NDA 22122/S-026

SUPPLEMENT APPROVAL

Haleon US Holdings LLC
Attention: Rita D. Patel
Regulatory Affairs Sr. Manager
184 Liberty Corner Rd Suite 200
Warren, NJ 07059

Dear Ms. Rita Patel:

Please refer to your supplemental new drug application (sNDA) dated February 8, 2024, received February 8, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Voltaren Arthritis Pain (diclofenac sodium) topical gel, 1%.

This "Prior Approval" supplemental new drug application provides for a 120 g (100 g + 20 g) bonus package and associated labeling.

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 with the agreed-upon editorial revisions listed below: insert the "*" symbol and the "†" symbol next to the corresponding tamper evident statement on the left panel to further ensure that consumers understand the 20 g and 100 g immediate containers have different container closure systems.

LABELING

Submit final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date of Submission
120 g (100 g + 20 g) bonus carton	July 31, 2024

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 22122/S-026.** 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 (301) 837-7461 or myla.dellupac@fda.hhs.gov.

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:
Carton 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
08/07/2024 04:46:09 PM