DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 091370

ANDA APPROVAL

INC Research, LLC
U.S. Agent for Alembic Pharmaceuticals Limited
4800 Falls of Neuse Road, Suite 600
Raleigh, North Carolina 27609
Attention: Shawna Richards
Senior Regulatory Associate

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C the Act), for Irbesartan and Hydrochlorothiazide Tablets USP, 300 mg/25 mg.

Reference is also made to the letter issued by this office on October 15, 2012, granting approval to your Irbesartan and Hydrochlorothiazide Tablets USP, 150 mg/12.5 mg and 300 mg/12.5 mg; and granting tentative approval to your Irbesartan and Hydrochlorothiazide Tablets USP, 300 mg/25 mg. We also refer to your amendments dated February 15 and April 21, 2016.

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 your Irbesartan and Hydrochlorothiazide Tablets USP, 300 mg/25 mg **is approved**, effective on the date of this letter. The Office of Bioequivalence has determined your Irbesartan and Hydrochlorothiazide Tablets USP, 300 mg/25 mg to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Avalide Tablets, 300 mg/25 mg, of Sanofi-Aventis U.S. LLC[1]. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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

[1] We note that the reference listed drug (RLD) upon which you have based your ANDA, Avalide Tablets, 300 mg/25 mg, NDA 20758, of Sanofi-Aventis U.S., LLC, is no longer being marketed in the United States, and is currently listed in the discontinued section of the agency's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). Reference is made to the Federal Register notice dated January 11, 2012 (77 FR 1695) in which the agency announced its determination that Avalide Tablets, 300 mg/25 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

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 FD&C 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(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.

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.

The Electronic Common Technical Document (eCTD) is CDER's standard format for electronic regulatory submissions. Beginning May 5, 2017 ANDA and Master Files must be submitted in eCTD format. Submissions that do not adhere to the requirements stated in the eCTD Guidance will be subject to rejection. For more information please visit: www.fda.gov/ectd.

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}

Carol A. Holquist, RPh
Deputy Director
Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

Carol Holquist

Digitally signed by Carol Holquist
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