DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-624/S-013

Aventis Pharmaceuticals, Inc.
Attention: Laura Cooper, Manager, US Regulatory Affairs Marketed Products
SC3-605A(Mail Code)
300 Somerset Corporate Boulevard, PO Box 6977
Bridgewater, NJ 08807-0977

Dear Ms. Cooper:

Please refer to your supplemental new drug application dated June 12, 2003, received June 13, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anzemet® (dolasetron mesylate) Injection.

We acknowledge receipt of your submission dated November 30, 2004.

Your submission of November 30, 2004 constituted a complete response to our December 12, 2003 action letter.

We refer to the May 26, 2005 teleconference between Dr. Betsy Scroggs, RPM of this Division and Dr. Steve Caffe of your firm and his subsequent agreement via email accepting FDA's labeling revision.

We also refer to the June 1, 2005 teleconference between Dr. Betsy Scroggs, RPM of this Division and you and your subsequent agreement via email to accept additional FDA revisions sent via facsimile on May 31, 2005. We also note that your have agreed to submit these agreements with labeling in writing to the document control room.

This supplemental new drug application provides to update the geriatric information in the package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-624/S-013**." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410
FDA
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 Betsy Scroggs, Regulatory Project Manager, at (301) 827-1250.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick

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