DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-473/S-041

Teva Pharmaceuticals, USA
Attention: J. Michael Nicholas, Ph.D.
Senior Director, Regulatory Affairs
Teva Neuroscience
425 Privet Road
P.O. Box 1005
Horsham, PA 19044 - 8055

Dear Dr. Nicholas:

Please refer to your supplemental new drug application dated April 21, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ORAP (pimozide) 1 and 2 mg tablets.

This supplemental application provides for the addition of a statement to the **CONTRAINDICATIONS** and **PRECAUTIONS-Drug Interactions** sections of labeling to contraindicate the use of pimozide with Lexapro (escitalopram oxalate) and Celexa (citalopram hydrobromide) based on the approved labeling for Celexa and Lexapro..

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

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call LCDR Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at (301) 796-4158.

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

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

/s/

Thomas Laughren
4/28/2009 09:26:59 PM