Attachment 1. Suitability Petition

Citizen Petition

Date. July 20, 2022

The undersigned submits this Suitability 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 Drug Administration to grant permission to file an Abbreviated New Animal Drug (ANADA) for a different dosage form of an approved pioneer product. The submitter, Noble Pharma, LLC requests that the FDA determine that Generic Flavored Soft Chewable Tablets of carprofen for dogs 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), Rimadyl® Chewable Tablet, was approved under NADA 141 – 111 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 pioneer label.

B. Statement of Grounds:

The active ingredients in the pioneer product, Rimadyl®, is carprofen. The product is commercially available as a liver-flavored half-scored hard compressed chewable form in three different strengths, brown in color for oral administration to dogs. Each tablet is formulated to provide a minimum of 2 mg/lb body weight of carprofen once daily or 1mg/lb body weight twice daily as needed for pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft-tissue and orthopedic surgery. The dosage of the pioneer product, Rimadyl® 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 three different colored plastic bottles to identify different strengths (see Table 1).

Table 1.

Parameter	Pioneer Product – Rimadyl® Chewable Tablet For Dogs	Proposed Generic Product – Trade Name (TBD) For Dogs
Regulatory ID	NADA – 141 – 111	ANADA – TBD
Species	Canine (Dog)	Canine (Dog)
Active Ingredient	Carprofen	Carprofen
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	Liver-flavored hard compressed chewable tablet	Chicken liver-flavored soft chewable tablet
How supplied	Rimadyl® is available as square, brown, half-scored tablets in three strengths, containing 25 mg, 75 mg, or 100 mg carprofen. Each tablet strength is supplied in 7, 30, 60, and 180 count in plastic bottles.	The proposed generic product will be available as a cuboid, half-scored soft chewable tablets in three strengths, containing 25 mg, 75 mg, or 100 mg carprofen. Each tablet strength is supplied in 7, 30, 60, and 180 count in plastic bottles.
Route of administration	Oral	Oral

The proposed generic drug will provide an alternative dosage form to veterinarians and dog owners. Dogs will find it easier to chew a soft chewable dosage form than a harder chewable tablet, 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 carprofen 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 liver-flavored hard 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).

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. Confidential and/or Proprietary Information:

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.

F. 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.

7-20-2022

David Nelson
President & CEO,
Noble Pharma, LLC
4602 Domain Dr.
Menomonie, WI 54751

Date