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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

Docket No. FDA-2020-P-1239: Supplement

PETITION FOR STAY OF ACTION
REGARDING DICLOFENAC GEL 1%

SUPPLEMENT

When Petitioner submitted its Petition for Stay of Action on March 30, 2020, it also submitted a Citizen Petition via Regulations.gov. Both were assigned docket numbers on April 1, 2020. The Citizen Petition (Docket No. FDA-2020-P-1237) requests that the Food and Drug Administration withdraw or rescind approval of NDA22122/S-14 because the labeling of over-the-counter (OTC) Voltaren Arthritis Pain (diclofenac sodium) topical gel 1% corresponding to NDA 22122 fails to contain, in a manner appropriate for consumer understanding, important safety information contained in seven specific sections of the most recently revised version of the prescription labeling for Voltaren Gel. Petitioner requested that specific revisions be made to any approved OTC labeling if Agency concludes, upon further reexaminerion, that diclofenac gel 1% is still an appropriate product to be sold OTC. Petitioner deferred to the Agency regarding the precise language of any revision and the most appropriate label placement of the revision.

An abbreviated new drug application (ANDA) held by PERRIGO UK FINCO (Perrigo) was approved for prescription use on May 16, 2019.[1] A supplement (SUPPL-5) to that ANDA was approved on April 1, 2020, and was identified as "Labeling-Container/Carton Labels, Labeling-Package Insert." *Id.* In a press release issued on April 6, 2020, Perrigo announced the approval by FDA of its ANDA for OTC diclofenac topical gel 1%.[2]

Labeling of Perrigo's OTC product is not yet publicly available but presumably it is identical, for purposes of the citizen petition in Docket No. FDA-2020-P-1937, to that of the reference listed drug corresponding to NDA 22122. Therefore, as permitted under 21 C.F.R. § 10.35(i),

[1] See Perrigo's ANDA 211253, information available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process - last visited on April 7, 2020.
[2] See https://www.prnewswire.com/news-releases/perrigo-announces-fda-approval-for-the-store-brand-equivalent-of-voltaren-arthritis-pain-301035806.html - last visited on April 7, 2020.

Petitioner revises the *Decision Involved* and *Action Requested* portions of the Petition for Stay of Action in the following manner:

A. Decisions 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 (OTC) labeling for Voltaren Arthritis Pain (diclofenac sodium) topical gel 1%, pertaining to NDA 22122 held by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC;

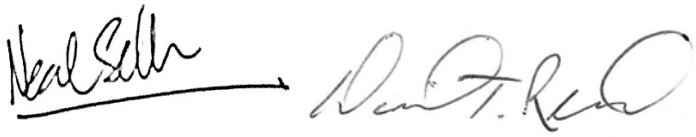
the approval, on April 1, 2020, of a supplement (SUPPL-5) to the abbreviated new drug application (ANDA) held by PERRIGO UK FINCO (Perrigo) (ANDA 211253), that provides for the OTC marketing of diclofenac gel 1% and

the approval of any pending ANDA, or pending labeling supplement to any ANDA, for which NDA 22122 is the reference listed drug.

B. Actions requested

That the Commissioner immediately stay the effective date of the approvals of NDA22122/S-14 and SUPPL-5 to ANDA 211253, and stay any pending approval of any ANDA or ANDA labeling supplement for which NDA 22122 is the reference listed drug. Petitioner requests that these stays remain in place no less than thirty days after the Agency issues a response, constituting final agency action, to the citizen petition (Docket No. FDA-2020-P-1237) submitted pursuant to 21 CFR 10.30.

Respectfully submitted,



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