NDA 18989/S-099

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 26, 2021, and your amendments, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil (ibuprofen) tablets, 200 mg.

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

Submitted Labeling	**Dates Submitted**
Regular-shaped tablets	
2ct pouch (back)	July 26, 2021
6ct (3x2 pouches) extended content "piggyback" label	October 11, 2021
10ct vial label	July 26, 2021
10ct short Backer card (pocket pack)	July 26, 2021
10ct long Backer Card (pocket pack)	September 17, 2021
20ct (2x10) Backer Card	September 17, 2021
24ct carton	July 26, 2021
36ct (24+12 "Bonus") carton	September 17, 2021
50ct carton	September 17, 2021
100ct carton	September 17, 2021

130ct “Value Size” carton	September 17, 2021
200ct carton	September 17, 2021
115ct (100+15 “Bonus”) carton	September 17, 2021
225ct (200+25 “Bonus”) carton	September 17, 2021
100ct (50X2ct) dispenser	October 11, 2021
200ct EZ open standalone	July 26, 2021
300ct standalone bottle label	September 17, 2021
360ct standalone bottle label	September 17, 2021
Capsule-shaped tablets	
24ct carton	July 26, 2021
Gelatin Coated Capsule-shaped tablets	
24ct carton	September 17, 2021
50ct carton	September 17, 2021
100ct carton	July 26, 2021
200ct carton	September 17, 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 18989/S-099**.” 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
12/14/2021 09:29:25 AM