DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-705/S-012

G. Pohl Boskamp GmbH & Co.
Attention: Mr. Frank Bohnenstengel
Kieler Strausse 11
D-25551 Hohenlockstedt
P.O. Box 1253
Germany

Dear Mr. Bohnenstengel:

Please refer to your supplemental new drug application dated December 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrolingual Pumpspray (nitroglycerin lingual spray), 400 mcg per spray.

We acknowledge receipt of your submissions dated April 23, June 21 and October 18, 2002. Your submission of October 18, 2002 constituted a complete response to our April 11, 2002 approvable letter.

This supplemental new drug application provides for a new 60 dose packaging configuration of Nitrolingual Pumpspray. It also provides for draft labeling revised as follows:

Package Insert

1) In the INFORMATION FOR THE PATIENT section, "75 sprays" has been replaced with "60" sprays throughout the section.

2) Under **DESCRIPTION,** "75" metered sprays has been replaced with "60" metered sprays.

3) Under **DOSAGE AND ADMINISTRATION**, 2nd paragraph, the number "75" has been replaced by "60" metered sprays per bottle.

4) Under **HOW SUPPLIED**, the 2nd sentence that reads: Each unit contains "5.7 g (NDC 59630-300-75)….75 metered sprays" has been changed to:

   Each unit contains "4.9 g (NDC 59630-300-65)…60 metered sprays."

Carton and Container Labeling

1) The commercial and physician container labels have been changed to list the fill weight as "4.9 g" and providing "60 metered sprays".

2) The commercial carton labels have been changed to list the fill weight as "4.9 g NET CONTENTS" and providing "60 metered sprays". A new NDC# of 59630-300-65 has used to reflect the new product configuration.

3) The physician carton label has been revised to list the fill weight as "4.9 g NET CONTENTS, PHYSICIAN SAMPLE" and providing "60 metered sprays". A new NDC# of 59630-300-66 has been used to reflect the new configuration for the physician sample.

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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert, immediate container and carton labels included in your submission of October 18, 2002).

Please submit the copies of FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 "FPL for approved supplement NDA 18-705/S-012." Approval of this submission by FDA is not required before the labeling is used.

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:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C.Throckmorton M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: First Horizon Pharmaceutical Corporation
Attention: Mr. Alan T. Roberts
6195 Shiloh Road
Alpharetta, GA 30005

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

/s/

Doug Throckmorton

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