



NDA 211733/S-004

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Alberto J. Garzon
Sr. Manager, Regulatory Affairs
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 29, 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 125 mg/acetaminophen 250 mg) tablet.

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 in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the labeling listed in the table below:

Submitted Labeling	Date Submitted
2-Count Pouch, Back Label	July 29, 2021
50 x 2-Count Pouch Dispenser	July 29, 2021
Peel-Back DFL for 4-Count Carton	July 29, 2021
8-Count Loose Vial	July 29, 2021
Peel-Back DLF for 8-Count Packed Vial Small Backer Card	July 29, 2021
8-Count Packed Vial Large Backer Card	January 18, 2022
Peel-back DFL for 18-Count, 24-Count (18+6-Count), and 36-Count Outer Carton	July 29, 2021

Peel-Back DFL for 72-Count and 90-Count (72+18-Count) Outer Carton	September 24, 2021
144-Count Outer Carton	July 29, 2021
144-Count Immediate Container (Stand-Alone Bottle) with “Easy Open” Cap	July 29, 2021
162-Count (144+18-Count) Outer Carton	September 24, 2021
162-Count (144+18-Count) Immediate Container (Stand-Alone Bottle) with “Easy Open” Cap	September 24, 2021
180-Count Immediate Container (Stand-Alone Bottle)	September 24, 2021
216-Count Outer Carton	September 24, 2021
216-Count Immediate Container (Stand-Alone Bottle)	January 18, 2022
240-Count Outer Carton	September 24, 2021
240-Count Immediate Container (Stand-Alone Bottle)	September 24, 2021
288-Count Immediate Container (Stand-Alone Bottle)	September 24, 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-004.**” 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 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

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
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