DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-449/S-017, S-019, S-022

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

Attention: Jacqueline Little, M.Sc.
Regulatory Liaison

Dear Ms. Little:

Please refer to your supplemental new drug application dated November 6, 2002, received November 7, 2002, 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 also refer to your final printed labeling dated November 6, 2002 (S-017 and S-019) submitted in response to our July 9 and 30, 2002 approval letters.

This "Changes Being Effected" supplemental new drug application (S-022) provides for the addition of new text to the ADVERSE REACTIONS, Post-marketing Experiences subsection of the package insert.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 6, 2002. We have also reviewed the final printed labeling that you submitted in accordance with our July 9 and 30, 2002 letters, and we find it acceptable.

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 the requirements for an approved NDA set forth under 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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