Dear Ms. Martinson:


Supplemental applications 18-644/S-028, 20-358/S-032, & 21-515/S-007, submitted as "Changes Being Effected" submissions, provide for the following changes to product labeling as requested in our Agency letter dated March 19, 2004, and revised in an electronic communication to you from Paul David, of this office, on April 19, 2004:

1. The addition of a new subsection under WARNINGS entitled Clinical Worsening and Suicide Risk.
2. Revisions to the PRECAUTIONS-Information for Patients section.
3. Delete the section in PRECAUTIONS-General entitled “Suicide”.
4. Add a reference to the WARNINGS section at the end of the PRECAUTIONS- Pediatric Use section, i.e., (see WARNINGS-Clinical Worsening and Suicide Risk).

We have completed the review of these supplemental applications and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in your labeling submitted on May 11, 2004. Accordingly, these supplemental applications are approved effective on the date of this letter.

We note that your supplemental applications, 18-644/S-027, 20-358/S-031, & 21-515/S-006, were superseded by your May 11, 2004 submission. Therefore, we are going to administratively close these supplements and retain them in our files.
If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

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
5/27/04 08:53:41 AM