NOBLE PHARMA LLC
a Vets Plus Company

June 7, 2022

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: ANADA Suitability Petition for an Alternate Dosage Form

Dear Sir or Madam:

Enclosed please find a Suitability Petition submitted by Noble Pharma, LLC pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. §§ 10.20, 10.30 and 314.93. This Suitability Petition requests the Commissioner of Food and Drug Administration to 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). The proposed generic product will be an extruded chicken liver flavored soft chewable tablet, whereas the pioneer product is a barbecue flavored compressed chewable tablet.

Thank you for reviewing this submission.

Sincerely,

David Nelson
President & Chief Executive Officer,
Noble Pharma, LLC

Enclosure

Attachment 1: Suitability Petition

4602 Domain Dr., Menomonie, WI 54751 | 715-231-1234

Citizen Petition

Date: June 7, 2022

The undersigned submits this petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDCA") and 21 C.F.R. §§ 10.20, 10.30 and 314.93 to request the Commissioner of Food and Drugs to grant permission to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form of an approved pioneer product. The Suitability Petition requests that the FDA determine that Generic Firocoxib Soft Chewable Tablets are suitable for submission in an ANADA.

A. Action Requested:

The petitioner requests permission from the Commissioner of the Food and Drug Administration to file an Abbreviated New Animal Drug Application (ANADA) for a different dosage form of an approved pioneer product. The pioneer product (reference product), PREVICOX® Chewable Tablet, approved under NADA 141 – 230 for dogs. The proposed generic product, trade name to be determined (TBD), is an extruded, chicken liver-flavored, and half-scored soft chewable tablet. The method of administration (oral) will be the same as that for the pioneer product. The amount of active ingredient will be the same for both the pioneer and generic products. The copy of the pioneer label is provided in Appendix 1. Proposed changes to the label of the generic product are highlighted on the label.

B. Statement of Grounds:

The active ingredients in the pioneer product, PREVICOX®, is firocoxib. The product is commercially available as a barbecue-flavored compressed chewable form in two different strengths for oral administration to dogs. Each tablet is formulated to provide a minimum of 2.25 mg/lb. (5.0 mg/kg) body weight of firocoxib once daily as needed for osteoarthritis and for 3 days as needed for postoperative pain and inflammation associated with soft-tissue and orthopedic surgery. The drug can be administered to dogs approximately two hours prior to surgery. The chewable tablet of PREVICOX is half-scored, and available in two different strengths, beige to tan in color, in blister packages. The dosage should be calculated in half tablet increments. The proposed generic product, administered orally, will have the same active ingredient, indications, and dosage, have the same therapeutic effect, and contain the same cautions and warnings as the pioneer product. The proposed generic product differs from the pioneer in size, shape, flavor, and texture. The product will be packaged in two different colors to identify different strengths (see Table 1).

Table 1.

Parameter	Pioneer Product – PREVICOX® Chewable Tablet For Dogs	Proposed Generic Product – Trade Name (TBD)
Regulatory ID	NADA – 141 – 230	ANADA – TBD
Species	Canine (Dog)	Canine (Dog)
Active Ingredient	Firocoxib	Firocoxib
Pharmacological category	Non-steroidal anti-inflammatory drug (NSAID)	Non-steroidal anti-inflammatory drug (NSAID)
Indications	For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.	For the control of pain and inflammation associated with osteoarthritis and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery in dogs.
Dosage form	Barbecue-flavored compressed chewable tablet	Chicken liver-flavored soft chewable tablet
How supplied	PREVICOX is available as round, beige to tan, half-scored tablets in two strengths, containing 57 mg or 227 mg firocoxib. Each tablet strength is supplied in 3 count, 10 count and 30 count blister packages and 60 count and 180 count bottles.	The proposed generic product will be available as a cuboid, light-to-dark brown, half-scored soft chewable tablets in two strengths, containing 57 mg or 227 mg firocoxib. Each tablet strength is supplied in 3 count, 10 count and 30 count blister packages and 60 count and 180 count bottles.
Route of administration	Oral	Oral

The proposed generic drug will provide an alternative dosage form to veterinarians and dog owners. Proposed soft chewable has high palatability, and dogs will find it easier to chew than a harder chewable form, thus making it easier to achieve compliance. When administered, dog may either chew the drug before swallowing or swallow it intact. Alternatively, the drug may be given with or without food. All the excipients in the new dosage form are already in use for products approved for dogs and will not adversely impact the safety and effectiveness of firocoxib in the new formulation.

The labeling for the proposed generic product will parallel the pioneer product and include the following categories: Description, Uses, Dosage and Administration, Retreatment, Side Effects, Warning, How Supplied, Storage Conditions, and the manufacturer's information.

The labels of the two products differ in the type of formulation: a barbecue-flavored compressed chewable tablet for the pioneer product compared to a chicken liver-flavored soft chewable tablet form for the proposed generic product. The labeling will also differ as it relates to the different companies manufacturing the two products, the trade name, the size, shape, flavor, and texture of the two products. The storage condition of the proposed product may differ from that of the pioneer depending on the results of the product stability testing. The parts of the proposed generic product label that will be different from those of the pioneer are highlighted and attached to this petition (See Appendix 1).

In accordance with applicable provisions of the Freedom of Information Act (FOIA) and 21 CFR 20.61, Petitioner declares that no information contained within this Suitability Petition constitutes privileged or confidential trade secrets and/or commercial or financial information exempt from disclosure under exemption 4 of FOIA.

C. Environmental Impact:

In accordance with 21 CFR 25.15, Noble Pharma, LLC claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

D. Economic Impact:

Noble Pharma, LLC will provide an economic impact analysis of this action if requested by the commissioner after review of this Suitability Petition.

E. Certification:

The Petitioner, Noble Pharma, LLC, certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petition relies, including representative data and information known to be unfavorable to the petition.

David Nelson

6-7-2022

David Nelson
President/Chief Executive Officer,
Noble Pharma, LLC
4602 Domain Dr.
Menomonie, WI 54751
715-231-1234 ext. 302

Date

Enclosures:

Appendix 1 - Pioneer Product Label