FDA-2024-P-1716

Aurora Pharmaceutical, Inc.
Attention: Patrick Wadzinski, PharmD
Medical Affairs Pharmacist
1196 Hwy 3 South
Northfield, MN 55057

Re: Suitability petition denied

Dear Dr. Wadzinski:

We deny your suitability petition (FDA 2024-P-1716) dated April 3, 2024. You requested permission to submit an abbreviated new animal drug application (ANADA) for a generic meloxicam oral solution (5 mg/mL) that differs in dosage form and strength from the reference listed new animal drug (RLNAD). The RLNAD is Metacam® (meloxicam oral suspension), sponsored by Boehringer Ingelheim Animal Health USA, Inc., under NADA 141-213. Metacam® is approved for the control of pain and inflammation associated with osteoarthritis in dogs.

Your proposed changes from the RLNAD (dosage form and strength) are changes that can be considered through a suitability petition under section 512(n)(3) of the Federal Food, Drug, and Cosmetic Act (the Act). However, since the proposed generic product, meloxicam, is a non-steroidal anti-inflammatory drug with a narrow margin of safety, there are concerns associated with your proposed generic drug product as presented in this suitability petition. You are proposing a 5 mg/mL strength solution, which is in an increase in strength from the RLNAD by a factor of ten (0.5 mg/mL to 5 mg/mL). The similarity in appearance of the two concentrations and the magnitude of difference between the strengths causes concern for user errors potentially resulting in significant adverse events. Additionally, the proposed calibration of syringe to a daily maintenance dose of 0.05 mg/lb is not acceptable because it will not deliver the RLNAD approved dose of 0.045 mg/lb. We find that the proposed changes would require you to conduct investigations to show the safety of the drug for its proposed intended uses. Therefore, we must deny the petition under section 512(n)(3)(C) of the Act.

If you wish to seek a reconsideration of our decision, you must follow the procedures found in 21 CFR Part 10 and submit the request in the format outlined in section 10.33 no later than 30 days after the date of this letter to the Dockets Management Staff, HFA-305, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must base your request solely on the information contained in your original petition (see 21 CFR 10.33(e)). If there is additional information, not included as part of your original petition that you would like us to consider, you should submit a new petition, including all the necessary information, under section 10.25(a) to the Dockets Management Staff.

A copy of this letter denying 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 Lauren.Feeney@fda.hhs.gov.

Sincerely,

Matthew A. Lucia -S

Digitally signed by Matthew A. Lucia -S
Date: 2024.06.27 11:36:30 -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)