DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18705/S-025

SUPPLEMENT APPROVAL

G Pohl Boskamp GmbH and Co. KG
C/o Espero Pharmaceuticals, Inc.
Attention: Quang Pham
Chief Executive Officer
14286-19 Beach Blvd #270
Jacksonville, Florida 32250

Dear Mr. Pham:

Please refer to your Supplemental New Drug Application (sNDA) dated April 17, 2018, received April 17, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nitrolingual® Pumpspray (nitrogylycerin lingual spray) 400 mcg per spray, 60 and 200 metered sprays.

This Prior Approval supplemental new drug application provides for revisions in accordance with the Pregnancy Lactation Labeling Rule, and minor editorial changes. Other modifications are as follows:

1. Under section**16, HOW SUPPLIED/STORAGE AND HANDLING** paragraph 3 was modified to include temperature ranges to read as follows:

   Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15 – 30°C (59 – 86°F) [see USP Controlled Room Temperature].

2. In the Instructions for Use under the first bullet of **How should I store Nitrolingual Pumpspray?** the temperature excursions were removed to read as follows:

   Store Nitrolingual Pumpspray at room temperature between 68°F – 77°F (20°C – 25°C).

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the prescribing information), with

the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Alexis Childers, Sr. Regulatory Project Manager, at (301) 796-0442.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARY R SOUTHWORTH
07/30/2018