NDA 211733/S-003

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Alberto J. Garzon
Regulatory Affairs Sr. Manager
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Mr. Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received July 13, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil Dual Action with Acetaminophen (ibuprofen 125mg/acetaminophen 250 mg) tablet.

This "Prior Approval" sNDA provides for the following:

- Addition of the proprietary name "Advil Dual Action with Acetaminophen Back Pain"
- Revised labeling to reflect the new proprietary name
- Revised ordering of indications under "Uses" on the Drug Facts Label
- Updated "If pregnant or breast-feeding" and "Keep out of reach of children" warnings on the Drug Facts Label, in response to FDA'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 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
2-Count Packet	October 15, 2021
100-Count (50 x 2-Count) Packet Dispenser	October 15, 2021
18-Count Outer Carton	October 15, 2021
18-Count Immediate Container (Bottle)	October 15, 2021
36-Count Outer Carton	October 15, 2021
36-Count Immediate Container (Bottle)	October 15, 2021
Peel-Back DFL for 18-Count and 36-Count Outer Carton	July 13, 2021
72-Count Outer carton	October 15, 2021
72-Count Immediate Container (Bottle)	October 15, 2021
Peel-Back DFL for 72-Count Outer Carton	July 13, 2021
144-Count Outer Carton	October 15, 2021
144-Count Immediate Container (Bottle)	October 15, 2021

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 211733/S-003**." 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

[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.

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 LCDR Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Director
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/

NUSHIN F TODD
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