



DEC 18 2014

**REGISTERED MAIL
RETURN RECEIPT REQUESTED**

Doug Rupp, Vice President, Regulatory Affairs
Pharmgate LLC
161 N. Franklin Turnpike, Suite 2C
Ramsey, New Jersey 07446

RE: FDA Guidance for Industry #213

Dear Mr. Rupp:

In the FEDERAL REGISTER of December 12, 2013, the Food and Drug Administration (FDA) announced the availability of Guidance for Industry #213, “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209” (GFI #213) in final form (78 FR, December 12, 2013). The availability of a draft version of GFI #213 had been announced last year (77 FR 22327, April 13, 2012) and comments solicited.

The referenced guidance, GFI #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals” was finalized on April 13, 2012. It represents the Agency’s current best thinking regarding use of antimicrobial drugs that are important in human medicine and are used in the feed or drinking water of food-producing animals. GFI #209 establishes two principles:

- Principle 1: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that are considered necessary for assuring animal health.
- Principle 2: The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation.

GFI #213 provides sponsors with specific recommendations on how to supplement their approved drug applications to align with GFI #209. FDA believes such a voluntary approach, conducted in a cooperative and timely manner, will be most effective in achieving the common goal of more judicious use of medically important antimicrobials in food-animal agriculture.

FDA's Center for Veterinary Medicine (CVM) is contacting you because our records indicate you are the sponsor of NADAs for products containing medically important antimicrobial new animal drugs for use in medicated feed (Type A medicated articles) or drinking water (soluble powders, concentrate solutions, etc.) for food-producing animals, as described in GFI #213 (*see Appendix 1*).

Voluntary participation in GFI #213 can involve requesting, where applicable: (1) the withdrawal of approval of those portions of your applications relating to production uses; and/or (2) a change in product marketing status to use by veterinary feed directive (VFD) or by prescription (Rx). Both of these requests will require approval of revised product labeling.

To assist FDA in monitoring adoption within the animal pharmaceutical industry and in planning, FDA is asking all sponsors of affected products to inform the Agency in writing whether they intend to engage in the voluntary process. Please note that we consider your response only an initial indication of your intentions and understand that further discussions with CVM may be needed.

Please refer to GFI #213 for recommendations on procedures for voluntary implementation of these changes. We anticipate holding discussions with sponsors regarding ways to administer these submissions in an equitable and efficient manner and ask that you contact us before making related submissions to your applications.

Our records also indicate that you are also the sponsor of abbreviated new animal drug applications (ANADAs) for generic copies of products previously described and/or NADAs/ANADAs for combination drug medicated feeds for food-producing animals containing medically important antimicrobial new animal drugs (*see Appendix 2*).

Revisions to the approved conditions of use in NADAs for pioneer products may affect the conditions of use in ANADAs and/or NADAs/ANADAs for combination drug medicated feeds that reference these pioneer applications. Should these pioneer applications be revised, FDA will work with you expeditiously to align your applications with the revised conditions of use in the pioneer (i.e., reference) applications.

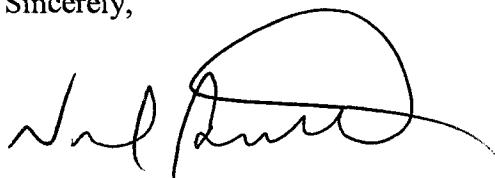
If you are the sponsor of any additional NADAs or ANADAs for products containing medically important antimicrobial new animal drugs for use in medicated feed or drinking water for food-producing animals that have not been listed in an attached appendix, please identify these additional applications and include them in your response.

The GFI #213 document may be viewed on the Internet at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Please send your written response to me at:

Dr. Neal Bataller
Director, Division of Surveillance (HFV-210)
FDA/Center for Veterinary Medicine
7519 Standish Pl.
Rockville, MD 20855

Sincerely,

A handwritten signature in black ink, appearing to read 'Neal Bataller', with a large, sweeping flourish at the end.

Neal Bataller, M.E., D.V.M.
Director, Division of Surveillance
Office of Surveillance and Compliance
Center for Veterinary Medicine

Appendix 1

NADAs for products containing medically important antimicrobial new animal drugs for use in medicated feed or drinking water of food-producing animals, as described in GFI #213

NADA/ ANADA	Product Name
065-480	Chlortetracycline Soluble Powder, Scour-Pneumonia Antibiotic
138-934	Pennchlor SP 250, Pennchlor SP 500
138-935	Pennchlor™ 100MR, Pennchlor™ 50, Pennchlor™ 50-G, Pennchlor™ 90, Pennchlor™ 90-G, Pennchlor™ 100-G, Pennchlor™ 100 Hi-Flo
138-938	Oxytetracycline - 100, Oxytetracycline - 100MR, Oxytetracycline - 50, Pennox™ 100, Pennox™ 100MR, Pennox™ 200, Pennox™ 50
138-939	NEO-OXY 100/100 MR®, NEO-OXY 100/100®, NEO-OXY 50/50®
140-680	Tylan® 10 Premix, Tylan® 20 Premix, Tylan® 40 Premix, Tylan® 5 Premix
140-681	Tylan® 10 Sulfa-G Premix, Tylan® 20 Sulfa-G Premix, Tylan® 40 Sulfa-G Premix, Tylan® 5 Sulfa-G Premix

Appendix 2

ANADAs for generic products and combination drug medicated feeds containing medically important antimicrobial new animal drugs for use in medicated feed or drinking water of food-producing animals, as described in GFI #213

NADA/ ANADA	Product Name
200-354	Pennchlor™ / Coban®
200-355	Pennchlor™ / Bio-Cox® / 3-Nitro®
200-356	Pennchlor™ / Denagard®
200-357	Pennchlor® / Bio-Cox®
200-358	Pennchlor/ BMD
200-359	Pennchlor™ / Deccox®
200-026	Pennox™ 343
200-295	Pennchlor™ 64
200-314	Pennchlor S®
200-510	DERACIN Meal (chlortetracycline) Type A medicated article