



NDA 12-827/SCP-049

First Horizon Pharmaceutical Corporation
Attention: Mark Pilato, CMC Manager, Regulatory Affairs
6195 Shiloh Road
Alpharetta, GA 30005

Dear Mr. Pilato:

Please refer to your supplemental new drug application dated June 27, 2002, received June 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Robinul[®] and Robinul[®] Forte (glycopyrrolate tablets, USP).

We acknowledge receipt of your submission dated March 26, 2003, which constituted a complete response to our December 23, 2002 action letter.

This "Changes Being Effected in 30 days" supplemental new drug application proposes the following change: a blister package configuration by (b)(4)-----of Robinul[®] Forte, 2 mg Tablets for physician samples using product manufactured Mikart, Inc, the approved drug product manufacturer that was the subject of supplement S-045.

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 26, 2003.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ryan Barraco, Regulatory Project Manager, at (301) 827-0191.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
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/

Joyce Korvick
7/25/03 02:47:54 PM
for Dr. Robert Justice