**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

March 31, 2020

A. Neal Seth
David T. Read
Wiley Rein, LLP
1776 K Street N.W.
Washington, DC 20006

*Sent via email to:* nseth@wiley.law

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to withdraw or rescind its approval of NDA22122/S-14, because the labeling of 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 the following sections of the most recently revised version of the prescription labeling for Voltaren Gel was received by this office on 03/30/2020.

It was assigned docket number FDA-2020-P-1237. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2020.04.01 07:56:26 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)