

June 8, 2022

David Nelson Noble Pharma, LLC 4602 Domain Drive Menomonie, WI 54751

Sent via email to: patrickf@noblepharmallc.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug determine suitability of an ANADA filing for a generic flavored soft chewable formulation of firocoxib, which differs in the dosage form from the reference product, PREVICOX® Chewable Tablet approved under NADA 141 - 230 for Merial Limited (Boehringer Ingelheim Animal Health USA, Inc. is the current manufacturer) was received and processed under CFR 10.30 & 10.35 by this office on 06/07/2022.

It was assigned docket number FDA-2022-P-1049. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the suitability petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin Acting Director Dockets Management Staff FDA/Office of Operations (OO)