



NDA 50-467/S-068
NDA 50-629/S-014

Pharmacia & Upjohn Company
Mail Code 0200-298-113
7000 Portage Road
Kalamazoo, MI 49001-0199

Attention: Mr. Gregory A. Brier, BSCHE, MBA
Senior Regulatory Manager, Global Regulatory Affairs

Dear Mr. Brier:

Please refer to your supplemental new drug applications (sNDAs) dated April 5, 2002, received April 8 and April 12, 2002, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Doxorubicin Hydrochloride for Injection, USP 10, 20, 50 and 150 mg, and Doxorubicin Hydrochloride Injection, USP 10, 20, 50, 75, 150 and 200 mg.

We also refer to the May 8, 2003 letter approving sNDAs (S-068 and S-014), which stated the approved indication as follows.

“Supplemental new drug applications (S-068 and S-014) provide for the use of Doxorubicin Hydrochloride for Injection and Doxorubicin Hydrochloride Injection for use in combination with cyclophosphamide as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.”

The purpose of this letter is to **correct** the approved indication as stated in the May 8, 2003 letter. The **corrected approved indication** is as follows:

“Supplemental new drug applications (S-068 and S-014) provide for use of Doxorubicin Hydrochloride for Injection and Doxorubicin Hydrochloride Injection as a component of adjuvant therapy in women with evidence of axillary lymph node involvement following resection of primary breast cancer.”

The above approved indication was communicated to you on February 13, 2003 and your acceptance was received on March 10, 2003. In addition, this indication is consistent with the labeling text included in the May 8, 2003 approval letter.

If you have any questions, call Brenda Atkins, Consumer Safety Officer, at 301-594-5767.

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

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Grant Williams
5/23/03 08:18:41 AM
Signed for Dr. Pazdur