DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 019908/S-036
NDA 021774/S-017

SUPPLEMENT APPROVAL

Sanofi-aventis U.S. LLC
Attention: John Cook
Senior Director, Global Regulatory Affairs Marketed Products
55 Corporate Drive, Mailstop: 55C-205A
Bridgewater, NJ 08807

Dear Mr. Cook:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received October 29, 2014, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Ambien (zolpidem tartrate) 5 mg and 10 mg tablets (NDA 019908) and Ambien CR (zolpidem tartrate extended-release) 6.25 mg and 12.5 mg tablets (NDA 021774).

We acknowledge receipt of your amendments dated February 11, 2016, which constituted complete responses to our April 29, 2015, action letter.

These Prior Approval sNDAs provide for revisions to the following sections of the labeling:

- Highlights, Drug Interactions
- Dosage and Administration, 2.1 Dosage in Adults
- Warnings and Precautions, 5.1 CNS Depressant Effects and Next-Day Impairment
- Drug Interactions, 7.1 CNS-active Drugs
- Drug Interactions, 7.2 Drugs that Affect Drug Metabolism via Cytochrome P450
- Highlights, Recent Major Changes revised to indicate that Sections 2.1 and 5.1 have been modified
- Highlights, Indications and Usage (NDA 019908) revised for consistency with class labeling

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA

automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert and Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, contact Dr. Brendan Muoio, Regulatory Project Manager, at (240) 402-4518 or brendan.muoio@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tiffany Farchione, MD
Deputy Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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.

/s/

TIFFANY R FARCHIONE
08/11/2016