DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-312/S-016

Schwarz Pharma, Inc.
Attention: Ms. Donna K. Multhauf
P. O. Box 2038
Milwaukee, WI 53201-2308

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated October 17, 2000 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Univasc (moexipril hydrochloride) Tablets.

This supplemental new drug application provides for final printed labeling revised as follows:

1. Under the ADVERSE REACTIONS/*Dermatologic* subsection, the term "alopecia" has been added, to read as follows:

   Dermatologic: Apparent hypersensitivity reactions manifested by urticaria, rash, pemphigus, pruritus, photosensitivity, alopecia.

2. In your submission, you indicated that the word "hyponatremia" has been added under the **ADVERSE REACTIONS/Clinical Laboratory Test Findings**/*Serum Electrolytes* subsection. We also note that you have added "hyperkalemia," to read as follows:

   Serum Electrolytes: Hyperkalemia (see PRECAUTIONS), hyponatremia.

3. The description "Manufactured for" and "By Schwarz Pharma AG, Monheim, Germany" has been omitted from the end of the package insert, to read as follows:

   SCHWARZ
   PHARMA
   Milwaukee, Wisconsin 53201

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 submitted final printed labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

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:

Ms. Sandra Birdsong
Regulatory Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research