



NDA 20-449/S-016

Aventis Pharmaceuticals, Inc.
200 Crossing Boulevard
P.O. Box 6890
Bridgewater, NJ 08807-0890

Attention: Cheryl Anderson
Senior Director and Therapeutic Area Head
Regulatory Oncology

Dear Ms. Anderson:

Please refer to your supplemental new drug application dated June 21, 2001, received June 25, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxotere (docetaxel) for Injection Concentrate, 20 mg and 80 mg.

We acknowledge receipt of your submissions dated December 20, 2001; July 15 and September 2, 2002; January 20, February 20, March 20 and 28, 2003.

Your submission of January 20, 2003 constituted a complete response to our December 21, 2001 action letter.

This supplemental new drug application provides for revisions to the carton, vial and blister and package insert labeling.

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 (package insert submitted) and to the immediate container and carton labels submitted March 20, 2003.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-449/S-016." 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, HF-2
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 Ann Staten, Regulatory Project Manager, at (301) 594-0490.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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