ANDA 76-134 December 20, 2001

Ranbaxy Pharmaceuticals Inc.
Attention: Abha Pant
U.S. Agent for Ranbaxy Laboratories Limited
600 College Road East
Princeton, NJ 08540

Dear Madam:

This is in reference to your abbreviated new drug application dated March 15, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Loratadine Tablets, 10 mg.

Reference is also made to your amendments dated May 16, August 30, October 10, and November 7, 2001.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. 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). The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Claritin Tablets of Schering Corp., is subject to periods of patent protection which expire on December 19, 2002 (U.S. Patent No. 4,282,233, the ‘233 patent), October 21, 2004 (U.S. Patent No. 4,659,716, the `716 patent), and March 15, 2009 (U.S. Patent No. 4,863,931, the ‘931 patent). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(III) of the Act for the ‘233 patent. Your application also contains patent certifications under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not

infringe upon the ‘716 or ‘931 patents, or that these patents are invalid or unenforceable. 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 Laboratories Limited (Ranbaxy) for infringement of one or more of the patents that are the subject of the certifications. This action must be brought against Ranbaxy prior to the expiration of forty-five (45) days from the date the notice provided by Ranbaxy under paragraph (2)(B)(I) is received. You have notified FDA that Ranbaxy has complied with the requirements of Section 505(j)(2)(B) of the Act and that litigation is underway in the United States District Court for the District of New Jersey involving a challenge to the ‘716 patent (Schering Corporation v. Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc., Civil Action No. 01-2990 (JAG)). Therefore, final approval cannot be granted until:

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

   c. the ‘716 patent has expired, and

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

You must amend your application prior to final approval. Your MINOR AMENDMENT – FINAL APPROVAL REQUESTED should notify the agency of the legal issues that may affect the effective date of final approval. This amendment and should also include:

1. a copy of a final order or judgement, 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 final-printed 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 – FINAL APPROVAL REQUESTED in your cover letter. Before you submit the amendment, or is you have questions concerning the status of this application, please contact Ruby Wu, R.Ph., Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

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

cc:
ANDA 76-134
Division File
FIELD COPY
HFD-610/RWest
HFD-330/
HFD-205/

Endorsements:
HFD-623/J.Franolic/11/19/01
HFD-623/D.Gill/11/19/01
HFD-617/R.Wu/11/19/01
HFD-613/D.Catterson/11/20/01
HFD-613/J.Grace/11/20/01
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F/T by: gp/11/19/01

TENTATIVE APPROVAL