

## Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2008 list were published in the Federal Register in September 2008.

### Supplemental Approval

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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.

#### NADA Number 141-240:

Trade Name: ReBalance® Antiprotozoal Oral Suspension  
Ingredients: Sulfadiazine/pyrimethamine  
Sponsor: Animal Health Pharmaceuticals, LLC  
Approval Date: August 27, 2008

This supplement provides for revision of the labeling to show Animal Health Pharmaceuticals LLC as the sponsor/owner of the NADA and IVX Animal Health, Inc. as the current manufacturer and sole label distributor of the ReBalance product at this time and revises the human food safety warning on the labeling to read "Do not use in horses intended for human consumption."

*21 CFR 520.2215 73 FR 53685*

### Labeling Revisions

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#### ANADA Number 200-185:

Trade Name: GenGard®  
Pioneer Product: NADA 133-836  
Ingredients: Gentamicin sulfate  
Sponsor: Agri Laboratories Ltd.

The effect of this supplement changes the symbol associated with GEN-GARD from a Trademark (™) to a Registered Trademark (®).

#### ANADA Number 200-377:

Trade Name: LinxMed-SP®  
Pioneer Product: NADA 111-636  
Ingredients: Lincomycin hydrochloride  
Sponsor: Cross Vetpharm Group Ltd.

The effect of this supplement is a trade name change from LINCOMED Soluble Powder to LinxMed-SP® Soluble Powder.

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