DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-830

Ranbaxy Laboratories Limited
US Agent: Ranbaxy Inc.
Attention: Scott Tomsky
600 College Road East
Princeton, NJ 08540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated August 4, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Esomeprazole Magnesium Delayed-Release Capsules, 20 mg (base) and 40 mg (base).

Reference is also made to your amendments dated June 17, September 14 and 21, and December 21, 2007, January 21, and February 4, 2008.

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 noted below. Therefore, the ANDA is **tentatively approved.** This determination is based upon information available to the agency at this time, (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product). This determination is subject to change on the basis of new information that may come to our attention.

The reference listed drug (RLD) upon which you have based your ANDA, Nexium, 20 mg and 40 mg, of AstraZeneca, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
4,738,974 (the '974 patent)	March 1, 2008

5,690,960	(the '960 patent)	May 25, 2015
5,714,504	(the '504 patent)	August 3, 2015
5,877,192	(the '192 patent)	November 27, 2014
5,900,424	(the '424 patent)	November 4, 2016
6,147,103	(the '103 patent)	April 9, 2019
6,166,213	(the '213 patent)	April 9, 2019
6,191,148	(the '148 patent)	April 9, 2019
6,369,085	(the '085 patent)	November 25, 2018
6,428,810	(the '810 patent)	May 3, 2020
6,875,872	(the '872 patent)	November 27, 2014

With respect to the '974 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that Ranbaxy Laboratories Limited (Ranbaxy) will not market Esomeprazole Magnesium Delayed-Release Capsules, 20 mg (base) and 40 mg (base), prior to the expiration of the '974 patent. Therefore, final approval of your ANDA may not be made effective pursuant to section 505(j)(5)(B)(ii) of the Act until the '974 patent has expired, currently, March 1, 2008.

With respect to all the other patents listed above, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable or will not be infringed by your manufacture, use, or sale of Esomeprazole Magnesium Delayed-Release Capsules, 20 mg (base) and 40 mg (base), 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 Ranbaxy for infringement of one or more of the listed patents. This action must have been brought prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder(s). You notified the agency that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '504, '192, '085, '810, and '872 patents was brought against Ranbaxy within the statutory 45-day period in the United States District Court for the District of New Jersey [AstraZeneca v. Ranbaxy Laboratories Limited, Civil Action No. 05-5553].

Therefore, final approval cannot be granted until the '974 patent has expired and:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),

b. the date the court decides[1] that the '504, '192, '085, '810, and '872 patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act), or

c. the '504, '192, '085, '810, and '872 patents have expired, and

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

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (cGMPs) are subject to agency review before final approval of the application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

[1] This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

This drug product 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 product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this application, or prior to submitting additional amendments, please contact Theresa Liu, Project Manager, at 240-276-8500.

Sincerely yours,

(See appended electronic signature page)

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert L. West
2/5/2008 02:58:05 PM
for Gary Buehler