DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020623/S-010
NDA 020624/S-023

SUPPLEMENT APPROVAL

Sanofi-Aventis U.S. LLC
Attention: Nancy Dougherty
U.S. Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Dougherty:

Please refer to your Supplemental New Drug Applications (sNDA) dated March 21, 2012 and April 25, 2012, received March 21, 2012 and April 25, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Anzemet (dolasetron mesylate) tablets, 50 mg and 100 mg, and Anzemet (dolasetron mesylate) injection, 20 mg/mL.

We acknowledge receipt of your amendments dated July 12, 2013.

This "Prior Approval" supplemental new drug application provides for the following:

NDA 020623/S-010: Revises the package insert label to remove all information for the prevention of postoperative nausea and vomiting based on current guidelines regarding the administration of oral Anzemet prior to surgery

NDA 020624/S-023: Updates the Indications section of the package insert label based on current guidelines regarding retreatment with receptor antagonist in postoperative patients who have failed a previous trial of a 5-HT_3 receptor antagonist

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in

pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

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 Mary Chung, Regulatory Project Manager, at (301) 796-0260.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Office of Drug Evaluation III
Division of Gastroenterology and Inborn Errors Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

JOYCE A KORVICK
09/16/2013