AKORN | ANIMAL HEALTH

March 10, 2020

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Submitted Electronically

Citizen Petition

Dear Sir or Madam:

The undersigned submits this Petition pursuant to § 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 CFR.§§ 10.20 and 10.30, to request the Commissioner of Food and Drugs to grant Akorn Animal Health Inc. permission to pursue approval of an Abbreviated New Animal Drug Application based on Corticosporin® Veterinary Ophthalmic Ointment under NADA 065-476 (the "RLNAD"), whereas the generic contains a change in dosage strength of one of the active ingredients (Polymixin B sulfate).

A. Action Requested

The petitioner requests permission from the Commissioner of the Food and Drug Administration to pursue approval of an Abbreviated New Animal Drug Application for Neomycin and Polymixin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment, USP, that differs from the RLNAD in dosage strength of the Polymixin component. The reference listed drug (RLNAD) product upon which this petition is based is Corticosporin® Veterinary Ophthalmic Ointment under NADA 065-476 held by Intervect Inc. The petitioner seeks a change in strength of the polymixin B sulfate component from 5,000 units/g in the RLNAD, to 10,000 units/g in the proposed generic product. A product comparison of RLNAD and proposed generic product is provided in Table 1.

B. Statement of Grounds

In accordance with Section 512(n)(3) of the Federal, Food, Drug and Cosmetic Act, a petition is allowed for an animal drug whose active ingredients, route of administration, dosage form, or strength differs from that of a new animal drug. In this petition, we are requesting a change of strength of the polymixin B sulfate active ingredient from 5,000 units/g present in the RLNAD to 10,000 units/g for the proposed generic product. The change in strength will not impact the safety or effectiveness of the drug.

Table 1- Comparison of the RLNAD and Proposed Generic Product

Parameter	RLNAD	Proposed Generic
Reg ID	NADA 065-476	ANADA
Sponsor	Intervect Inc.	Akorn Inc.
Name	Corticosporin® Veterinary Ophthalmic Ointment	Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment, USP
Species	Dogs and Cats	Dogs and Cats
Dosage Form	Ointment	Ointment
Route of Administration	Ophthalmic	Ophthalmic
Indication	For the treatment of acute and chronic conjunctivitis in dogs and cats caused by organisms susceptible to the antibiotics contained in the ointment.	For the treatment of acute and chronic conjunctivitis in dogs and cats caused by organisms susceptible to the antibiotics contained in the ointment.
Strength(s)	Each gram of ointment contains 400 units of bacitracin zinc, 5,000 units of polymixin B sulfate, 5 mg of neomycin sulfate (equivalent to 3.5 mg of neomycin base) and 10 mg of hydrocortisone.	Each gram of ointment contains 400 units of bacitracin zinc, 10,000 units of polymixin B sulfate, 5 mg of neomycin sulfate (equivalent to 3.5 mg of neomycin base) and 10 mg of hydrocortisone.
Dosage and Administration	Express a small quantity of ointment into the conjunctival sac beneath the lower eyelid three or four times daily	Express a small quantity of ointment into the conjunctival sac beneath the lower eyelid three or four times daily
How Supplied	1/8 oz tube with ophthalmic tip.	3.5 mg (1/8 oz) tube with ophthalmic tip.

The FDA Approved Animal Products "Green Book", Section 1.1, listing for Cortisporin® Veterinary Ophthalmic Ointment is provided in Attachment 1. The RLNAD product has not been marketed for a number of years. The last available labeling for the RLNAD is provided in Attachment 2. The proposed labeling for the generic product is provided in Attachment 3.

The change in strength of the Polymixin B sulfate from 5,000 units/g in the RLNAD to 10,000 units/g will not affect the safety and efficacy of the product. This statement is based on the fact that an equivalent veterinary product used for the same indication and same dosing regimen, Vetropolycin® HC (NADA 065-015, Dechra LTD), is currently approved and marketed. Vetropolycin® HC is used for the same indication and has the same active ingredient components in the same amounts as the proposed generic: each gram contains bacitracin zinc 400 units, neomycin sulfate 5mg (equivalent to 3.5 mg neomycin base), polymixin B sulfate 10,000 units, and hydrocortisone acetate 10 mg, respectively. The only difference is that the hydrocortisone is present in the acetate form in the Dechra product, whereas it is the base in the proposed generic.

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C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis, if requested by the Agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Regards,

John Franolic

Digitally signed by John Franolic
Date: 2020.03.10 11:34:00 -04'00'

John D. Franolic, Ph.D.
Vice President of Regulatory Affairs
Akorn Animal Health Inc.

Attachments:
1. FDA Approved Animal Products "Green Book", Section 1.1 – Trade Names and Sponsors, page 16 (March 20, 2020)
2. Labeling for Corticosporin® Veterinary Ophthalmic Ointment
3. Draft Insert Labeling Proposed for Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment, USP.
4. Labeling for Vetropolycin® HC (NADA 065-015, Dechra LTD