SUITABILITY PETITION

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

Action Requested:

The petitioner requests an FDA permission to submit an abbreviated new animal drug application (ANADA) for a generic firocoxib oral solution (0.9% w/v) for use in horses that differs from reference listed new animal drug (RLNAD) in both **dosage form** and **strength**. The RLNAD is Equioxx® (firocoxib) Oral Paste, sponsored by Boehringer Ingelheim Animal Health USA, Inc. under NADA 141-253 for the control of pain and inflammation associated with osteoarthritis in horses. The petition is submitted under the provisions of Section 512(n)(3) of the Federal Food Drug and Cosmetic Act.

Statement of Grounds:
The proposed generic copy will utilize the same active as RLNAD. Recommended dosage is not changed. The justification for the proposed change of the dosage form and strength is convenience to use a multi-dose packaging.

Equioxx® (firocoxib) Oral Paste is an oral paste containing 8.2 mg of firocoxib per gram of paste. The approved dosage of firocoxib for oral administration in horses is 0.045 mg/lb (0.1 mg/kg) of body weight once daily for up to 14 days.

The proposed generic dosage form is an oral solution of different strength 0.900% w/v. The same dosage schedule and route of administration will be recommended in the labeling: 0.045 mg/lb (0.1 mg/kg) of body weight once daily for up to 14 days.

No patents are listed in the Green Book for the approved NADA 141-253.

Marketing exclusivity for Equioxx® (firocoxib) Oral Paste was expired 12/30/2008.

Side-by side comparison of Aurora's generic product Firocoxib Oral Solution 0.9% w/v with reference listed new animal drug Equioxx® (firocoxib) Oral Paste is presented hereinafter.

Subject	RLNAD	Aurora's generic
Proprietary name (strength)	Equioxx® Oral Paste (firocoxib 8.2 mg/g)	Firocoxib Oral Solution 0.9% w/v (firocoxib 9.0 mg/mL)
Established name	Firocoxib	Firocoxib
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	Paste	Solution
Active ingredient	Each g contains 8.2 mg of firocoxib	Each mL contains 9.0 mg of firocoxib (~7.8 mg/g)
How supplied	1) 20 packs of individually-boxed or wrapped syringes. Each syringe contains 6.93 g of EQUIOXX paste sufficient to treat a 1250 lb. horse. Each pack contains enough paste to provide 20 daily doses for a 1250 lb. horse. (Total deliverable mg Firocoxib/pack = 1,136 mg) 2) 72 packs of individually-boxed or wrapped syringes. Each syringe contains 6.93 g of EQUIOXX paste sufficient to treat a 1250 lb. horse. Each pack contains enough paste to provide 72 daily doses for a 1250 lb. horse. (Total deliverable mg Firocoxib/pack = 4,091 mg)	Multi-dose 90 mL bottle. 6.25 mL is sufficient liquid solution to treat a 1250 lb. horse once. A 90 mL bottle of solution is sufficient to treat a 1250 lb. horse for no more than 14 days (total deliverable Firocoxib/bottle = 810 mg).
How dispensed	Rx	Rx
Route of administration	Oral	Oral
Species/Class	Equine	Equine
Recommended dosage	0.045 mg/lb (0.1 mg/kg) body weight daily for up to 14 days	0.045 mg/lb (0.1 mg/kg) body weight daily for up to 14 days
Indications	Equioxx® Oral Paste is administered for up to 14 days	Firocoxib Oral Solution 0.9% w/v is administered for up to 14 days

Subject	RLNAD	Aurora's generic
	for the control of pain and inflammation associated with osteoarthritis in horses.	for the control of pain and inflammation associated with osteoarthritis in horses.

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 Firocoxib Oral Solution 0.9% w/v will be essentially the same as the reference listed new animal drug Equioxx® (firocoxib) Oral Paste labeling (attachment 1), except the changes in dosage form and strength, and information specific for the generic drug, namely proprietary name, how supplied, dosage regimen and directions for use, "manufactured by" information, NDC#, label ID and revision; 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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10/19/2020 11:29:55 am 10/19/2020

Alina Garbar, PhD Date
RA Director
Aurora Pharmaceutical, Inc.

Attachment 1. Equioxx® (firocoxib) Oral Paste, labeling by Merial, rev 02-2015