DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

Monarch Pharmaceuticals, Inc.
Attention: Greg Carrier
Senior Director, Regulatory Affairs
501 Fifth Street
Bristol, TN 37620

Dear Mr. Carrier:

Please refer to your supplemental new drug application dated August 1, 2001, received August 2, 2001, submitted under the Federal Food, Drug, and Cosmetic Act for Viroptic (trifluridine ophthalmic solution) 1% Sterile.

We acknowledge receipt of your submission dated October 10, 2001.

This "Changes Being Effected" supplemental new drug application provides for inclusion of a **Geriatric** subsection within the **PRECAUTIONS** section of the product package insert.

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 agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling.

We recommend that the **DESCRIPTION** section of the package insert be revised at the time of the next printing, in order to clarify that the phrase "F_3TdR,F_3T" is actually "F_3TdR, F_3T".

It is recommended that the **HOW SUPPLIED** section of the package insert be revised at the time of the next printing, in order to include the target fill volume for the container size, color, and type of plastic for the bottle, tip and cap.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-299/S-014." Approval of this submission by FDA is not required before the labeling is used.

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 Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Enclosure

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

/s/

Wiley Chambers

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