DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-337/S-025

Actavis Mid Atlantic LLC
Attention: Elizabeth Trowbridge, R.A.C.
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Ms. Trowbridge:

Please refer to your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated February 28, 2008, received February 29, 2008, for FeverAll (80 mg, 120 mg, 325 mg, and 650 mg acetaminophen) rectal suppositories.

We acknowledge receipt of your submission dated April 30, 2008.

This supplemental new drug application provides for a change in the manufacturing, packaging, and testing site for the 80 mg and the 120 mg dosage strengths from the Minneapolis, MN site to the Lincolnton, NC site and associated label revisions.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) for the FeverAll 80 mg and 120 mg rectal suppositories 6- and 50-count carton labels submitted April 30, 2008, and the suppository wrap label and package insert submitted February 28, 2008.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer
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