DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 017473/S-046

SUPPLEMENT APPROVAL

Teva Pharmaceuticals USA
Attention: Dennis E. Ahern, MS,
Director, Regulatory Affairs
425 Privet Road
Horsham, PA 19044-8005

Dear Mr. Ahern:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 15, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Orap (pimozide) 1 mg and 2 mg Tablets.

Reference is also made an Agency letter dated August 17, 2011, requesting revised labeling based upon our review of pharmacokinetic and safety information for pimozide as related to intrinsic defects in CYP2D6 metabolism.

This "Prior Approval" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY-Metabolism and Pharmacokinetics**, **CONTRAINDICATIONS**, **PRECAUTIONS-Drug Interactions**, and **DOSAGE AND ADMINISTRATION** sections as well as the addition of a new subsection under **PRECAUTIONS** entitled **Pharmacogenomics**.

We note that you have incorporated our requested revisions, verbatim.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact CDR Kofi Ansah, Senior Regulatory Project Manager, at (301)796-4158 or email: Kofi.Ansah@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
09/27/2011