NDA 20-491/S-001

Pharmacia & Upjohn Company
Attention: Ms. Rebecca K. Tong
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Tong:

Please refer to your supplemental new drug application dated December 19, 1997, received December 22, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Corvert (ibutilide fumarate) Injection, 0.1 mg/ml.

We acknowledge receipt of your submission dated February 25, 1999. Your submission of February 25, 1999 constituted a complete response to our November 19, 1998 action letter.

This supplemental new drug application, as amended, provides for final printed labeling revised to add information to the **CLINICAL PHARMACOLOGY/Clinical Studies**, **ADVERSE REACTIONS** and **DOSAGE AND ADMINISTRATION** sections regarding post-cardiac surgery patients treated with Corvert.

We have completed the review of this supplemental application, 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 final printed labeling included in your February 25, 1999 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

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, please contact:

Ms. Diana Willard
Regulatory Health Project Manager
(301) 594-5300

Sincerely yours,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research