DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019908 /S-029 **SUPPLEMENT APPROVAL**

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.

Please refer to your September 16, 2009 Supplemental New Drug Application (sNDA), received September 16, 2009, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ambien IR (zolpidem tartrate), 5 and 10 mg Tablets.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to, except for including the revisions in the enclosed labeling (text for package insert, and text for Medication Guide). These revisions are terms of the sNDA approval. For administrative purposes, please designate this submission, **"SPL for approved NDA 019908/S-029".**

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling text for the Package Insert and the Medication Guide and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission

"Final Printed Labeling for approved NDA 019908/S-029." Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 19908 for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Cathleen Michaloski, MPH, Regulatory Project Manager, at (301) 796-1123.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert and Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19908	SUPPL-29	SANOFI AVENTIS US LLC	AMBIEN (ZOLPIDEM TABLETS_)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

CATHLEEN B MICHALOSKI
04/07/2010

RUSSELL G KATZ
04/14/2010