DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-337/S-024

Actavis Mid Atlantic LLC
Attention: Janak Jadeja, R.Ph.
Director, Regulatory Affairs
200 Elmora Avenue
Elizabeth, New Jersey 07207

Dear Mr. Jadeja:

Please refer to your new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act dated June 29, 2007, received July 2, 2007, for Fever All (80 mg, 120 mg, 325 mg, and 650 mg acetaminophen) rectal suppositories.

We acknowledge receipt of your submission dated October 23, 2007.

This supplemental new drug application provides for a change in the manufacturing, packaging, and testing site for the 325 mg and the 650 mg dosage strengths from the Minneapolis, MN site to the Lincolnton, NC site.

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

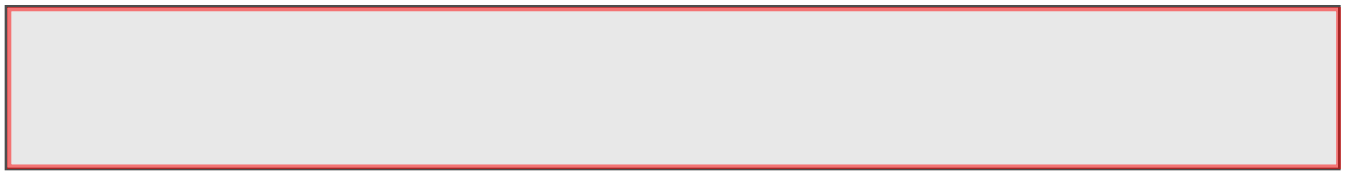
The final printed labeling (FPL) must be identical to the enclosed labeling:

1. Fever All (325 mg acetaminophen) rectal suppositories for the 6- and 50-count carton labels, suppository wrap label, and package insert submitted on October 23, 2007.

2. Fever All (650 mg acetaminophen) rectal suppositories for the 50-count carton and suppository wrap label submitted on June 29, 2007.

The final printed labeling must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 18-337/S-024**." Approval of this submission by FDA is not required before the labeling is used.



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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