DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 17-943/S-016

Monarch Pharmaceuticals, Inc.
Attention: Michael B. Barrett
Supervisor, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Barrett:

Please refer to your supplemental new drug application dated August 25, 2000, received August 28, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Proloprim® (trimethoprim) Tablets.

We acknowledge receipt of your submission dated May 16, 2002.

This supplemental new drug application provides for the addition of a **Geriatric Use** subsection to the **PRECAUTIONS** section in accordance with the Final Rule entitled "Specific Requirements on Content and Format of Labeling for Human Prescription Drugs: Addition of 'Geriatric Use' Subsection in the Labeling" and the addition of three references in the **REFERENCES** section.

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 May 16, 2002). Accordingly, the supplemental application is approved effective on the date of this letter.

However, at the time of the next printing, please make the following editorial revision to your label:

> In the second paragraph of the **OVERDOSAGE** section, the last sentence should read "…and hemodialysis is only moderately effective in eliminating the drug."

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

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, call Beth Duvall-Miller, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
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/

Janice Soreth

8/26/02 12:53:47 PM