DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-599/S-011 and 012

Sanofi Aventis U.S., L.L.C.
Attention: Jo Beth Crimmins, Specialist, Product Support
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Crimmins:

Please refer to your supplemental new drug applications dated November 16, 2006 and January 19, 2007, received November 16, 2006 and January 19, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rilutek (riluzole) Tablets.

We acknowledge receipt of your submissions dated October 5, 2007 and March 12, 2008.

Supplemental new drug application 011 provides for label revisions to the WARNINGS and PRECAUTIONS sections to add information about hepatitis; the ADVERSE REACTIONS section to add information about anaphylaxis; and the OVERDOSAGE section.

"Changes Being Effected" supplemental new drug application 012 provides for label revisions to the Special Populations subsections of the CLINICAL PHARMACOLOGY and PRECAUTIONS sections to add information from a pharmacokinetic trial that showed that dosing adjustments for the Japanese population are not necessary.

We completed our review of these applications, as amended and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the 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 this submission "**FPL for approved supplement NDA 20-599/S-011 and 012**." Approval of this submission by FDA is not required before the labeling is used.

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

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: Labeling

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

7/10/2009 11:44:53 AM