The following corrections or additions to the January 2006 list were published in the Federal Register in April 2006.

New Approvals

NADA Number: 141-250

Trade Name: Aureomycin® and Bovatec®
Ingredients: Chlortetracycline and lasalocid sodium
Sponsor: Alpharma Inc.
Approval Date: March 31, 2006
Status: Over-the-counter
Route: Oral via feed
Species: Cattle, various classes
Drug Form: Type A Medicated Articles used in the manufacture of Type C medicated feeds.
Concentration: Chlortetracycline – 50 to 100 grams activity per pound of Type A Medicated Article
Lasalocid – 68 or 91 grams activity per pound of Type A Medicated Article, Lasalocid Liquid has 90.8 grams activity per pound of Type A Medicated Article.
Indications: Indicated for the following numbered indications of combinations of chlortetracycline and lasalocid sodium: 1 and 5, 1 and 6, 1 and 7, 1 and 8, 2 and 7 (with the exception of dairy replacement heifers), 3 and 5, 3 and 6, 3 and 7 (with the exception of dairy replacement heifers), 3 and 8 (with the exception of dairy cattle), 4 and 5, 4 and 6, 4 and 7 (with the exception of dairy replacement heifers), 4 and 8 (with the exception of dairy cattle).

Chlortetracycline:

1) 500 to 4,000 g/ton hand feed continuously for not more than 5 days to provide 10 mg/lb per day – for the treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* organisms susceptible to chlortetracycline in calves, beef, and non-lactating dairy cattle.
2) 0.5 mg/lb bodyweight daily – for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in beef cattle over 700 pounds.
3) 350 mg per head daily – for control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline in beef cattle under 700 pounds.
4) 350 mg per head daily – for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline in beef cattle.

Lasalocid sodium:

5) 10 to 30 g/ton to provide 100 to 360 mg lasalocid per head per day – for improved feed efficiency in cattle fed in confinement for slaughter.
6) 25 to 30 g/ton to provide 250 to 360 mg lasalocid per head per day – for improved feed efficiency and rate of weight gain in cattle fed in confinement for slaughter.
7) 30 to 600 g/ton to provide 60 to 300 mg/head/day in at least one pound of feed – for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, dairy and beef replacement heifers).
8) 30 to 181.8 g/ton to provide 1 mg/2.2 lb bodyweight per day – for the control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in cattle weighing up to 800 pounds with a maximum of 360 mg of lasalocid per head per day.

Tolerance: 21 CFR 556.347 Lasalocid: The tolerance for lasalocid in bovine liver is 0.7 part per million.
21 CFR 556.150 Chlortetracycline: Tolerances for chlortetracycline in edible tissue of cattle are established as 2 parts per million in muscle, 6 parts per million in liver, and 12 parts per million in fat and kidney.
Withdrawal: Zero days

21CFR 558.128 & 558.311

ANADA Number: 200-422

Pioneer Product: 125-476
Trade Name: Heifermax 500 Liquid Premix and Rumensin®
Ingredients: Melengestrol acetate and monensin sodium
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date: March 22, 2006

Status:	Over-the-counter
Route:	Oral via feed
Species:	Cattle beef, heifers fed in confinement for slaughter
Drug Form:	Type A Medicated Articles for use in combination for the manufacture of two-way Tupe C medicated feeds.
Concentration:	Melengestrol acetate – 500 milligrams activity per pound of Type A Medicated Article. Monensin sodium – 20, 30, 40, 60, or 80 grams activity per pound of Type A medicated Article.
Indications:	For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in heifers being fed in confinement for slaughter.
Tolerance:	21 CFR 556.380 Melengestrol acetate: A tolerance of 25 parts per billion is established for residues of the parent compound in fat of cattle. 21 CFR 556.420 Monensin: The tolerance for residues of monensin are 0.05 part per million in edible tissues.
Withdrawal:	Zero days

21CFR 558.342

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: 200-229

Trade Name:	Tri-Otic® Ointment
Ingredients:	Gentamicin sulfate, bethamethasone valerate, and clotrimazole
Sponsor:	Med-Pharmex, Inc.
Approval Date:	February 27, 2006

This application provides for a new container size, 15 gram bottle.

21CFR 524.1044g

NADA Number: 138-935

Trade Name:	Pennchlor® 50™, Pennchlor® 50 G™, Pennchlor® 90 G™, Pennchlor® 100 Hi-Flo™, Pennchlor® 100 G™ Type A Medicated Article
Ingredients:	Chlortetracycline
Sponsor:	Pennfield Oil Co.
Approval Date:	February 28, 2006

This application provides for a 0-day preslaughter withdrawal time following use of chlortetracycline in cattle feed.

21CFR 558.128

NADA Number: 121-473

Trade Name:	Safe-Guard® Canine
Ingredients:	Fenbendazole
Sponsor:	Intervet, Inc.
Approval Date:	March 17, 2006

This application provides for minor changes to the labeling of over-the-counter fenbendazole granules used for treatment and control of certain internal parasites.

21CFR 520.905b

Actions Taken by FDA Center for Veterinary Medicine

Change of Sponsor

NADA: 065-107
From: Veterinary Specialties, Inc.
To: Alpharma Inc.
Drug labeler code: 046573

Addition of Patent Number

NADA Number: 141-214

Patent Number: 7,001,889 **Expiration Date:** June 21, 2022

Suitability Petition Action

Number:	06P-0060/CP1
Sponsor:	Macleod Pharmaceuticals, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Phenylzone® Paste, Schering-Plough Animal Health Corp., NADA 116-087 by the following characteristics: The generic product will have a different dosage form, granules, whereas the pioneer product is a paste.
Action:	Approved April 4, 2006.

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The supplemental ANADA provides for a new container size, a 15-gram bottle, from which gentamicin sulfate, betamethasone valerate, clotrimazole ointment may be dispensed for the treatment of acute and chronic canine otitis externa.

This rule is effective April 3, 2006.

For further information contact: Christopher Melluso, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0169, e-mail: christopher.melluso@fda.hhs.gov.

Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed a supplement to ANADA 200-229 that provides for use of TRI-OTIC (gentamicin sulfate, USP; betamethasone valerate, USP; and clotrimazole, USP) Ointment for the treatment of canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin. The supplement provides for a new container size, a 15-gram bottle. The supplemental ANADA is approved as of February 27, 2006, and the regulations are amended in Sec. 524.1044g (21 CFR 524.1044g) to reflect the approval. The basis of approval is discussed in the freedom of information summary.
In addition, FDA has noticed that a 215-gram bottle size was approved for this product under ANADA 200-229 but not codified. At this time, that bottle size is being added to Sec. 524.1044g. This action is being taken to improve the accuracy of the regulations.

Notice(s)

The Food and Drug Administration (FDA) is announcing the availability for comment of a draft revised guidance for industry (73) entitled ``Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision)" VICH GL3(R). This draft revised guidance, which updates a guidance on the same topic for which a notice of availability was published in the Federal Register of October 12, 1999 (64 FR 55293) (the 1999 guidance), has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft revised document is intended to provide guidance regarding the development of stability testing data new animal drug applications (referred to as registration applications in the guidance) submitted to the European Union (EU), Japan, and United States.

Submit written or electronic comments by May 15, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the guidance and the docket number [2006D-0139].

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section of this notice for electronic access to the guidance document.

For further information contact: Dennis Bensley, Center for Veterinary Medicine, (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dennis.bensley@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (178) entitled ``Recommended Study Design and Evaluation of Effectiveness Studies for Swine Respiratory Disease Claims." This draft guidance provides recommendations to industry relating to study design and describes the criteria that the Center for Veterinary Medicine (CVM) intends to use to evaluate effectiveness studies for swine respiratory disease (SRD) claims.

Submit written or electronic comments on this draft guidance by June 28, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Comments should be identified with the full title of the guidance and the docket number [2006D-0138]. Submit electronic comments on the guidance via the Internet at http://www.fda.gov/dockets/ecomments

Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section of this notice for electronic access to the draft guidance document.

For further information contact: Michelle L. Stull, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5058, e-mail: michelle.stull@fda.hhs.gov.