DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-729/S-010

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

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated August 30, 2001 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Uniretic (moexipril hydrochloride/hydrochlorothiazide) 7.5/12.5 and 15/25 mg Tablets.

We acknowledge receipt of your submission dated December 27, 2001 that constituted a complete response to our December 18, 2001 action letter.

This supplemental new drug application provides for a new dosage strength tablet, 15/12.5 mg, including final printed labeling that incorporated this change.

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 (package insert submitted December 27, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

We also refer to conversations between and Ms. Carol Holquist, Office of Drug Safety (ODS, formerly the Office of Post-Marketing Drug Risk Assessment, OPDRA) and Schwarz Pharma, Inc. on December 20, 2001. We note the corrections to the labeling listed in your letter and agree with your point-by-point responses to our comments and requests in our December 18, 2001 approvable letter, as follows:

1. Schwarz Pharma, Inc. will revise the labels and labeling to include “Tablets” in the established name.
2. The current corporate logo size is acceptable.
3. The strength of the drug product will be centered under the established name and color coded in red, as below:

   15 mg / 12.5 mg

4. The underline will be removed from beneath the proprietary name and strength, and brackets will be added to the product’s established name.
5. No other changes will be made to the bottle label or professional sample labeling.

These changes to the labeling should be included in your next annual report.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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

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

/s/

Raymond Lipicky
2/14/02 11:00:38 AM