NDA 20-449/S-005, S-006

June 22, 1998

Rhone-Poulenc Rorer Pharmaceuticals, Inc.
500 Arcola Road
P.O. Box 1200
Collegeville, PA 19426-0107

Attention: Anne-Margaret Martin
Associate Director
Worldwide Regulatory Affairs

Dear Ms. Martin:

Please refer to your supplemental new drug applications dated December 22, 1997 (S-005) and March 23, 1998 (S-006), received December 22, 1997 and March 24, 1998 respectively, 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 January 16, 19, February 19, March 11, 17, 30, April 7, 15, 17, May 1, 14, June 15, and 16, 1998.

The User Fee goal dates for these applications are June 22, 1998 (S-005) and March 24, 1999 (S-006).

These supplemental applications provide for the use of TAXOTERE® (docetaxel) for Injection Concentrate for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy (S-005) and change the label to reflect the three day corticosteroid premedication regimen (S-006).

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

This NDA was approved under the regulations for accelerated approval of new drugs for serious or life-threatening illnesses, specifically, 21 CFR 314.510. Approval of this supplement (S-005) fulfills your commitments made under 21 CFR 314.510.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and the patient package insert. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 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 "FINAL PRINTED LABELING" for approved supplemental NDA 20-449/S-005, S-006. Approval of this submission by FDA is not required before the labeling is used.

We remind you of the Phase 4 commitment specified in your submission dated June 15, 1998 as follows:

(b)(4)----------

We also remind you of your Phase 4 commitments as stated in the approval letter dated May 14, 1996 as follows:

(b) (4)----------

(b) (3), (b)(4)----------

Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter submitted to this NDA. In addition, we request that, under 21 CFR

commitment. The status summary should include the number of patients entered in each study,

study reports, a list of the dates of all submissions related to these commitments, and any changes

labeling changes, relating to these commitments should be clearly designated "Phase 4

Should a letter communicating the important information about this drug product (i.e., a "Dear

submit a copy of the letter to this NDA and a copy to the following address:

FDA

Rockville, MD 20852-9787

to use for this product. All proposed materials should be submitted in draft or mock-up form, not
Oncologic Drug Products and two copies of

Division of Drug Marketing, Advertising,
nd Communications, HFD-40

5600 Fishers Lane

We remind you that you must comply with the requirements for an approved NDA set forth

If you have any questions, please contact Ann Staten, Project Manager, at (301) 594-5770.

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Draft Labeling