FDA-2020-P-2234

Ray Law Firm, PLLC
Attention: Harry B. Ray
6150 Shallowford Road, Suite 105
Chattanooga, TN 37421

Re: Suitability petition approved

Dear Mr. Ray:

We approve your suitability petition (FDA 2020-P-2234) dated November 24, 2020. You requested permission to submit an abbreviated new animal drug application (ANADA) for generic cefpodoxime proxetil tablets that differs from the reference listed new animal drug (RLNAD) by the addition of a 50 mg strength and the elimination of the tablet score on all proposed strengths (50, 100, and 200 mg tablets). The RLNAD is Simplicef® (cefpodoxime proxetil tablets), sponsored by Zoetis Inc, under NADA 141-232. Simplicef® is approved for the treatment of skin infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, *Streptococcus canis* (Group G, ß hemolytic), *Escherichia coli*, *Pasteurella multocida*, and *Proteus mirabilis*.

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 FD&C 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 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 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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

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.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2021.02.16 17:28:05 -05'00'

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