

May 9, 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

**AMENDMENT – ANADA SUITABILITY PETITION**

**DOCKET #FDA-2020-P-1074**

Dear Sir or Madam:

The undersigned submits this amendment to the Citizen Petition filed on March 10, 2020 (Docket #FDA-2020-P-1074) pursuant to § 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 CFR. §§ 10.20 and 10.30. The Citizen Petition requested that the Commissioner of Food and Drugs grant Akorn Animal Health Inc. permission to pursue approval of an Abbreviated New Animal Drug Application based on CORTISPORIN® OPTHALMIC OINTMENT VETERINARY under NADA 065-476 (the "RLNAD"), whereas the generic contains a change in dosage strength of one of the active ingredients (Polymixin B sulfate).

This amendment provides the following additional information and/or revisions:

1. Email contact for the ANADA Suitability Petition: **john.franolic@akorn.com.**
2. Correct name for the RLNAD drug product is **“CORTISPORIN® OPTHALMIC OINTMENT Veterinary.”**
3. Correct sponsor name for the RLNAD is **Intervet, Inc.**
4. Correct “How Supplied” for the proposed generic product is **“3.5 g (1/8 oz) tube with ophthalmic tip.”**
5. Akorn Animal Health Inc. is amending the “Environmental Impact” as follows: **“In accordance with 21 CFR 25.15, Akorn Animal Health Inc. 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 under 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 under 21 CFR 25.21.”**

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