paragraph IV certifications. This infringement action must be brought against Mylan prior to the expiration of forty-five days from the date the notice Mylan provided under paragraph (2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Mylan complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for infringement of either the '473 patent or the '725 patent was brought against Mylan Pharmaceuticals, Inc. within the statutory forty-five day period.

With respect to 180-day generic drug exclusivity, we note that Mylan was the first ANDA applicant to submit a substantially complete ANDA containing a paragraph IV certification to the '473 and '725 patents. Therefore, with this approval, Mylan is eligible for 180-days of market exclusivity with respect to these patents for Nitrofurantoin (Monohydrate/Macrocrystals) Capsules, 100 mg. This exclusivity will begin to run from the date Mylan begins commercial marketing of the drug product.

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 Mylan 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.

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) [redacted]

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