DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-705/S-017

Pohl Boskamp GmbH & Co. KG
c/o Sciele Pharma, Inc.
Attention: Dia P. Hill, Manager, Regulatory Affairs
Five Concourse Parkway, Suite 1800
Atlanta, GA 30328

Dear Ms. Hill:

Please refer to your supplemental new drug application dated March 31, 2008, received April 1, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nitrolingual (nitroglycerin) Spray, 400 mcg per spray.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional packaging configuration for the approved Nitrolingual Pumpspray 60 and 200 metered spray bottles.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 31, 2008 and following agreed upon revisions to the carton and immediate container labels.

1. Revise the "Duo-" portion of the name "Duopack" so it is not similar in color and prominence to the proprietary name and is not a focal point of the packaging.

2. Revise the statement of contents directly under the name "Duopack" to include the number of spray bottles in the packaging configuration. For Example:

   Each Duopack contains two metered dose spray bottles, one each of the following sizes:
   60 Metered Sprays, 4.9 g net contents
   200 Metered Sprays, 12 g net contents

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the submitted carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 18-705**." Approval of this submission by FDA is not required before the labeling is used.

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

If you have any questions, call Teshara G. Bouie, Regulatory Health Project Manager, at (301) 796-1649.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

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

/s/

Jim Vidra

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