DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20729/S-021 **SUPPLEMENT APPROVAL**

Schwarz Pharma
Attention: Donna Multhauf
Director, Regulatory Affairs
P.O. Box 2038
Milwaukee, WI 53201

Dear Ms. Multhauf:

Please refer to your supplemental new drug application dated 15 September 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Uniretic (moexipril hydrochloride and hydrochlorothiazide) 7.5/12.5 mg, 15/12.5 mg and 15/25 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PRECAUTIONS, Drug Interactions section of the package insert in response to our letter dated March 8, 2008. As requested, you made the following change:

Under PRECAUTIONS, Drug Interactions, the following new subsection was added:

> Gold: Nitritoid reactions (symptoms include facial flushing, nausea, vomiting and hypotension) have been reported rarely in patients on therapy with injectable gold (sodium aurothiomalate) and concomitant ACE inhibitor therapy including Uniretic.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on 15 September 2009.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (*i.e.*, a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

> MedWatch
> Food and Drug Administration
> 5600 Fishers Lane, Room 12B05

Rockville, MD 20857

REPORTING REQUIREMENTS

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, please call:

Michael Monteleone, MS
Regulatory Project Manager
(301) 796-1952

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm. D.
Deputy Director for Safety
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Cc:
UCB, Incorporated
Attention: Kimberly Christopher
Director, US Marketed Products
1950 Lake Park Drive
Smyrna, GA, 30080

Enclosure
Approved labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20729	SUPPL-21	SCHWARZ PHARMA INC	UNIRETIC (MOEXIPRIL HCL/HCTZ) TABLETS

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

/s/

MARY R SOUTHWORTH
01/13/2010