

1196 Hwy. 3 South · Northfield, MN 55057 · 888-215-1256 · www.aurorapharmaceutical.com

Date: August 08, 2024

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Suitability Petition for Afoxolaner Oral Solution 1.84% w/v

Enclosed please find Suitability Petition submitted by Aurora Pharmaceutical, Inc., located at 1196 Hwy 3 South, Northfield, MN, 55057, under Section 512(n)(3) of the Federal Food Drug and Cosmetic Act to request an FDA permission to submit an abbreviated new animal drug application for generic animal drug Afoxolaner Oral Solution 1.84% w/v, that differs from reference listed new animal drug Nexgard® (afoxolaner) Chewables (11.3 mg, 28.3 mg, 68 mg, and 136 mg afoxolaner per chewable), sponsored by Boehringer Ingelheim Animal Health USA Inc. under NADA 141-406, in dosage form.

For additional information please contact:

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08/08/2024 09:32:03 am

Patrick Wadzinski, PharmD

Medical Affairs Pharmacist

Aurora Pharmaceutical, Inc.