DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018337/S-028 **SUPPLEMENT APPROVAL**

Actavis Mid Atlantic LLC
Attention: Lucy Gary
Manager, Regulatory Affairs
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Ms. Gary:

Please refer to your October 5, 2009 Supplemental New Drug Application (sNDA), received October 6, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for FeverAll (80 mg, 120 mg, 325 mg, and 650 mg acetaminophen) rectal suppositories.

We acknowledge receipt of your submissions dated December 31, 2009, and March 26, 2010.

This "Changes Being Effected" supplemental new drug application provides for the addition of the warning statement "Do no use if you are allergic to acetaminophen" to the Drug Facts label in response to the August 21, 2009 supplemental labeling request letter. This supplemental NDA also provides for revised labeling in accordance with the April 29, 2009 final monograph for Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use.

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

LABELING

Submit final printed carton labels as soon as they are available, but no more than 30 days after they are printed. The final printed labels (FPL) must be identical to the enclosed [80 mg (6- and 50-count), 120 mg (5- and 50-count), 325 mg (6- and 50-count), and 650 mg (50-count)] carton labels submitted on March 26, 2010, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the immediate container, we request that you submit immediate container labels for the 80 mg (6- and 50-count), 120 mg (5- and 50-count), 325 mg (6- and 50-count), and 650 mg (50-count) sizes in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 018337/S-028**." Approval of this submission by FDA is not required before the labeling is used.

We also want to remind you that a liver injury warning is required to be on the immediate container label (i.e. aluminum foil wraps) in accordance with the Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use Final Rule, published on April 29, 2009. The requirements outlined by this rule making will be effective on April 29, 2010. Please revise the immediate container label and submit the revision to FDA in the form of a "Supplement – Changes Being Effected."

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure
Carton Labels

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-18337	SUPPL-28	ACTAVIS MID ATLANTIC LLC	ACETAMINOPHEN

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
04/05/2010