Dear Ms. Mulligan:


These “Changes Being Effected” supplements provide for adding adverse events to the Post-Marketing Experience section of labeling. Specifically, the following adverse events were added:

**Hepatobiliary Disorders:** elevated liver enzymes, hepatitis

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

**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 Teresa Wheelous, Sr. Regulatory Project Manager, at (301) 796-1161.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
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.

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/s/
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RUSSELL G KATZ
03/01/2012