DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077492

Ohm Laboratories Inc.
Attention: Sameer Manan
(Official Agent for Ohm Laboratories, Inc.)
Senior Manager, Regulatory Affairs
600 College Road East
Suite 2100
Princeton, NJ 08540

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) received on December 28, 2004, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg.

Reference is made to the Tentative Approval letter issued by this office on October 25, 2007, and to your amendments dated February 25, May 19, and September 30, 2011; April 9, July 13, July 16, July 18, August 14, August 17, September 14, September 18, September 19, September 24, October 11, November 1, and November 7, 2012; March 28, May 7, May 16, and December 26, 2013; and February 26, March 24, March 25, April 9, April 28, May 12, and June 2, 2014.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Diovan Tablets 40 mg, 80 mg, 160 mg and 320 mg, respectively, of Novartis Pharmaceuticals Corporation. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Novartis' Diovan Tablets, is subject to periods of patent protection. As noted

in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 5,972,990 (the '990 patent) and 6,294,197 (the '197 patent) are scheduled to expire (with pediatric exclusivity added) on April 26, 2017, and December 18, 2017, respectively.

With respect to the '990 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent that does not claim any indication for which you are seeking approval under your 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 this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg, under this ANDA. You have notified the agency that Ohm Laboratories Inc. (Ohm) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of the '197 patent was brought against Ohm within the statutory 45-day period.

With respect to 180-day generic drug exclusivity, we note that Ohm was the first ANDA applicant for Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg, to submit a substantially complete ANDA with a paragraph IV certification.[1] Your ANDA was received by the agency on December 28, 2004, and was tentatively approved on October 25, 2007. This ANDA, therefore, was not granted tentative approval within the 30-month period described in section 505(j)(5)(D)(i)(IV). Nevertheless, the agency has determined that the failure to obtain tentative approval within the 30-month period was caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application was filed.[2] We therefore conclude

[1] Following review of Ranbaxy's written submission pursuant to paragraph XIV.A of the consent decree entered in *United States v. Ranbaxy Laboratories, Ltd., et al.*, Civ. No. JMF-12-230 (D.Md.), FDA determined and notified Ranbaxy that this ANDA appeared to have been substantially complete at the time it was filed on December 28, 2004. Ltr. fr. K. Webber, Dep. Dir., Office of Pharmaceutical Science, CDER, to A. Sawhney, Ranbaxy, dated May 4, 2012. FDA subsequently reviewed Ranbaxy's audit plan, validity assessments, and other materials submitted pursuant to paragraph XIV.B of the consent decree and determined and notified Ranbaxy that this ANDA did not appear to contain any untrue statements of material fact or contain a pattern or practice of data irregularities affecting approval. Ltr. fr. S. Lynn, Dir., Office of Manufacturing and Product Quality, Office of Compliance, CDER, to A. Sawhney, Ranbaxy, dated July 6, 2012.

[2] The publication on May 1, 2007, of the official USP drug substance monograph for valsartan with which FDA required compliance prior to approval,

that the 180-day exclusivity period described in section 505(j)(5)(B)(iv) of the Act was not forfeited by Ohm, and that with this approval Ohm is eligible for 180 days of generic drug exclusivity for Valsartan Tablets USP, 40 mg, 80 mg, 160 mg, and 320 mg. This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the date of the commercial marketing identified in section 505(j)(5)(B)(iv).[3]

Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. You should advise the Office of Generic Drugs of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these

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constituted a change in the requirements for approval. The applicant's effort to comply with this new requirement, and FDA's review of that effort, was a cause of the applicant's failure to obtain tentative approval by the 30-month forfeiture date described in section 505(j)(5)(D)(i)(IV). This determination by the agency was upheld by the court in *Mylan Laboratories Ltd.; Mylan Pharmaceuticals, Inc., v. FDA, and Ranbaxy Laboratories Limited*, Civil Action No. 12-1637 (JDB)(D.D.C.), in a memorandum opinion dated December 27, 2012, denying plaintiff's motion for preliminary injunction and granting defendants' motion for summary judgment.

[3] The Agency notes the submission of a citizen petition dated May 5, 2014, by attorneys representing a generic manufacturer with an unidentified tentatively approved ANDA. Docket No. FDA-2014-P-0594. This petition requests that FDA determine that Ranbaxy has forfeited or is not eligible for first-to-file status for valsartan, among other drugs, and that FDA must immediately approve all tentatively approved ANDAs for which final approval is blocked by Ranbaxy's alleged eligibility for 180-day exclusivity. The agency has not made a decision with respect to this petition, and any such decision, when made, will be announced in the petition docket per the usual procedures. Because ANDA 077492 is eligible for final approval today regardless of the ultimate decision on the issues raised in the petition, today's action with respect to ANDA 077492 is taken in order not to further delay the availability of generic valsartan while the issues raised in the petition are under consideration.

submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

You have been requested to provide information after the drug application has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response". To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE".

The Generic Drug User Fee Amendments of 2012 (GDUFA)(Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Kathleen Uhl, M.D.
Acting 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

06/26/2014

Deputy Director, Office of Generic Drugs, for
Kathleen Uhl, M.D.