DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020802/S-031

SUPPLEMENT APPROVAL

GSK Consumer Healthcare
Attention: Bhargavi Pandit RPh, MS, RAC
Associate, US Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Ms. Bhargavi:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 12, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Excedrin® Migraine (acetaminophen 250 mg/aspirin 250 mg/caffeine 65 mg) tablets.

This "Changes Being Effected" (CBE-0) sNDA provides for the addition of a new warning to the Drug Facts labeling to inform consumers that over use of this product may lead to an exacerbation of headache, referred to as "medication overuse headache" in accordance with the Agency's CBE-0 Request Letter dated December 19, 2016.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 must be identical to the submitted labeling identified in the table below. The final printed labeling must also be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission date
2-ct tablet (capsule-shaped) immediate container (pouch)	April 12, 2017
24-ct tablet (capsule-shaped) outer container	April 12, 2017
50-ct tablet (capsule-shaped) outer container	April 12, 2017
100-ct tablet (capsule-shaped) outer container	April 12, 2017
125-ct tablet (capsule-shaped) outer container (100-ct + 25 Bonus Pack) "25% MORE FREE" flag	April 12, 2017
200-ct tablet (capsule-shaped) outer container	April 12, 2017
250-ct tablet (capsule-shaped) outer container (200-ct + 50 Bonus Pack) "25% MORE FREE" flag	April 12, 2017
300-ct tablet (capsule-shaped) outer container	April 12, 2017
20-ct tablet (gelatin coated) outer container	October 11, 2017
80-ct tablet (gelatin coated) outer container	October 11, 2017

In addition, prior approval labeling supplements must be submitted for the following discontinued products if you plan to market them in the future.

- Tablets (capsule-shaped): 8-ct, 10-ct, 30-ct (24-ct + 6 Bonus Pack), 100-ct (stand-alone bottle), 125-ct (stand-alone bottle), and 250-ct (stand-alone bottle)
- Tablets: 6-ct, 30-ct, 50-ct, 125-ct, and 250-ct
- Tablets (gelatin coated): 160-ct (2x80-ct)

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 (May 2015, Revision 3)." For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 020802/S-031**." 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 any questions, call CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
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/

VALERIE S PRATT
10/12/2017