DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-473/SLR-039

Teva Pharmaceuticals
Attention: Tu Tu
1090 Horsham Rd.
P.O Box 1090
North Wales, PA 19454-1090

Dear Mr. Tu:

Please refer to your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Orap (pimozide) tablets.

We acknowledge receipt of your submission dated June 23, 2003.

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 sertraline.

We have completed the review of this application and it is approved effective the date of this letter.

The final printed labeling (FPL) must be identical to the June 23, 2003 submitted labeling text (identified Rev. L 5/03).

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 Melina Griffis, R.Ph., Senior Regulatory Project Manager, at (301) 594-5526.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
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/

Russell Katz

10/27/03 08:45:23 AM