DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020802/S-019 **SUPPLEMENT APPROVAL**

Novartis Consumer Health, Inc.
Attention: Michael Kenny
North America Regional Liaison, Pain Category
Global Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Mr. Kenny:

Please refer to your supplemental new drug application dated September 17, 2009, received September 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Excedrin® Migraine (250 mg acetaminophen/ 250 mg aspirin/ 65 mg caffeine) tablets.

We acknowledge receipt of your submissions dated December 16, 2009, and January 13, 2010.

This "Prior Approval" supplemental new drug application 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 and the addition of the aspirin allergy warning in accordance with the November 16, 1988 tentative final monograph for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products for Over-the-Counter Human Use. This supplemental NDA also provides for the addition of the warning statement "Do not use if you are allergic to acetaminophen" to the Drug Facts label in response to the August 21, 2009 supplemental labeling request letter.

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) must be identical to the enclosed labeling (Excedrin Migraine 24-, and 50-count geltab carton and immediate container labels, 100-count geltab carton label, and 100-, and 250-count caplet immediate container bottle labels submitted January 13, 2010, 2-count tablet pouch label, and 2-count tablet professional sample pouch label submitted December 16, 2009, and the 24-, 50-, 100-, 200-, 250-, and 300-count caplet, and 24-, 50-, 100-, and 250-count tablet carton and immediate container labels submitted September 17, 2009), 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 020802/S-019**." Approval of this submission by FDA is not required before the labeling is used.

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, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20802	SUPPL-19	NOVARTIS CONSUMER HEALTH INC	EXCEDRIN (MIGRAINE)

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
02/04/2010