ANDA 40-298/S-004, S-005, S-006

December 6, 2001

Mylan Pharmaceuticals, Inc.
Attention: Frank Sisto
781 Chestnut Ridge Road
Morgantown, WV 26504-4310

Dear Sir:

This is in reference to your supplemental new drug applications dated February 23, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Extended Phenytoin Sodium Capsules USP, 100 mg.

Reference is also made to your amendments dated May 18, June 18, June 29, September 21, September 28, October 26, and November 16, 2001.

The supplemental applications provide for:

S-004: additional strengths of Extended Phenytoin Sodium Capsules USP, 200 mg and 300 mg;

S-005: labeling revisions associated with the new 200 and 300 mg strengths; and

S-006: packaging for the new dosage strengths.

We have completed the review of these supplemental applications as amended, and have concluded that the new 200 mg and 300 mg strengths of the drug product are safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The new strengths of Extended Phenytoin Sodium Capsules USP, 200 mg and 300 mg, can be expected to have the same therapeutic effect as that of the listed drug product upon which the Agency relied as the basis of safety and effectiveness.

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 _____ The test product should meet the following interim specifications based on 12 capsules:

		Range
NMT ___	(Q) in 30 minutes	_____
___	(Q′) in 60 minutes	_____
NLT ___	(Q″) in 120 minutes	

The "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.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described 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 campaign for the new 200 mg and 300 mg strengths. 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 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 the Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

The material submitted is being retained in our files.

Sincerely yours,

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