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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

PETITION FOR STAY OF ACTION
REGARDING DICLOFENAC GEL, 1%

The undersigned submits this petition pursuant to 21 C.F.R. § 10.35 requesting that the Commissioner immediately stay the effective date of the following matter.

A. Decision involved

The approval, on February 14, 2020, of the supplemental new drug application (NDA 22122/S-14) for the full switch from prescription to over-the-counter labeling for Voltaren Arthritis Pain (diclofenac sodium) topical gel 1%, corresponding to NDA 22122 held by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC.

B. Action requested

That the Commissioner immediately stay the effective date of the approval of NDA22122/S-14 and that the stay of approval remain in place no less than thirty days after the Agency issues a response, constituting final agency action, to the citizen petition submitted pursuant to 21 CFR 10.30 that accompanies this petition for stay of action.

C. Statement of Grounds

The bases for this request are the many significant safety concerns detailed in the citizen petition accompanying this petition for stay of action. The citizen petition sets forth several instances in which safety information that is contained in the previously-approved prescription labeling of diclofenac topical gel,1%, are not reflected in any manner in the over-the-counter labeling approved on February 14, 2020.

Respectfully submitted,

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