DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 14-399/S-063

Sanofi-Aventis U.S., Inc.
Attention: Emmanuel Hamon, U.S. Regulatory Affairs
300 Somerset Boulevard
Bridgewater, N.J. 08807-0977

Dear Mr. Hamon:

We acknowledge receipt of your supplemental new drug application dated February 3, 2006, and received February 6, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norpramin (desipramine hydrochloride) Tablets.

The supplement provides for additions to the **OVERDOSAGE** section denoting a higher mortality rate of desipramine overdosage when compared to other tricyclic antidepressants.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted February 3, 2006), which incorporates the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter. The approved labeling is attached to this letter.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Renmeet Gujral, Pharm. D., Regulatory Project Manager, at 301-796-1080.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment

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

/s/

Thomas Laughren
4/11/2006 10:54:27 AM