DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-885

JAN 17 2006

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 dated October 30, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Rabeprazole Sodium Delayed-release Tablets, 20 mg.

Reference is also made to your amendments dated June 3, June 30, July 30, 2004; June 10, 2005 (2 amendments) and August 10, 2005.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issues discussed below. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The Division of Bioequivalence has determined your Rabeprazole Sodium Delayed-release Tablets, 20 mg to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Aciphex®. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution test and tolerances are:

Acid Resistance Stage: The dissolution testing should be conducted in [redacted] of 0.1N HCL for 2 hours using Apparatus II (Paddle) at [redacted] with specifications NMT [redacted] dissolved in 2 hours. The test product should meet the following "interim" specifications:

Time (hours)	Percent Dissolved
2	NMT [redacted]

Buffer Stage: The dissolution testing should be conducted in [redacted] buffer, pH 8.0 @ 37°C with sampling times of 10, 20, 30, 40, 50 and 60 minutes using Apparatus II (Paddle) with specifications NLT [redacted] dissolved in 60 minutes. The test product should meet the following "interim" specifications:

Time (hours)	Percent Dissolved
1	[redacted]

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data from the first three production size batches in a supplemental application. The supplemental application should be submitted under Section 505(j) of the Act as a "Special Supplement - Changes Being Effected" (CBE-0) 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 supplement should be submitted under 505(j) of the Act as a prior approval supplement.

The reference listed drug product (RLD) upon which you have based your application, Aciphex® Tablets, 20 mg, of Eisai Medical Research Inc. (Eisai), is currently subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
5,035,899 (the '899 patent)	April 4, 2009
5,045,552 (the '552 patent)	May 8, 2013

Your ANDA contains paragraph IV patent certifications to the '899 and '552 patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of

Rabeprazole Sodium Delayed-release Tables, 20 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 action was brought against Mylan Pharmaceuticals Inc. (Mylan) for infringement of one or more of the patents that were the subjects of paragraph IV certifications. You notified the Agency that Mylan complied with the requirements of section 505(j)(2)(B) of the Act, and no action for patent infringement involving the '899 patent was brought against Mylan within the statutory 45-day period. However, litigation was brought within the statutory 45-day period against Mylan in the United States District Court [redacted] involving a challenge to the '552 patent [redacted]. This litigation is ongoing. Therefore, final approval cannot be granted until:

1. a. the expiration of the 7 ½ year period provided for in section 505(j)(5)(D)(ii) from the date of receipt of the 45-day notice required under section 505(j)(2)(B)(i), unless the court has extended or reduced the period because of the failure of either party to reasonably cooperate in expediting the action, or,

   b. the date of court decision [505(j)(5)(B)(iii)(I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,

   c. the patents have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. Your amendment must provide:

1. A copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing

agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

   b. a statement that no such changes have been made to the application since the date of tentative approval.

Any changes in the conditions outlined in this abbreviated application and the status of the manufacturing and testing facilities' compliance with current good manufacturing procedures are subject to Agency review before final approval of the application will be made.

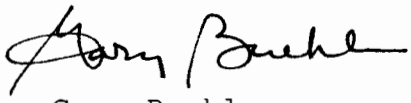
In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Yoon Kong, Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,



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