FDA-2017-P-6968

Ceva Animal Health, LLC.
Attention: Alicia Henk
Director, Development and Regulatory Affairs
8735 Rosehill Road
Lenexa, KS 66215

Re: Request for approval of a suitability petition

Dear Ms. Henk:

We approve your suitability petition (FDA-2017-P-6968) dated December 21, 2017. You requested permission to submit an abbreviated new animal drug application (ANADA) for a proposed generic new animal drug that differs in dosage form from the reference listed new animal drug (RLNAD). The RLNAD is ATOPICA™ (cyclosporine capsules) USP MODIFIED, sponsored by Elanco US, Inc., under NADA 141-218. ATOPICA is indicated for the control of atopic dermatitis in dogs weighing at least 4 pounds body weight. The proposed generic new animal drug is an un-encapsulated, non-aqueous solution of cyclosporine with the same indications and dosage schedule approved for the RLNAD, which is a gelatin encapsulated, non-aqueous solution of cyclosporine.

Your proposed changes from the RLNAD are changes that can be considered through a suitability petition, as defined under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). We find that the proposed changes do 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 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 reference listed new animal drug referred to in this suitability petition and include a copy of this letter. We recommend that you request a presubmission conference, according to 21 CFR 514.5, to discuss the requirements and potential pathways for approval of the application.

A copy of this letter approving your petition will be placed on public display at www.regulations.gov with the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. If you have any questions, please contact Dr. Matthew A. Lucia, Director, Division of Generic Animal Drugs, at 240-402-0811.

Sincerely,

Elizabeth A. Rettie -S

Digitally signed by Elizabeth A. Rettie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300058148, cn=Elizabeth A. Rettie -S
Date: 2018.03.14 18:12:19 -04'00'

Elizabeth A. Rettie, D.V.M.
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine