FDA-2020-P-1074

Akorn Animal Health Inc.
Attention: John D. Franolic, Ph.D.
Vice President of Regulatory Affairs
1925 West Field Court
Suite 300
Lake Forest, IL 60045

Re: Suitability petition approved

Dear Dr. Franolic:

We approve your suitability petition (FDA-2020-P-1074) dated March 10, 2020, and amended May 9, 2020. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic neomycin and polymyxin B sulfates, bacitracin zinc, and hydrocortisone ophthalmic ointment, USP, that differs from the reference listed new animal drug (RLNAD) ophthalmic ointment in terms of the strength of one of the active pharmaceutical ingredients. Specifically, the RLNAD contains 5,000 units of polymyxin B sulfate per gram of ophthalmic ointment, while the proposed generic product contains 10,000 units of polymyxin B sulfate per gram of ophthalmic ointment. The RLNAD is CORTISPORIN® OPHTHALMIC OINTMENT Veterinary (polymyxin B, bacitracin, neomycin, hydrocortisone), sponsored by Intervet, Inc., under NADA 065-476. CORTISPORIN® OPHTHALMIC OINTMENT Veterinary is approved in dogs and cats for the treatment of acute and chronic conjunctivitis due to organisms susceptible to the antibiotics contained in the ointment.

Your proposed change from the RLNAD is a change that can be considered through a suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). We find that the proposed change does not require you to conduct investigations to show the safety and effectiveness of the generic new animal drug for its proposed intended uses. Therefore, we approve the petition under section 512(n)(3)(C) of the FD&C Act.

Approval of this suitability petition does not guarantee approval of the ANADA for your proposed generic new animal drug. We will make that determination after you have submitted your ANADA for our review.

When you submit your ANADA for your proposed generic new animal drug, you must identify the RLNAD referred to in this suitability petition and include a copy of this letter.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Lauren (Gypsi) Feeney, DVM, Director, Division of Generic Animal Drugs, at 240-402-0848 or at Lauren.Feeney@fda.hhs.gov. You may also contact Yazmin M. Collie, DVM, Team Leader, Review Team 1, at 301-348-3928 or at Yazmin.Collie@fda.hhs.gov.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2020.06.03 17:47:27 -04'00'

Matthew Lucia, DVM
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

cc: HFV-170 (Petition File)
HFA-305 (Dockets Management Staff)