DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-705/S-013

Attention: Alicia A. Washington
First Horizon Pharmaceutical Corporation
6195 Shiloh Road
Alpharetta, GA 30005

Dear Ms. Washington:

Please refer to your supplemental new drug application dated November 20, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrolingual Pumpspray (nitroglycerin lingual spray), 400 mcg per spray.

This "Changes Being Effected in 30 days" supplemental new drug application provides for more inclusive information to the **CONTRAINDICATIONS, WARNINGS, PRECAUTIONS (INFORMATION FOR PATIENTS), DRUG INTERACTIONS** and in the **INFORMATION FOR PATIENTS** sections of the package insert labeling.

We have completed our review of this supplemental new drug application, as amended and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 4, 2004.

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 call Mr. John David, Regulatory Project Manager, at (301) 594-5368.

Sincerely,

*{See appended electronic signature page}*

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal 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/

---

Norman Stockbridge
9/2/04 04:52:49 PM