DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-908 S-024, S-027

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-024	March 27, 2007	March 28, 2007	"Changes Being Effected" Supplement; revisions to Overdose section.
S-027	February 28, 2008	February 29, 2008	"Prior Approval" Supplement: incorporation of all new language approved for Ambien CR (NDA 21774/S-003) on December 20, 2007

We acknowledge receipt of your submission dated February 28, 2008.

We have completed our review of **S-027** and it is approved, effective the date of this letter for use as recommended in the enclosed agreed- upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text (text for the package insert and the medication guide submitted on February 28, 2008.

Supplemental Application S-024:

We note that you provided a complete response to our October 4, 2007 approvable letter to supplemental application **S-024** on February 28, 2008. However, we also note that all of the proposed changes included in that submission are approved in **S-027**. Therefore, we will not complete a review of this supplemental application and it will be retained in our files with no further action.

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-027**." 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, BSN/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

5/7/2008 05:39:17 PM