

NDA 021393/S-022

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Alberto Jose Garzon
Senior Regulatory Affairs Manager, US Regulatory
184 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Alberto Garzon:

Please refer to your supplemental new drug application (sNDA) dated and received January 22, 2024, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Advil PM Liqui-Gels (ibuprofen 200 mg and diphenhydramine hydrochloride 25 mg) capsules.

This “Prior Approval” sNDA provides for a new, smaller liquid-filled capsule (described as “minis”) and associated labeling under NDA 021393. Additionally, this sNDA provides for labeling changes to the currently approved capsule (non-minis) product.

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 must be identical to the following labeling:

Submitted Labeling	Date(s) Submitted
Advil PM Liqui-Gel with “minis” descriptor	
2-ct pouch (immediate container)	January 22, 2024
50-ct dispenser (50 packets of 2-count pouch)	March 14, 2024
8-ct long backer-card (immediate container) vial	January 22, 2024

Submitted Labeling	Date(s) Submitted
8-ct long backer-card (outer container)	April 8, 2024
8-ct short backer-card "piggyback"	January 22, 2024
8-ct short backer-card	March 14, 2024
8-ct stand-alone vial	January 22, 2024
20-ct carton (outer container)	April 8, 2024
20-ct bottle (immediate container)	January 22, 2024
30-ct (20+10) "10 FREE" bonus carton	March 14, 2024
30-ct (20+10) "10 FREE" bonus bottle	January 22, 2024
40-ct carton	April 8, 2024
40-ct bottle	January 22, 2024
50-ct (40+10) "10 FREE" bonus carton	March 14, 2024
50-ct (40+10) "10 FREE" bonus bottle	January 22, 2024
80-ct carton	April 8, 2024
80-ct bottle	January 22, 2024
100-ct (80+20) "20 FREE" bonus carton	March 14, 2024
100-ct (80+20) "20 FREE" bonus bottle	January 22, 2024
120-ct carton	March 14, 2024
120-ct bottle	January 22, 2024
160-ct carton	April 8, 2024
160-ct bottle	January 22, 2024
240-ct stand-alone bottle	March 14, 2024
Advil PM Liqui-Gels non-minis (without "minis" descriptor)	
20-ct carton	April 24, 2024
30-ct (20 +10) "10 Free" carton	April 24, 2024
40-ct carton	April 24, 2024
50-ct carton	April 24, 2024

Submitted Labeling	Date(s) Submitted
80-ct carton	April 24, 2024
100 (80 + 20)-ct "20 FREE" carton	April 24, 2024

Additionally, remove the word "NEW" from the flag featured on your product labels six months from the time of marketing.

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 021393/S-022.**" 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 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, contact Myla Dellupac, RPh, Regulatory Project Manager, at Myla.Dellupac@fda.hhs.gov or (301) 837-7461.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
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

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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