SUITABILITY PETITION

Petitioner:
Aurora Pharmaceutical, Inc.
1196 Hwy 3 South
Northfield, MN, 55057

Action Requested:

The petitioner requests FDA permission to submit an abbreviated new animal drug application (ANADA) for a generic meloxicam oral solution in a 3 mg/mL strength (for use in dogs weighing more than 10 lbs.) that differs from reference listed new animal drug (RLNAD) in **dosage form and strength.** The RLNAD is Metacam® (meloxicam) Oral Suspension 0.5 mg/mL and 1.5 mg/mL strength, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-213 for the control of pain and inflammation associated with osteoarthritis in dogs. The petition is submitted under the provisions of Section 512(n)(3) of the Federal Food Drug and Cosmetic Act.

Statement of Grounds:

Metacam® (meloxicam) Oral Suspension is an oral suspension that requires shaking the liquid and is approved in two strengths, 1.5 mg and 0.5 mg meloxicam per mL of liquid. The approved dosage of meloxicam for oral administration in dogs is 0.09 mg/lb (0.2 mg/kg) of body weight only on the first day of treatment, and for all treatments after day 1, 0.045 mg/lb (0.1 mg/kg) of body weight.

The proposed generic copy will utilize the same active as RLNAD. The recommended dosage is not changed. Previously, CVM accepted Aurora's similar suitability petition for the change in dosage form only, reference CVM docket number FDA-2022-P-2795, approved on 11/07/2022 for meloxicam oral solution 0.5 mg/mL and 1.5 mg/mL strengths. Aurora intends to pursue all three strengths of meloxicam oral solution for approval – 0.5 mg/mL, 1.5 mg/mL strengths to match RLNAD, and the additional 3 mg/mL for larger dogs.

Justification for the proposed change of the dosage form is improved uniformity and convenience of a solution vs. suspension that requires shaking. Additionally, the higher dosage strength of 3 mg/mL being proposed exclusively for dogs over 10 lbs. making delivery easier as the volume is reduced by half vs. the 1.5 mg/mL improving the likelihood of complete delivery in larger dogs. For the 0.045 mg/lb. maintenance dose described in the RLNAD labeling for dogs over 10 lbs., Aurora is planning to provide a calibrated oral syringe(s) at 1 lb. increments from 10 lbs. to 30 lbs, and at 5 lb. increments from 30 lbs. up to 200 lbs. (3 mL at 200 lbs. for the

maintenance dose). This would correspond to the weights available on the RLNAD syringes for the 1.5 mg/mL product and extend it from 120 lbs. to 200 lbs. for larger breed dogs. For the initial dose, Aurora would provide instructions to give the maintenance dose twice. The reduced volume combined with precise dosing should result in improved dose compliance without any significant reduction in safety as this product is only at 2X the RLNAD strength and the RLNAD FOIA (see attachment 3) safety study summaries did not show significant NSAID toxicity until at least 3X the dose, and then only during the 26-week study.

No patents are listed in the Green Book for the approved NADA 141-213.

Marketing exclusivity for Metacam® (meloxicam) Oral Suspension expired 4/15/2008.

A side-by side comparison of Aurora's generic product Meloxicam Oral Solution with reference listed new animal drug Metacam® (meloxicam) Oral Suspension is presented hereinafter.

Subject	RLNAD	Aurora's generic
Proprietary name (strengths)	Metacam® Oral Suspension (meloxicam 1.5 mg/mL; meloxicam 0.5 mg/mL)	Meloxicam Oral Solution (meloxicam 3 mg/mL)
Established name	Meloxicam	Meloxicam
Sponsor	Boehringer Ingelheim Animal Health USA, Inc. 3239 Satellite Blvd., Duluth, GA 30096	Aurora Pharmaceutical, Inc. 1196 Hwy 3 South, Northfield, MN 55057
Pharmacological category	Non-steroidal anti-inflammatory drug	Non-steroidal anti-inflammatory drug
Dosage form	Suspension	Solution
Active ingredient	Each mL of suspension contains 1.5 mg or 0.5 mg of meloxicam after shaking	Each mL of solution contains 3 mg of meloxicam
How supplied	1) Metacam® 1.5 mg/mL Oral Suspension: 10, 32, 100, and 180 mL dropper bottles with measuring syringe(s). 2) Metacam® 0.5 mg/mL Oral Suspension: 15 and 30 mL dropper bottles with measuring syringe.	Meloxicam 3 mg/mL Oral Solution: 16, 50, and 90 mL bottles with measuring oral syringe(s).
How dispensed	Rx	Rx
Route of administration	Oral	Oral
Species/Class	Dog	Dog

Subject	RLNAD	Aurora's generic
Recommended dosage	0.09 mg/lb (0.2 mg/kg) of body weight only on the first day of treatment, and for all treatments after day 1, 0.045 mg/lb (0.1 mg/kg) of body weight.	0.09 mg/lb (0.2 mg/kg) of body weight only on the first day of treatment, and for all treatments after day 1, 0.045 mg/lb (0.1 mg/kg) of body weight.
Indications	Metacam® Oral Suspension is administered for the control of pain and inflammation associated with osteoarthritis in dogs.	Meloxicam Oral Solution is administered for the control of pain and inflammation associated with osteoarthritis in dogs.

Environmental Impact:
In accordance with 21 CFR 25.15, Aurora Pharmaceutical, Inc. claims that the agency requested action in this suitability petition qualifies for categorical exclusion from the requirement to prepare an environmental assessment as set forth in 21 CFR 25.30(h). We confirm that to our knowledge no extraordinary circumstances exist that may significantly affect the quality of the human environment as described in 21 CFR 25.21.

Economic Impact:
An economic impact analysis will be provided if requested after review of this petition.

Labeling:
General labeling information for the proposed generic Meloxicam Oral Solution will be essentially the same as the reference listed new animal drug Metacam® (meloxicam) Oral Suspension labeling (attachment #1 and #2), except the changes in dosage form from suspension to solution, no shaking instructions to suspend meloxicam, appropriate changes to the dosing instructions for 3.0 mg/mL strength including limiting the use to dogs over 10 lbs., and information specific for the generic drug, namely proprietary name, how supplied and directions for use, "manufactured by" information, NDC#, label ID and revision date; NADA# will be replaced with ANADA#.

Certification:
The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

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Patrick Wadzinski, PharmD Date
Medical Affairs Pharmacist
Aurora Pharmaceutical, Inc.

Attachment 1. Metacam® (meloxicam) 1.5 mg/mL Oral Suspension, labeling by Boehringer Ingelheim Animal Health USA, Inc. rev 04/2022

Attachment 2. Metacam® (meloxicam) 0.5 mg/mL Oral Suspension, labeling by Boehringer Ingelheim Animal Health USA, Inc. rev 11/2023

Attachment 3: Metacam® (meloxicam) Oral Suspension FOIA.