



NDA 19-908 [redacted] S-025

Sanofi- Synthelabo Research
Attention: Daryl DeKarske, MPH
9 Great Valley Parkway
Malvern, PA 19355

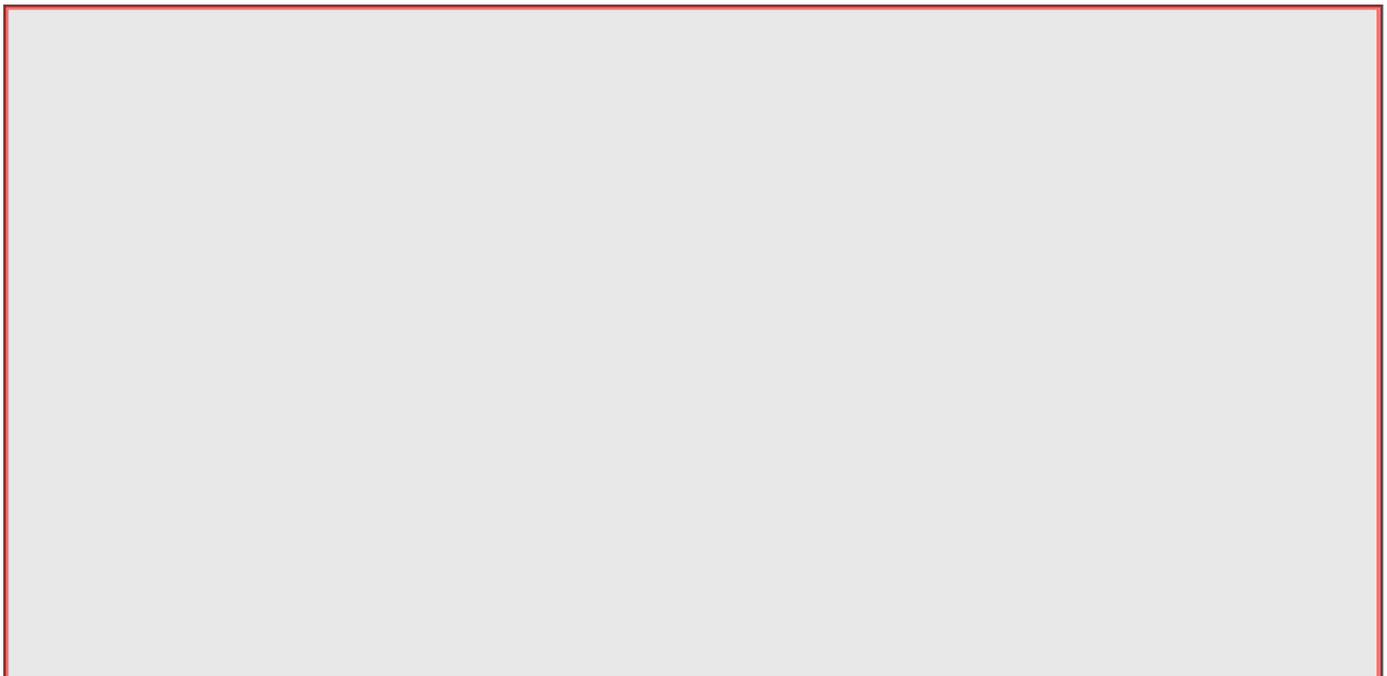
Dear Mr. DeKarske:

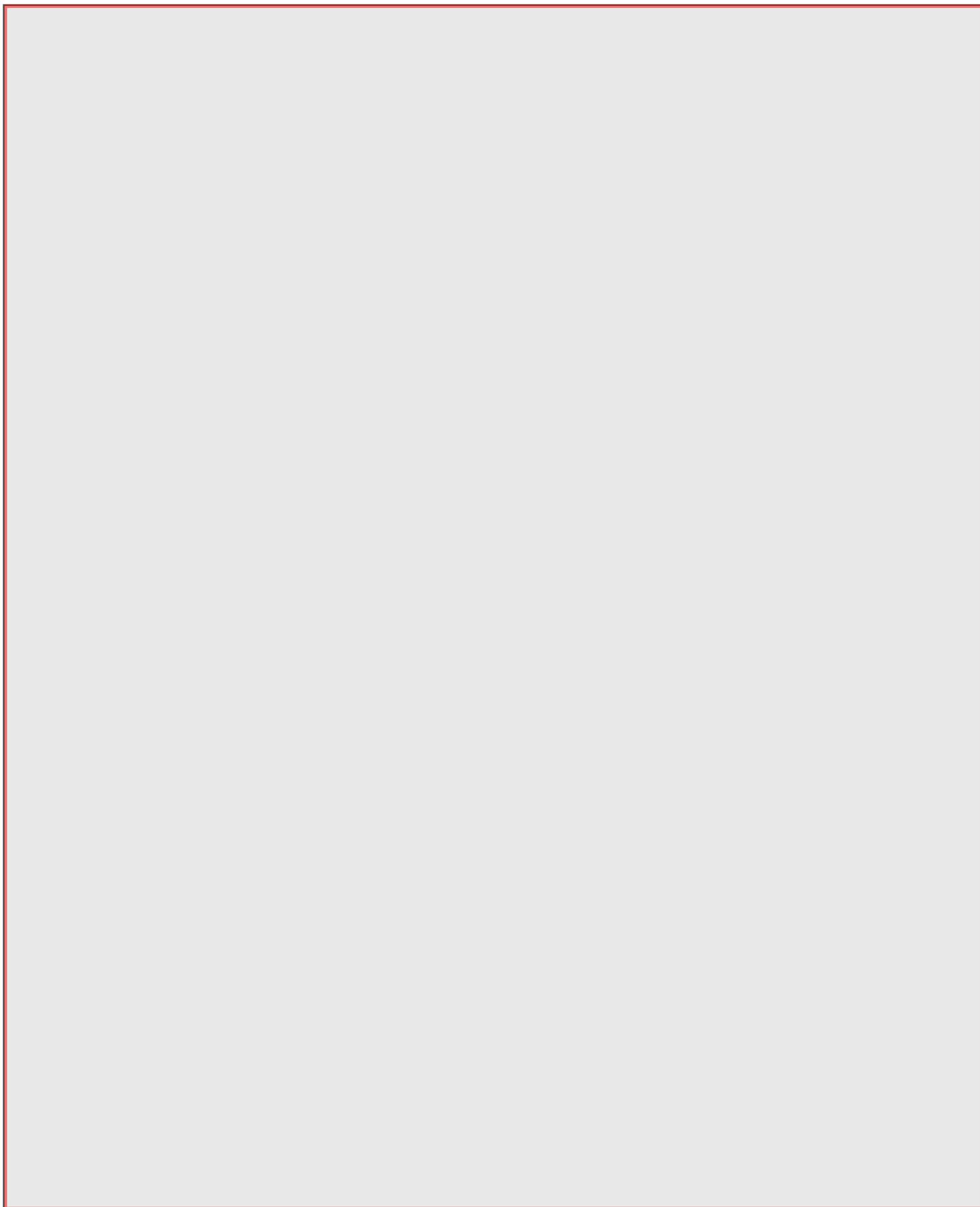
Please refer to the supplemental new drug applications noted below submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ambien (zolpidem tartrate) Tablets.

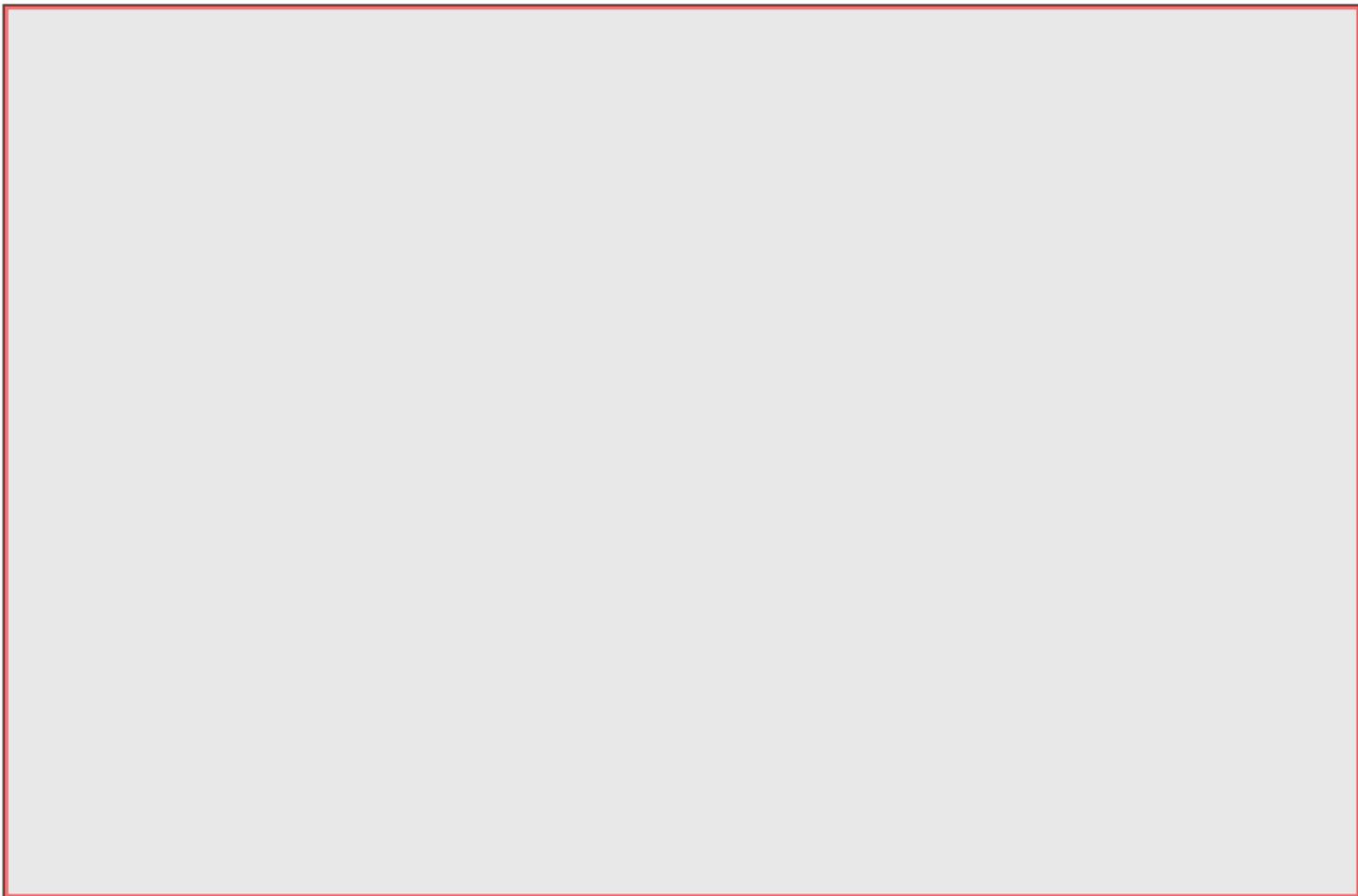
Application	Submitted on:	Received on:	Provides for:
S-025	August 14, 2007	August 15, 2007	“Prior Approval” Supplement: Medication Guide.

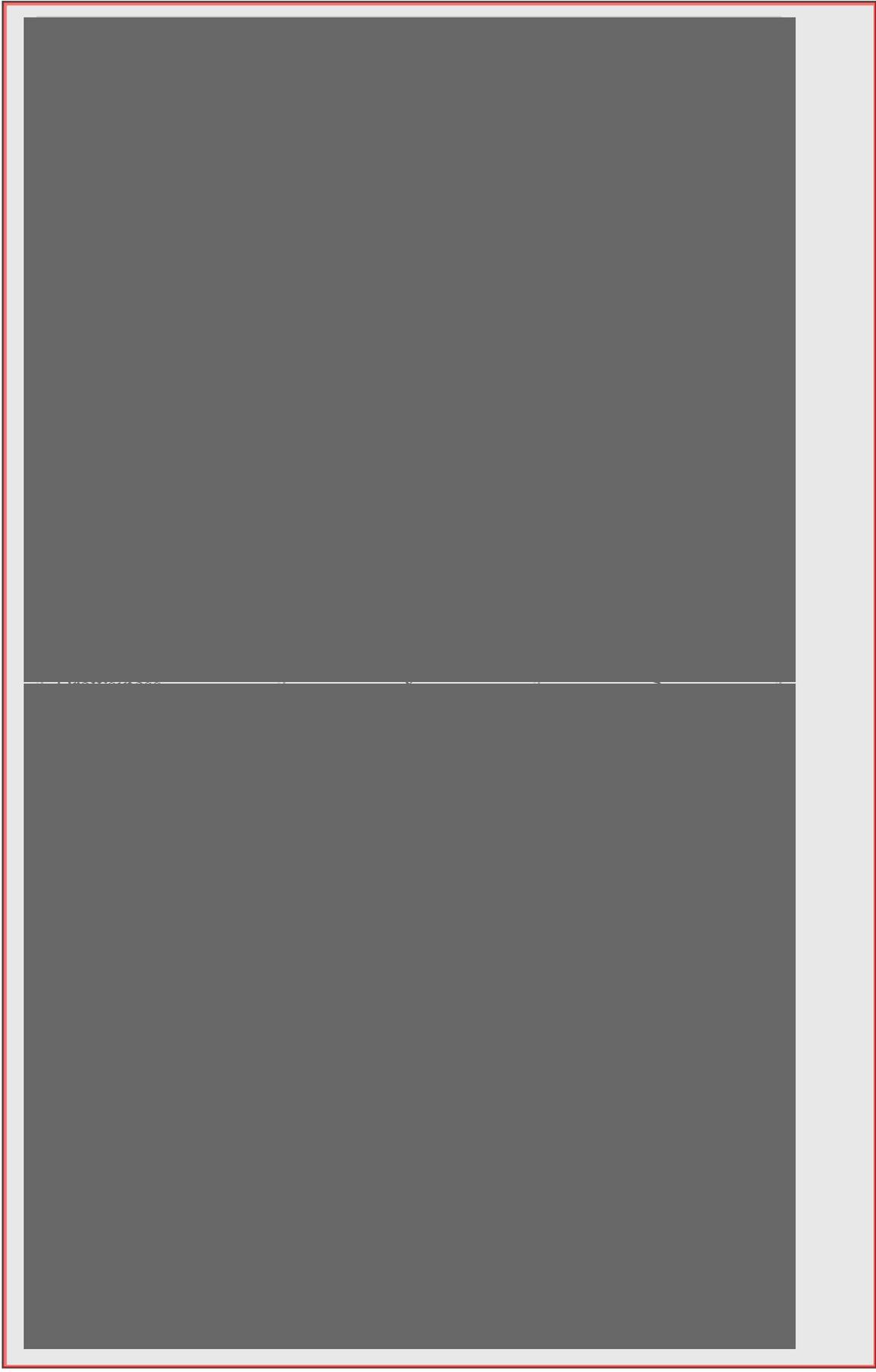
We note that Supplemental Application **S-025** was submitted in response to an Agency request included in a December 4, 2006 letter.

We have completed our review of supplemental application (**S-025**) and it is approved, effective on the date of this letter.









Please note that we have attached to this letter labeling that includes the approved Medication Guide (**S-025**) and all of the additional revisions to the package insert (in ~~strikeout~~/redline format) discussed above. We ask that you submit final printed labeling (FPL) that is identical to this labeling.

Incorporate all previous revisions as reflected in the most recently approved package insert. To facilitate review of your submission, provide a highlighted or marked-up copy that shows the changes that are being made.



With regard to “approved” Supplemental Application S-025:

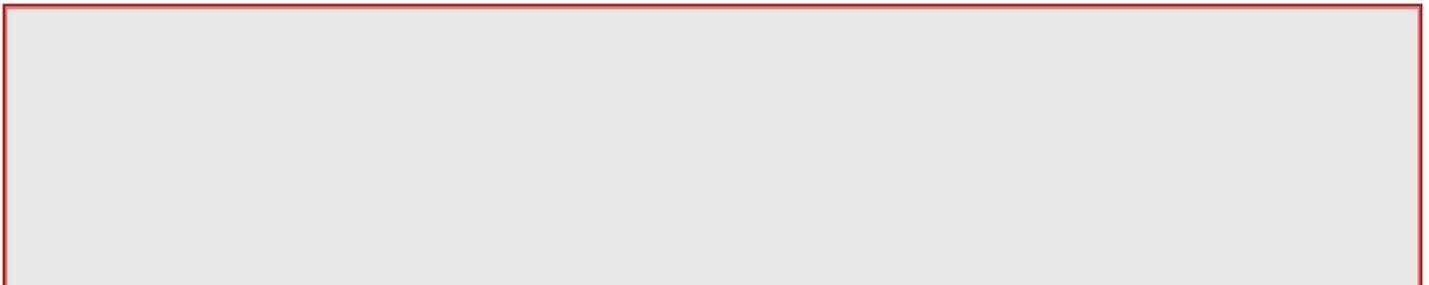
If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

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

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplemental application NDA 19-908 S-025.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, submit revised content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at the following website:

<http://www.fda.gov/oc/datacouncil/spl.html>



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 Cathleen Michaloski, MPH, Regulatory Project Manager, at 301-796-1123.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD

Director

Division of Neurology Products

Office of Drug Evaluation I

Center for Drug Evaluation and Research

Enclosure: Package Insert including Medication Guide

**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
10/4/2007 04:40:30 PM