

020449_5028

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

20-449/S-028

Trade Name: Taxotere Injection Concentrate, 20
& 80 mg

Generic Name(s): (docetaxel)

Sponsor: Aventis Pharmaceuticals, Inc.

Agent:

Approval Date: May 19, 2004

Indication: Provides for use in combination with prednisone as a treatment for patients with androgen independent (hormone refractory) metastatic prostate cancer

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RESEARCH**

APPLICATION NUMBER:

20-449-S-028

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Reviews / Information Included in this NDA Review.

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Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
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Administrative Document(s)	X
Correspondence	X

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Approval Letter(s)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-449/S-028

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

Attention: Michael Rozycki, Ph.D.
Director, US Regulatory Affairs

Dear Dr. Rozycki:

Please refer to your supplemental new drug application dated January 26, 2004, received January 27, 2004, 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 March 29, April 6, 16, 28 and May 13, 2004.

This supplemental new drug application provides for the use of Taxotere® (docetaxel) in combination with prednisone as a treatment for patients with androgen independent (hormone refractory) metastatic prostate cancer.

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 (text for the package insert, text for the patient package insert).

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 15 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-028.” Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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In addition, submit three copies of the introductory promotional materials that you propose to use for this product. 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 insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Ann Staten, Regulatory Project Manager, at (301) 594-0490.

Sincerely,

{See attached 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
5/19/04 11:53:12 AM