

NDA 201803/S-016

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 August 27, 2021, and your amendment, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil (ibuprofen sodium) tablets, 256 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 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
<i>Advil Film-Coated Tablets</i>	
2-Count Pouch (Back Label)	August 27, 2021
8-Count Backer Card (Vial)	August 27, 2021
8-Count Loose w/Peel Back (Vial)	November 15, 2021
20-Count Carton	November 15, 2021
40-Count Carton	November 15, 2021
80-Count Carton	November 15, 2021
100 (80 + 20)-Count Carton	November 15, 2021
100 (50 x 2)-Count Carton	November 15, 2021
160-Count Carton	November 15, 2021
180 (160 + 20)-Count Carton	November 15, 2021

<i>Advil Film-Coated Caplets</i>	
20-Count Carton	August 27, 2021
40-Count Carton	November 15, 2021
80-Count Carton	November 15, 2021
<i>Advil Menstrual Pain</i>	
2-Count Pouch (Back Label)	November 15, 2021
8-Count Short Backer Card Peel Back Label	November 15, 2021
8-Count Tall Backer Card	November 15, 2021
20-Count Outer Carton	August 27, 2021
40-Count Carton	November 15, 2021
100 (50 x 2)-Count Dispenser	November 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 201803/S-016.**” 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).

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

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>

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
02/08/2022 02:38:27 PM