



NDA 018060/S-063

**SUPPLEMENT APPROVAL**

G & W Laboratories, Inc.  
Attention: Dominick DiPaolo  
Vice President, QA/RA  
111 Coolidge Street CN-1024  
South Plainfield, NJ 07080

Dear Mr. DiPaolo:

Please refer to your Supplemental New Drug Application (sNDA) dated November 2, 2009, received November 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Acephen (120 mg, 325 mg, and 650 mg acetaminophen) suppositories.

We acknowledge receipt of your submission dated April 13, 2010.

This “Changes Being Effected” supplemental new drug application provides for revised labeling for the 120 mg dosage strength 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 labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) for the Acephen 120 mg dosage strength must be identical to the enclosed labeling (12-, 50-, and 100-count carton labels submitted April 13, 2010), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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 018060/S-063.**” Approval of this submission by FDA is not required before the labeling is used.

We also remind you of the following:

1. As stated in our February 19, 2010 advice letter, the liver injury warning is required to be on the 12-, 50-, and 100- count immediate container labels in accordance with the Organ-Specific Warnings; Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use Final Rule published 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.”
2. According to your January 5, 2010 annual report, the manufacturing of the 325 mg and 650 mg dosage strength suppositories were discontinued. If you choose to re-introduce these dosage strengths into the marketplace, you should submit 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 in the form of a “Supplement – Changes Being Effected” application.

### **LETTERS TO HEALTH CARE PROFESSIONALS**

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch  
Food and Drug Administration  
Suite 12B-05  
5600 Fishers Lane  
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

NDA 018060/S-063

Page 3

Enclosure: Labeling

Application  
Type/Number

Submission  
Type/Number

Submitter Name

Product Name

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NDA-18060

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SUPPL-63

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G AND W  
LABORATORIES  
INC

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ACEFEN

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOEL SCHIFFENBAUER

04/28/2010