



NDA 20-623/S-007

NDA 20-624/S-017

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 December 06, 2006, received December 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anzemet® (dolasetron mesylate) Tablets and Injection.

These supplemental new drug applications provides for changes to the label under the Adverse Reactions section. The following changes were proposed:

Post-marketing

There are rare reports of wide complex tachycardia or ventricular tachycardia and of ventricular fibrillation cardiac arrest following intravenous administration.

We completed our review of these applications and these applications are approved, effective on the date of this letter for use as recommended with the following agreed upon labeling changes:

1. The subsection title of **Post-marketing** will be changed to **Postmarketing Experience.**
2. The word will be removed from your proposed sentence to read:

There are rare reports of wide complex tachycardia or ventricular tachycardia and of ventricular fibrillation cardiac arrest following intravenous administration.

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 your label approved on May 30, 2007 with the addition of the above agreed upon changes. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

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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

**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
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