DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-574/S-010

Monarch Pharmaceuticals, Inc.
Attention: Ms. Karen C. Baker
501 Fifth Street
Bristol, TN 37620

Dear Ms. Baker:

Please refer to your supplemental new drug application dated September 11, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Thalitone (chlorthalidone) 15 mg Tablets.

We acknowledge receipt of your submissions dated April 26, 2002 and February 17, 2004, which constituted a complete response to our approvable letter dated April 16, 2002.

This supplemental new drug application provides for final printed labeling revised to add a **Geriatric Use** subsection at the end of the **PRECAUTIONS,** as follows:

> **PRECAUTIONS**
> **Geriatric Use** Clinical studies of Thalitone® 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 be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal or cardiac function, and of concomitant disease or other drug therapy.
>
> This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

In addition, we note the following editorial changes:

1. The reference to the 25 mg tablet was deleted from the **DESCRIPTION** and **HOW SUPPLIED** sections.

2. The tablet code and the NDC number were updated.

3. **Rx Only** was added to the end of the labeling.

4. The revised date was updated.

5. The manufacturer information was changed from Horus Therapeutics, Inc to:

   Monarch Pharmaceuticals®
   Distributed by:
   Monarch Pharmaceuticals, Inc., Bristol, TN 37620
   (A wholly owned subsidiary of King Pharmaceuticals, Inc.)

   Manufactured by:
   King Pharmaceuticals, Inc., Bristol, TN 37620

We have completed our review of this supplemental new drug application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 17, 2004.

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

MEDWATCH, HFD-410
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, please call:

Mr. Daryl Allis
Regulatory Health Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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/

Norman Stockbridge

6/1/04 04:01:37 PM