DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-312/S-024
NDA 20-729/S-012

Schwartz Pharma, Inc.
Attention: Ms. Donna K. Multhauf
PO Box 2038
Milwaukee, WI 53201

Dear Ms. Multhauf:

Please refer to your supplemental new drug applications dated May 30, 2003 (NDA 20-312) and May 13, 2003 (NDA 20-729), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Univasc (moexipril hydrochloride) 7.5 and 15 mg Tablets (NDA 20-312) and Uniretic (moexipril hydrochloride/hydrochlorothiazide) 7.5/12.5, 15/12.5 and 15/25 mg Tablets (NDA 20-729).

These "Changes Being Effected" supplemental new drug applications provide for changes to the **WARNINGS** section of labeling as follows:

1. Under **WARNINGS,** the **Angioedema** subsection was re-titled "**Head and Neck Angioedema**".

2. Following the **Head and Neck Angioedema** subsection and before the paragraph entitled "In large U.S. postmarketing study…" the following text has been added:

   Intestinal Angioedema: Intestinal angioedema has been reported in patients treated with ACE inhibitors. These patients presented with abdominal pain (with or without nausea or vomiting); in some cases there was no prior history of facial angioedema and C-1 esterase levels were normal. The angioedema was diagnosed by procedures including abdominal CT scan or ultrasound, or at surgery, and symptoms resolved after stopping the ACE inhibitor. Intestinal angioedema should be included in the differential diagnosis of patients on ACE inhibitors presenting with abdominal pain.

In addition, we note the following revisions:

NDA 20-312/S-024
NDA 20-729/S-012

- In the last paragraph under the **DESCRIPTION** section, hydroxypropyl methylcellulose has been deleted and hypromellose has been added to the list of inactive ingredients.

NDA 20-729/S-012

- Under the **WARNINGS** section, the **Hepatic Failure** subsection has been capitalized for consistency.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) dated on May 30, 2003 (NDA 20-312) and May 13, 2003 (NDA 20-729).

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Alisea Sermon, Pharm.D.
Regulatory Project Manager
(301) 594-5334

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, 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/

Doug Throckmorton

10/29/03 02:46:26 PM