



NDA 22122/S-018

**SUPPLEMENT APPROVAL**

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC  
Attention: Rita D. Patel, RAC  
Senior Manager, Regulatory Affairs  
184 Liberty Corner Road, Suite 200  
Warren, NJ 07059

Dear Ms. Patel:

Please refer to your supplemental new drug application (sNDA) dated and received May 26, 2021, and your amendment, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Voltaren Arthritis Pain (diclofenac sodium) topical gel, 1%.

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 identical to the labeling listed in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Label Component</b>	<b>Date of Submission</b>
20 g tube label (immediate container)	May 26, 2021
20 g extended peel back DFL (carton) – same label for sample and retail	May 26, 2021
50 g tube label (immediate container)	July 12, 2021
50 g carton	July 12, 2021
100 g tube label (immediate container)	May 26, 2021
100 g carton	May 26, 2021

120 g tube label (immediate container)	July 12, 2021
120 g carton	July 12, 2021
150 g tube label (immediate container)	July 12, 2021
150 g carton	July 12, 2021
200 g (2x100 g) carton	July 12, 2021
350 g (2x150 g) Club Pack-Back Backerboard	May 26, 2021
450 g (3x150 g) Club Pack-Back Backerboard	July 12, 2021
User Guide for 20 g SKU (Black and White)	July 12, 2021
User Guide (Color)	May 26, 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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 22122/S-018.**” 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.<sup>2</sup> 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).

<sup>1</sup> 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>.

<sup>2</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

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

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

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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.**  
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/s/  
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VALERIE S PRATT  
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