

NDA 20802/S-034

## SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC  
Attention: Rita D. Patel  
Regulatory Affairs Manager  
184 Liberty Corner Road  
Suite 200  
Warren, NJ 07059

Dear Ms. Patel:

Please refer to your supplemental new drug application (sNDA) dated and received August 29, 2019, and your amendment, 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 supplemental new drug application provides for changes to 2-count tablet (caplet) pouch secondary package labels.

### **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, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20802/S-034.**” Approval of this submission by FDA is not required before the labeling is used.

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<sup>1</sup> 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>.

<b>Submitted Labeling</b>	<b>Submission Date(s)</b>
1 Packet of 2 capsule-shaped tablets (front card/back blister card)	November 8, 2019
2 Packets of 2 capsule-shaped tablets each (front card/back blister card)	November 8, 2019
3 Packets of 2 capsule-shaped tablets each (front card/back blister card)	November 8, 2019
3 Packets of 2 capsule-shaped tablets each (carton)	November 8, 2019
30 Packets of 2 capsule-shaped tablets each (dispenser carton)	November 8, 2019
40 Packets of 2 capsule-shaped tablets each (dispenser carton)	November 8, 2019
50 Packets of 2 capsule-shaped tablets each (dispenser carton)	November 8, 2019

## **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 FDA.gov.<sup>2</sup> 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).

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

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

Sincerely,

*{See appended electronic signature page}*

Karen Murry Mahoney, MD, FACE  
Acting Deputy Director, Office of Nonprescription Drugs  
Acting Deputy Director, Division of Nonprescription Drugs I  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

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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.**  
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/s/  
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KAREN M MAHONEY  
02/27/2020 06:14:51 PM