DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 076274

Apotex Corp.
U.S. Agent for: Apotex Inc.
Attention: Kiran Krishnan
Director, North American Regulatory Affairs
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated November 16, 2001, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act) for Clopidogrel Tablets USP, 75 mg. We acknowledge receipt of an amendment dated January 24, 2011, providing for Clopidogrel Tablets USP, 300 mg.

Reference is made to the tentative approval letter issued by this office on June 22, 2009 (75 mg strength), and to your amendments dated October 30, 2009; January 24, February 1, March 16, August 31, and September 1, 2011; and February 29, March 9, March 15, April 13, April 26, and May 8, 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, insofar as it pertains to the 75 mg strength, is approved, effective on the date of this letter. As explained below, the 300 mg strength is tentatively approved.

The reference listed drug (RLD) upon which you have based your ANDA, Plavix Tablets, 75 mg and 300 mg, of Sanofi Aventis U.S. LLC (Sanofi), 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. 6,429,210 (the '210 patent) and 6,504,030 (the '030 patent) expire on December 10, 2019 (with pediatric exclusivity added).

Your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Clopidogrel Tablets USP, 75 mg and 300 mg, under this ANDA. You have notified the agency that Apotex Corp. (Apotex) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of either patent was brought against Apotex.

I. Approval of Clopidogrel Tablets USP, 75 mg.

The Division of Bioequivalence has determined your Clopidogrel Tablets USP, 75 mg, to be bioequivalent and, therefore, therapeutically equivalent to the RLD, Plavix Tablets, 75 mg, 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.

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/U_CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

II. Tentative Approval of Clopidogrel Tablets USP, 300 mg.

As noted above, your Clopidogrel Tablets USP, 300 mg, is tentatively approved. Prior to the submission of your amendment for the 300 mg strength, another applicant submitted a substantially complete ANDA providing for Clopidogrel Tablets USP, 300 mg, and containing paragraph IV certifications to the listed patents. Your ANDA will be eligible for final approval on the date that is 180 days after the date the agency receives notice, with respect to the other ANDA, of the commercial marketing date identified in section 505(j)(5)(B)(iv) of the Act.

Our decision to tentatively approve your Clopidogrel Tablets USP, 300 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practice (cGMP) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

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 TO ORIGINAL #2 – 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' cGMP are subject to agency review before final approval of the ANDA 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.

Please note that under section 505 of the Act, your Clopidogrel Bisulfate Tablets USP, 300 mg, may not be marketed without final agency approval. The introduction or delivery for introduction into interstate commerce of your 300 mg strength before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, your 300 mg strength 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 Linda Park, Project Manager, at (240) 276-8536.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

05/17/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.