

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in February 2009.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-286

Trade Name: Phoenectin® Paste 1.87%
Pioneer: NADA 134-314
Ingredients: Ivermectin
Sponsor: IVX Animal Health, Inc.
Approval Date: December 18, 2008

The effect of the supplement provides for the addition of the following parasite species that are no longer protected by marketing exclusivity: *Craterostomum acuticaudatum*, *Coronocylus coronatus*, *Coronocylus labratus* and *Petrovinema poculatum*.

21 CFR 520.1192 74 FR 6541

ANADA Number: 200-387

Trade Name: Flunazine™ Injectable Solution
Pioneer: NADA 101-479
Ingredients: Flunixin meglumine
Sponsor: Cross Vetpharm Group Ltd.
Approval Date: December 18, 2008

The effect of the supplement provides for the addition of a new indication for the control of pyrexia associated with acute bovine mastitis that is no longer protected by marketing exclusivity.

21 CFR 522.970 74 FR 6994

NADA Number: 140-916

Trade Name: Denagard® Liquid Concentrate
Ingredients: Tiamulin
Sponsor: Novartis Animal Health US, Inc.
Approval Date: January 27, 2009

The effect of the supplement provides for removal of a 250 pound weight restriction and the addition of a reproductive caution statement to labeling.

21 CFR 520.2455 74 FR 7180

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2009 list were published in the Federal Register in February 2009.

Label Revisions

NADA Number: 140-971

Trade Name: Heartgard® Plus Chewables
Ingredients: Ivermectin/pyrantel
Sponsor: Merial Ltd.
Approval Date: January 27, 2009

The effect of the supplement provides for a change to the trademark symbol from TM to ® for the “Dog and Hand” logo.