FDA-2020-P-0963

Aurora Pharmaceutical, Inc.
Attention: Alina Garbar, PhD
RA Director
1196 Hwy 3 South
Northfield, MN 55057

Re: Suitability petition approved

Dear Dr. Garbar:

We approve your suitability petition (FDA 2020-P-0963) dated February 27, 2020, and amended March 27, 2020. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic deracoxib oral solution (1.80% w/v), that differs in dosage form and strength from the reference listed new animal drug (RLNAD). The RLNAD is Deramaxx™ (deracoxib) Chewable Tablets, available in 12, 25, 75, and 100 mg strengths, sponsored by Elanco US Inc., under NADA 141-203. Deramaxx™ is approved for the control of postoperative pain and inflammation associated with orthopedic and dental surgery and for the control of pain and inflammation associated with osteoarthritis in dogs.

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.

A copy of this letter approving/denying 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 me 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

Date: 2020.05.14 16:40:26 -04'00'

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

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