

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in September 2018.

Sponsor Change

(A)NADA Numbers: 010-092, 010-346, 012-123, 035-157, 035-455, 035-456, 038-661, 044-756, 046-780, 049-187, 055-059, 065-383, 065-505, 065-506, 092-150, 093-515, 095-218, 096-671, 096-672, 098-288, 099-169, 099-604, 099-605, 099-606, 099-607, 101-690, 107-506, 109-305, 118-032, 118-550, 118-979, 119-141, 120-615, 122-447, 124-241, 126-504, 130-136, 138-405, 140-582, 140-583, 141-420, 200-050, 200-069, 200-103, 200-115, 200-117, 200-144, 200-146, 200-176, 200-247, 200-253, 200-312, 200-313, 200-317, 200-318, 200-326, 200-328, 200-350, 200-364, 200-368, 200-374, 200-376, 200-377, 200-380, 200-386, 200-387, 200-391, 200-434, 200-447, 200-455, 200-460, 200-464, 200-468, 200-481, 200-482, 200-488, 200-489, 200-494, 200-496, 200-501, 200-508, 200-523, 200-529, 200-538, 200-581

Previous Sponsor: Cross Vetpharm Group Ltd.
New Sponsor: Bimeda Animal Health Limited
Drug Labeler Code: 061623

Suitability Petitions

Number: 2018-P-3211

Petitioner: Aurora Pharmaceutical LLC
Date Filed: August 17, 2018
Description: The petitioner requests to file an ANADA for a generic firocoxib oral solution for use in horses that differs from the reference listed new animal drug (RLNAD), Equioxx® (firocoxib) Oral Paste, sponsored by Merial, Inc. under NADA 141-253. The proposed change is in dosage form and strength. The petitioner proposes a generic product that is an oral solution with a strength of 1.14% w/v (weight per volume). The RLNAD is approved as an oral paste; the strength of the RLNAD is 8.2 mg/g.

Number: 18-P-2344

Petitioner: Noble Pharma, LLC
Date Filed: June 15, 2018
Action: Approved
Action Date: September 6, 2018
Description: The petitioner requests to file an ANADA for a generic praziquantel tablet for use in dogs that differs from the pioneer product, Tapeworm Dewormer for Dogs (praziquantel) 34 mg tablet, sponsored by Bayer HealthCare, LLC, Animal Health Division under 111-798. The proposed change is for a soft, chewable scored tablet - light brown in color.