DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 5-010/S-049

Sanofi Aventis U.S.
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807

Attention: Debra L. Kolb
US Regulatory Affairs Marketed Products

Dear Ms. Kolb:

Please refer to your supplemental new drug application dated September 10, 2008, received September 12, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Demerol® (meperidine hydrochloride) Tablets and Oral Solution.

This changes being effected supplemental new drug application provides for the change to the **ADVERSE REACTIONS** section of the package insert to include an additional statement regarding hypersensitivity reactions including anaphylaxis.

We have completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text, submitted September 12, 2008.

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 Kathleen Davies, Regulatory Health Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and
Rheumatology Products
Office of Drug Evaluation II
Center for Drug 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/

Bob Rappaport

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