



NDA 019071/S-012

SUPPLEMENT APPROVAL

Mission Pharmacal
Attention: Mary Walter, Ph.D.
38505 IH 10 West
Boerne, TX 78006-8994

Dear Dr. Walter:

Please refer to your supplemental new drug application dated February 12, 2009, received February 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Urocit-K (Potassium citrate) 15 mEq potassium extended-release Tablets.

We acknowledge receipt of your submissions dated October 29 and December 14, 2009.

Your submission of December 14, 2009, constituted a complete response to our September 21, 2009, action letter.

This "Prior Approval" supplemental new drug application provides for a new 15 mEq Extended-release strength tablet. In addition, this supplement provides revision of the labeling to the new PLR format.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the draft labeling submitted on December 14, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved NDA 019071/S-012."

Please submit final printed carton and container labels that are identical to the agreed-upon carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission

“Final Printed Carton and Container Labels for approved NDA 019071/S-012.” Approval of this submission by FDA is not required before the labeling is used.

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

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 Anna Park, Regulatory Project Manager, at (301) 796-1129.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: draft-labeling text

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-19071	SUPPL-12	MISSION PHARMACAL CO	UROCIT-K (POTASSIUM CITRATE) TABS

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

/s/

NORMAN L STOCKBRIDGE
12/30/2009