ANDA 76-953

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 17, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Tolterodine Tartrate Tablets, 1 mg and 2 mg.

Reference is also made to your amendments dated August 20, November 1, December 21, 2004; and May 24, 2005, July 27, 2005 and August 8, 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 application at this time because of the patent issue noted 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 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 product (RLD) upon which you have based your application, Detrol® Tablets of Pharmacia and Upjohn Company (Pharmacia), is currently 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. 5,382,600 (the '600 patent) is scheduled to expire on March 25, 2012. Your application contains a paragraph III certification to the '600 patent under

section 505(j)(2)(A)(vii)(III) of the Act. This certification states that Ranbaxy Pharmaceuticals, Inc. will not market its Tolterodine Tartrate Tablets, 1mg and 2 mg, prior to the expiration of the '600 patent.

However, section 505A of the Act entitles the sponsor of the RLD to an additional six months of marketing exclusivity (pediatric exclusivity) if, in accordance with the requirements of section 505A, the sponsor of the RLD submits data previously requested by the Agency relating to the use of the drug in the pediatric population. Pharmacia has submitted data to the Agency relating to the use of Tolterodine Tartrate Tablets in the pediatric population, and the Agency has determined that these data meet the requirements of section 505A. The expiration of the '600 patent has, therefore, been effectively extended until September 25, 2012, and the Agency may not issue a final approval letter to your application pursuant to section 505(j)(5)(B)(ii) of the Act prior to that date. The final approval date may be further extended if upon review of the pediatric data submitted by Pharmacia the Agency decides that Pharmacia is eligible for an additional period of Hatch-Waxman exclusivity.

Your ANDA currently contains a paragraph IV certification to U.S. Patent No. 5,559,269 (the '269 patent) under section 505(j)(2)(A)(vii)(IV) of the Act. We note that the '269 patent was delisted from the Orange Book at the request of the NDA holder. You may need to address this delisting. See 21 CFR 314.94(a)(12)(viii)(B).

To reactivate your application prior to final approval, please submit a “MINOR AMENDMENT – FINAL APPROVAL REQUESTED” 60 days prior to the date you believe that your application will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval, and it should also identify changes, if any, in the conditions under which the product 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 application, or may result in a delay in the issuance of the final approval letter.

Any 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 categorized as representing either “major” or “minor” changes, and they will be reviewed according to the OGD policy in effect at the time of receipt. The submission of multiple amendments prior to final approval may also lead to a delay in the issuance of the final approval letter.

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 501 of the Act and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the Orange Book. If you believe there are grounds for issuing the final approval letter prior to September 25, 2012, you should amend your application accordingly.

For further information on the status of this application or upon submitting an amendment to the application, please contact Yoon Kong, Project Manager, at 301-827-5791.

Sincerely yours,

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

cc: ANDA 76-953
Division File
Field Copy
HFD-610/R. West
HFD-205
HFD-610/Orange Book Staff

Endorsements:
HFD-640/S.Read/
HFD-645/B.Arnwine/4/28/05
HFD-617/Y.Kong/
HFD-613/K.Lee/
HFD-613/L.Golson/

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F/T by rad4/29/05

TENTATIVE APPROVAL