



NDA 20802/S-043



SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare
Attention: Kishan Patel
Manager Regulatory Affairs
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Patel:

Please refer to your supplemental new drug application (sNDA) dated October 14, 2022, received October 17, 2022, 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, and caffeine 65 mg) tablets.

This Prior Approval supplemental new drug application provides for the following labeling changes on the Principal Display Panel:

- Revision of the proprietary name from “Excedrin Migraine” to Excedrin Migraine Relief”
- Background color change to green
 (b) (4)
- Addition of a head silhouette image
 (b) (4)

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
24-Count immediate container label (Caplets)	April 13, 2023
30-Count immediate container label (Caplets)	April 13, 2023
50-Count immediate container label (Caplets)	April 13, 2023

Submitted Labeling	Date Submitted
100-Count immediate container label (Caplets)	April 13, 2023
125-Count immediate container label (Caplets)	April 13, 2023
200-Count immediate container label (Caplets)	April 13, 2023
250-Count immediate container label (Caplets)	April 13, 2023
300-Count immediate container label (Caplets)	April 13, 2023
24-Count outer carton label (Caplets)	April 13, 2023
30-Count outer carton label (Caplets)	April 13, 2023
50-Count outer carton label (Caplets)	April 13, 2023
100-Count outer carton label (Caplets)	April 13, 2023
125-Count outer carton label (Caplets)	April 13, 2023
200-Count outer carton label (Caplets)	April 13, 2023
250-Count outer carton label (Caplets)	April 13, 2023
300-Count outer carton label (Caplets)	April 13, 2023
Draft display tray	April 17, 2023

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.¹ For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20802/S-043.**” 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 are 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 FDA.gov.² Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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).

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

If you have any questions, call LCDR Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton, Container, and Display Tray Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
04/17/2023 08:27:07 PM