NDA 22122/S-14

SUPPLEMENT APPROVAL

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC
Attention: Daniel P. Keravich, RPh, MSc, MBA, RAC
Director, US OTC Switch, Global Regulatory Affairs
1804 Liberty Corner Road
Suite 200
Warren, NJ 07059

Dear Mr. Keravich:

Please refer to your supplemental new drug application (sNDA) dated and received December 21, 2018, and your amendments, submitted under section 505(b) 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 the full prescription (Rx) to over-the-counter (OTC) switch of diclofenac sodium gel, 1% for the temporary relief of arthritis pain only in the following areas:
- hand, wrist, elbow (upper body areas)
- foot, ankle, knee (lower body areas)

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.

In the approved Drug Facts label, in the Uses section, this statement appears: "this product may take up to 7 days to work for arthritis pain; it is not for immediate relief. If no pain relief in 7 days, stop use." This is important information regarding what the consumer may expect regarding time to onset of pain relief. In the future, if you wish to propose less restrictive labeling regarding onset of pain relief, you will need to provide information regarding time to clinically meaningful pain relief from an appropriately designed study using a population that is consistent with the nonprescription Use of diclofenac sodium gel 1%. If you choose to conduct such a study, we recommend that you submit the protocol to the appropriate nonprescription review division for review and comment, and that you do not begin the study until you have received feedback from the division.

We have the following additional labeling recommendations for your consideration for future submission(s):

1. Although the net quantity for the 350 g and 450 g Club Packs are compliant with §201.62, consider expressing the quantity in a way that may be more clear to consumers.

2. Consider adding a website URL to the "Question or comments?" section of labeling on all immediate containers (tube).

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

Submitted Labeling	Date of Submission
20 g / 0.7 oz - 1-count carton (tube) - *professional sample*	November 24, 2019
20 g / 0.7 oz - 1-count carton (tube) - *retail*	November 24, 2019
20 g / 0.7 oz - 1-count immediate container (tube)	October 19, 2019
Dosing card for 20 g / 0.7 oz stock-keeping unit (SKU)	October 17, 2019
"Extended" Peel-back DFL for 20 g / 0.7 oz carton	November 24, 2019
Consumer Information Leaflet / "User Guide" for 20 g / 0.7 oz SKU- *Black and White*	November 24, 2019
50 g / 1.76 oz - 1-count carton (tube)	November 24, 2019
50 g / 1.76 oz - 1-count immediate container (tube)	October 19, 2019
100 g / 3.53 oz - 1-count carton (tube)	November 24, 2019
100 g / 3.53 oz - 1-count immediate container (tube)	October 19, 2019
150 g / 5.29 oz - 1-count carton (tube)	November 24, 2019

Submitted Labeling	Date of Submission
150 g / 5.29 oz - 1-count immediate container	October 19, 2019
12.34 oz / 350 g Club Pack (2 x 150 g + 50 g) - Front	October 17, 2019
12.34 oz / 350 g Club Pack (2 x 150 g + 50 g) - Back	November 24, 2019
12.34 oz / 350 g (2 x 150 g + 50 g) Clamshell principle display panel image insert	October 19, 2019
15.87 oz / 450 g (3 x 150 g) Club Pack (front)	October 18, 2019
15.87 oz / 450 g (3 x 150 g) Club Pack (back)	November 24, 2019
15.87 oz / 450 g (3 x 150 g) Clamshell principle display panel image insert	October 19, 2019
Consumer Information Leaflet / "User Guide" - *Color*	November 24, 2019
Dosing card - standard	October 17, 2019

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-14**." 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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

If you have any questions, call LT Sally Doan, PharmD, Regulatory Project Manager, at 301-796-8025.

Sincerely,

{See appended electronic signature page}

Karen M. Mahoney, MD, FACE
Acting Deputy Director, Office of Nonprescription Drugs
Acting Deputy Director, Division of Nonprescription Drugs I
Center for Drug Evaluation and Research

ENCLOSURES: 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/

KAREN M MAHONEY
02/14/2020 02:00:14 PM