NDA 211733/S-007

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Alberto J. Garzon
Regulatory Affairs Sr. Manager
184 Liberty Corner Road, Suite 200
Warren, NJ 07059

Dear Alberto J. Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received November 5, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Advil Dual Action with Acetaminophen (ibuprofen and acetaminophen) tablets, 125 mg/250 mg.

This “Prior Approval” supplemental new drug application provides for updating “Actual Size” tablet images on outer containers (carton) and standalone bottles, adding an "8 Hour Relief" claim, removing tablet images from bottle labels, updating distributor information, and introducing a new 96-count vial dispenser stock keeping unit (SKU).

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 following:

Submitted Labeling	Date Submitted
2-ct pouch, front label	February 14, 2025
2-ct pouch, back label	November 5, 2024
2-ct pouch, alternate packager	February 14, 2025
18-ct immediate container label (bottle)	January 10, 2025
18-ct outer carton label	January 10, 2025
36-ct immediate container label (bottle)	January 10, 2025

36-ct outer carton label	January 10, 2025
72-ct immediate container label	January 10, 2025
72-ct outer carton label	January 10, 2025
(72 + 18) 90-ct immediate container label	January 10, 2025
(72 + 18) 90-ct outer carton label	January 10, 2025
(2 x 50) 100-ct dispenser	January 10, 2025
144-ct immediate container label	January 10, 2025
144-ct outer carton label	January 10, 2025
216-ct immediate container label	January 10, 2025
216-ct outer carton label	January 10, 2025
240-ct standalone bottle label	January 10, 2025
8-ct standalone vial label	January 10, 2025
8-ct short backer card label	January 10, 2025
8-ct long backer card label	January 10, 2025
8-ct backer card vial label	April 15, 2025
(12 x 8) 96-ct vial dispenser label	March 27, 2025

We remind you that a new submission to the FDA is required if you wish to reintroduce the discontinued stock keeping units to the U.S. Market. 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-007**." Approval of this submission by FDA is not required before the labeling is used.

[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.

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.[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, please contact Odongerel Pount, PharmD, Regulatory Project Manager, at (240) 402-7144 or Odongerel.Pount@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Martha Lenhart, MD, PhD
Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New 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/

MARTHA K LENHART
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