DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 09818/S-018

SUPPLEMENT APPROVAL

Monarch Pharmaceuticals, Inc.
c/o King Pharmaceuticals, Inc.
Attention: Karen Baker
Director Regulatory Affairs
501 5th Street
Bristol, TN 37620

Dear Ms. Baker:

Please refer to your Supplemental New Drug Application (sNDA) dated September 17, 2003, received September 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kemadrin (procyclidine hydrochloride) 5mg Tablets.

This "Prior Approval" supplemental new drug application provides for the inclusion of a "Geriatric Use" subsection in the product labeling.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

Specifically, the following text is being added to the "Geriatric Use" subsection of the product labeling:

> "Clinical studies of KEMADRIN did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should start at the low end of the dosing range(see Dosage and Administration) and the dose should be increased only as needed with monitoring for the emergence of adverse events (see Precautions and Adverse Reactions)."

CONTENT OF LABELING

We note that you are longer marketing Kemadrin Tablets and that labeling is not yet in compliance with the requirements for content and format of labeling described at 21 CFR 201.56 and 201.57. However, we are granting an extension of the date for compliance with the labeling requirements until you resume marketing of the product.

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, call Stacy Metz, PharmD, Regulatory Project Manager, at (301) 796-2139.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

RUSSELL G KATZ
07/01/2011