DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 77-492

Ranbaxy Inc.
U.S. Agent for Ranbaxy Laboratories Ltd.
Attention: Scott Tompsky
600 College Road East
Princeton, NJ 09540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 24, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Valsartan Tablets, 40 mg, 80 mg, 160 mg, and 320 mg.

Reference is also made to your amendments dated June 20, and December 21, 2005; January 24, 2006; and June 17, 2007.

We have completed the review of this ANDA 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 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 of the facilities used in the manufacturing and testing of the drug product) and is therefore 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, except to note that for purposes of sections 505(j)(5)(B)(iv) and 505(j)(5)(D)(i)(IV), the agency regards the change in the USP monograph for Valsartan, published on May 1, 2007, (b) (4) to be a change in the requirements for approval imposed after the date on which your ANDA was filed.

The reference listed drug (RLD) upon which you have based your ANDA, Diovan Tablets, 40 mg, 80 mg, 160 mg, and 320 mg, of Novartis Pharmaceuticals Corp., is subject to periods of patent protection. The following patents and expiration dates 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
6,294,197 (the '197 patent)	June 18, 2017
5,399,578 (the '578 patent)	March 21, 2012
5,972,990 (the '990 patent)	October 26, 2016

With respect to the '990 patent, your ANDA contains a statement section 505(j)(2)(A)(viii) of the Act indicating that this is a method of use patent that does not claim any indication for which you are seeking approval under this ANDA.

With respect to the '197 patent, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Valsartan Tablets, 40 mg, 80 mg, 160 mg, and 320 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 is brought against Ranbaxy Laboratories Ltd. (Ranbaxy) for infringement of the '197 patent that was the subject of a paragraph IV certification. You notified the agency that Ranbaxy complied with the requirements of section 505(j)(2)(B) of the Act, and Ranbaxy was not sued within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii).

With respect to the '578 patent, your ANDA contains a paragraph III certification under section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of the patent. Therefore, final approval of your ANDA cannot be granted until March 21, 2012, when the '578 patent has expired.

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.

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 ANDA, or prior to submitting additional amendments, please contact Benjamin Danso, Pharm.D, Project Manager, at 301-827-5848.

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
10/25/2007 04:00:27 PM
for Gary Buehler