



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
Rockville, MD 20857

ANDA 202910

Hetero USA, Inc.  
U.S. Agent for: Hetero Labs Limited Unit V  
Attention: Soma Raju, Ph.D.  
1035 Centennial Avenue  
Piscataway, NJ 08854

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated March 24, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Irbesartan Tablets USP, 75 mg, 150 mg and 300 mg.

Reference is also made to the tentative letter issued by this office on August 17, 2012, and to your amendment dated September 18, 2012.

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 Irbesartan Tablets USP, 75 mg, 150 mg and 300 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Avapro Tablets, 75 mg, 150 mg and 300 mg, respectively, of Sanofi Aventis US, LLC. 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, Avapro Tablets, 75 mg, 150 mg and 300 mg, of Sanofi Aventis US, LLC (Sanofi Aventis), is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 6,342,247 (the '247 patent), is scheduled to expire on December 7, 2015 (pediatric exclusivity included).

Your ANDA contains a paragraph IV certification to the '247 patent 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 Irbesartan Tablets USP, 75 mg, 150 mg and 300 mg, under this ANDA. You notified the agency that Hetero complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Hetero within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

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. The Office of Generic Drugs should be advised 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 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 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.

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}*

Gregory P. Geba, M.D., M.P.H.  
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

09/27/2012

Deputy Director, Office of Generic Drugs, for  
Gregory P. Geba, M.D., M.P.H.