DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20802/S-032

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. Pandit:

Please refer to your Supplemental New Drug Application (sNDA) dated and received July 5, 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), tablet.

This "Prior Approval" sNDA provides for changes to the Drug Facts labeling by adding the FDA-requested "**Medication overuse headache**" safety warning, as well as minor editorial changes to your Drug Facts labeling. We note that the labels approved in this supplement are for nonmarketed products (that you do not wish to remove from the NDA). We agreed that these labels could be submitted separately from the April 12, 2017, Changes Being Effected (CBE-0) submission (NDA 20802/S-031) that included safety changes to the labels for marketed Excedrin® products.

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), as soon as they are available, but no more than 30 days after they are printed. Even though no revisions were made to the immediate container (bottle) labels for the 24-ct, 50-ct, 100-ct tablets (regular-shaped), and 24-ct, 50-ct, 100-ct geltabs (gelatin coated tablets), you should submit these immediate container (bottle) labels as part of the FPL for this supplement to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this sNDA 020802/S-032.

The FPL must be identical to the following labeling below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Submission date
2-ct tablets immediate container (pouch)	July 5, 2017
2-ct tablets immediate container (pouch) (professional sample)	July 5, 2017
24-ct tablets outer container carton	July 5, 2017
2 x 50-ct tablets outer container carton (Club Pack)	July 5, 2017
100-ct tablets outer container carton	July 5, 2017
24-ct geltabs (gelatin coated tablets) outer container carton	November 3, 2017
50-ct geltabs (gelatin coated tablets) outer container carton	November 3, 2017
100-ct geltabs (gelatin coated tablets) outer container carton (two 50-ct bottles)	November 3, 2017

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain 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 20802/S-032**." 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 Tinya Sensie, Regulatory Project Manager at (240) 402-40230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling