DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-802/S-015

Novartis Consumer Health, Inc.
Attention: Nicholas Romano
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Mr. Romano:

Please refer to your supplemental new drug application dated July 28, 2006, received July 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Excedrin® Migraine (250 mg acetaminophen/ 250 mg aspirin/ 65 mg caffeine) tablets.

This supplemental new drug application provides for the addition of a "SEE ACETAMINOPHEN WARNINGS" statement to the Principal Display Panel, highlighting acetaminophen in the active ingredients section of the Drug Facts label, and revisions to the acetaminophen warnings in the Drug Facts label for Excedrin Migraine.

We have completed our review of this application. 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 submitted labeling (50-count carton label submitted July 28, 2006), and 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 supplements NDA 20-802/S-015**". Approval of this submission by FDA is not required before the labeling is used.

On December 26, 2006, the Agency published a proposed rule amending its over-the-counter (OTC) labeling regulations and the tentative final monograph (TFM) for OTC internal analgesic, antipyretic, and antirheumatic (IAAA) drug products in the Federal Register to include organ-specific warnings for OTC drug products containing acetaminophen and/or NSAIDS at 71 FR 77314. We refer you to section IX. Voluntary Implementation directed towards holders of approved NDAs for OTC IAAA drug products, where it is stated "FDA considers the proposed labeling in this document to be important to the safe use of OTC IAAA drug products and strongly encourages manufacturers of these products to voluntarily implement the proposed labeling changes before FDA issues a final rule."

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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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