DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-623/S-006
NDA 20-624/S-016

Sanofi-Aventis U.S. LLC
Attn: Sanjukta Bhaduri
Senior Manager
300 Somerset Corporate Boulevard
PO Box 6977
Bridgewater, NJ 08807-0977

Dear Dr. Bhaduri:

Please refer to your supplemental new drug applications dated November 8, 2006, received November 9, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anzemet® (dolasetron mesylate) Tablets and Injection.

We acknowledge receipt of your submissions dated March 16, 2007.

These supplemental new drug applications provide for changes for the Precautions (Pediatric Use) section of both the tablets and injection package inserts.

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

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package inserts 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

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

Please submit one market package of the drug product when it is available.

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 Giuseppe Randazzo, Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., MPH
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (text for the package insert for NDA 20-623 (Tablet) and NDA 20-624 (Injection)

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

/s/

Joyce Korvick

5/30/2007 02:00:13 PM