NDA 20802/S-038

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: King D. Gyasi, PharmD, MBA
Senior Associate, Regulatory Affairs
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Dr. Gyasi:

Please refer to your supplemental new drug application (sNDA) dated and received May 26, 2021, and your amendments, submitted under 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" supplemental new drug application provides for an update under the "If pregnant or breast-feeding" warning in the Drug Facts labeling in response to the Agency's CBE Supplement Request letter dated April 28, 2021.

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 labeling listed below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted on July 13, 2021:

1. 2-count pouch (caplets)
2. 24-count immediate container (caplets)
3. 30-count immediate container (caplets)
4. 50-count immediate container (caplets)

Submitted on May 26, 2021:

5. 100-count immediate container (caplets)

Submitted on July 13, 2021:

6. 125-count immediate container (caplets)
7. 200-count immediate container (caplets)
8. 250-count immediate container (caplets)
9. 300-count immediate container (caplets)

10. 24-count outer carton (caplets)
11. 30-count outer carton (caplets)
12. 50-count outer carton (caplets)

Submitted on May 26, 2021:

13. 100-count outer carton (caplets)

Submitted on July 13, 2021:

14. 125-count outer carton (caplets)
15. 200-count outer carton (caplets)
16. 250-count outer carton (caplets)
17. 300-count outer carton (caplets)

Submitted on July 29, 2021:

18. 2-count packet (caplets; 1 packet of 2-count) blister card
19. 4-count packet (caplets; 2 packets of 2-count) blister card
20. 6-count packet (caplets; 3 packet of 2-count) blister card
21. 6-count packet (caplets; 3 packet of 2-count) outer carton
22. 60-count packet (caplets; 30 packets of 2-count) blister card
23. 80-count packet (caplets; 40 packets of 2-count) dispenser carton
24. 100-count packet (caplets; 50 packets of 2-count) dispenser carton

Submitted on July 13, 2021:

25. 20-count immediate container (geltabs)
26. 20-count outer carton (geltabs)

Submitted on May 26, 2021:

27. 80-count immediate container (geltabs)
28. 80-count outer carton (geltabs)

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-038**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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).

If you have any questions, call Helen Lee, Safety Regulatory Project Manager, at 301-796-6848.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):

- Carton and Container Labeling

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

VALERIE S PRATT
11/03/2021 04:42:05 PM