DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 071258/S-040 (50 mg)
071196/S-063 (100 mg, 150 mg, and 300 mg)

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

Dear Sir:

This is in reference to your supplemental new drug applications dated July 12, 2013, submitted pursuant to 21 CFR 314.70 (c) (6) [Supplement – Changes Being Effected], regarding your abbreviated new drug applications for Trazodone Hydrochloride Tablets, USP.

Reference is also made to your amendments dated August 26, 2013 and August 28, 2013.

The supplemental new drug applications provide for revised insert and Medication Guide to be in accordance with the Agency's request dated July 25, 2012. In addition, revised container labels were also submitted.

We have completed the review of your supplemental applications, as amended, and they are approved. However, at the time of your next printing, please make the following revisions to the labeling. You may submit these changes in the next annual report provided the changes are described in full.

INSERT & MEDICATION GUIDE

a. Please include the botanical source of pregelatinized starch in the DESCRIPTION section of the insert and "What are the ingredients in trazodone hydrochloride tablets?" in the Medication Guide.

b. For the Medication Guide, please include the phonetic spelling of the established name in accordance with 21 CFR 208.20 (b) (1).

c. For the Medication Guide, please revise "trazodone hydrochloride tablets" to read "trazodone hydrochloride" in the seventh bullet in What should I tell my healthcare provider before taking trazodone hydrochloride tablets?/are breastfeeding or plan to breastfeed.

We 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.

CONTENT OF LABELING

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.

PROMOTIONAL MATERIALS

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

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 materials submitted are being retained in our files.

Sincerely,

{See appended electronic signature page}

Wm. Peter Rickman
Director
Division of Labeling and Program Support
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/

CHI-ANN Y WU
11/19/2013
For Wm. Peter Rickman