DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-649/S-015

Schwarz Pharma, Inc.
Attention: Michelle Witt
Regulatory Affairs Manager
P.O. Box 2038
Milwaukee, WI 53201-2038

Dear Ms. Witt:

Please refer to your supplemental new drug application dated January 16, 2006, received January 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EDEX® (alprostadil for injection).

We also refer to your submission dated May 10, 2006, which constituted a Complete Response to the March 24, 2006, Approvable Letter.

This supplemental new drug application submitted as "Prior Approval" provides for changes in the Physician Insert (PI) and Patient Package Insert (PPI) regarding the potential for needle breakage.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed PI and PPI.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplement NDA 20-649/SLR-015**." Approval of these submissions by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to Division of Reproductive and Urologic Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 796-2130.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
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/

Daniel A. Shames
6/9/2006 10:28:13 AM