DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20802/S-022

SUPPLEMENT APPROVAL

Novartis Consumer Health, Inc.
Attention: Kimberly Burns, MA
Manager, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054

Dear Ms. Burns:

Please refer to your Supplemental New Drug Application (sNDA) dated October 15, 2013, received October 15, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Excedrin Migraine (acetaminophen 250 mg, aspirin 250 mg, caffeine 65 mg) Tablets, Caplets, and Geltabs.

We acknowledge receipt of your amendment dated March 21, 2014.

This "Changes Being Effected" sNDA proposes to add information to the allergy alert on the capsule-shaped tablet (caplet) product label to read:

> **Allergy alert:** acetaminophen may cause severe skin reactions. Symptoms may include:
> - skin reddening
> - blisters
> - rash
>
> If a skin reaction occurs, stop use and seek medical help right away.

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 (FPL) for Excedrin Migraine caplets as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the 8-, 24- and 300- count immediate container and outer carton labels and 100-count immediate container and outer carton labels (representative of 50-, 200- and 250-count labels) that were submitted March 21, 2014, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. As representative labeling is not acceptable in the FPL, also submit the 50-, 200-, and 250- count immediate container and outer carton labels.

The FPL 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 (June 2008)." 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 20802/S-022**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 questions, contact Jade Pham, Regulatory Health Project Manager, at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LUCIE L YANG
04/15/2014
signing on behalf of Dr. Theresa Michele