DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-908/S-022

sanofi-aventis, U.S. Inc.
9 Great Valley Parkway
P.O. Box 30-26
Malvern, PA 19355

Attention: Qinghua (Sarah) Ji, M.D.
Assistant Director, Regulatory Development

Dear Dr. Ji:

Please refer to your supplemental new drug application dated September 29, 2006, received September 29, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ambien (zolpidem tartrate) 5 and 10 mg tablets.

We also acknowledge receipt of your additional submissions dated January 26, 2007, and March 2, 2007.

This supplemental application was submitted to provide the pediatric clinical study report that responded to the Agency's Pediatric Written Request dated July 31, 2006.

This supplemental new drug application provides for the use of Ambien for the treatment of Attention-Deficit-Hyperactivity-Disorder-associated insomnia in the pediatric population (ages ≥ 6 years old to ≤ 17 years old).

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

Final Printed Labeling

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and the patient package insert).

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 the submission "**FPL for approved supplement NDA 19-908/S-022".** Approval of this submission by FDA is not required before the labeling is used.

Fulfillment of Pediatric Research Equity Act (PREA) Study Requirements

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

However, your juvenile study in rats did not include histopathology assessment of a standard battery of tissues; only central and peripheral nervous and reproductive tissues were examined. If you intend to pursue the use of Ambien in the pediatric population, you will need to conduct an additional study in juvenile animals to evaluate potential microscopic changes in a standard battery of tissues.

Promotional Materials

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed the enclosed product labeling and has determined that it contains significant new risk information relating to your drug product. Therefore, we are hereby informing you that all promotional materials that include representations about Ambien should be revised to include the new risk information immediately. These revisions should include prominent disclosure of the important new information described in the WARNINGS and PRECAUTIONS sections that appear in the revised package labeling. If you have any questions about the promotion of your drug products, please contact DDMAC by facsimile at (301)796-9878 or at the address provided below.

In addition, please send one copy to the Division of Neurology Products and two copies of both the promotional materials and the proposed package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

Dear Healthcare Professional Letter

We note that, on March 14, 2007, you issued a Dear Health Care Professional Letter (DHCP) that informed healthcare professional about the risks of sleep-driving and anaphylaxis. If you have not yet done so, 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

If, in the future, additional DHCP letters are necessary, we ask that you also submit copies to this NDA and to MEDWATCH as described above.

Other

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 G. Katz, M.D.
Director, Division of Neurology Products
Office of Drug Evaluation 1
Center for Drug and Evaluation and Research

Enclosure

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

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