

Neal Seth
202.719.4179
nseth@wiley.law



Wiley Rein LLP
1776 K Street NW
Washington, DC 20006
Tel: 202.719.7000

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wiley.law

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

**REQUEST FOR LEAVE TO SUBMIT PETITION FOR STAY OF ACTION
REGARDING DICLOFENAC GEL 1% AND REQUEST FOR MEETING**

The undersigned submitted a Petition for Stay of Action pursuant to 21 C.F.R. § 10.35 on March 30, 2020 via Regulations.gov corresponding to Docket No. FDA-2020-P-1239. The Petition was submitted 45 days from the date of the approval of NDA22122/S-14, which was February 14, 2020. Under 21 CFR 10.35(g), Petitioner requests that the Commissioner permit the filing of this petition for stay of action for at least the following reasons:

- As the Commissioner is aware, supplements to NDAs are confidential, and therefore nobody apart from the applicant and FDA had knowledge of a proposed switch of diclofenac topical gel 1% from prescription to OTC. Accordingly, nobody other than the applicant and FDA had access to the proposed labeling of a diclofenac gel 1% OTC product.
- Public posting of the OTC labeling on drugs@fda occurred after the approval; the exact date is not known to Petitioner. Concern about certain aspects of the OTC labeling was not immediate, but rather came only after the OTC labeling was reviewed and compared to the prescription labeling. Preparation of the petition for stay of action and accompanying citizen petition was expeditiously initiated thereafter and submitted without delay.
- The requested stay of action is premised on substantive, legitimate safety reasons that warrant the Agency's careful review.
- The foregoing review and comparison of the prescription and OTC labeling, as well as the preparation of the instant Petition and accompanying citizen petition, were conducted under the extraordinary conditions brought about by the novel coronavirus.


We appreciate consideration of the foregoing request for leave.

In addition, Petitioner requests the opportunity to meet with representatives of the Agency, including appropriate people from CDER and the Office of Chief Counsel, as soon as possible. The Petition for Stay of Action requests an immediate stay of action and we wish to

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answer any concerns about this request, most particularly the need for it to be addressed immediately.

Respectfully submitted,

The image shows two handwritten signatures in black ink. The signature on the left is 'A. Neal Seth' and the signature on the right is 'David T. Read'.

A. Neal Seth

David T. Read