

**DEC 12 2013****REGISTERED MAIL
RETURN RECEIPT REQUESTED**

Samantha C. Kublank, D.V.M.
Elanco Animal Health, A Division of Eli Lilly & Co.
2500 Innovation Way
Greenfield, Indiana 46140

RE: FDA Guidance for Industry #213

Dear Dr. Kublank:

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 within three (3) months from the date of publication of GFI #213 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

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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.

Copies of GFI #213 may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and 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, stylized loop at the end of the signature.

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
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010-918	Hygromix 8™
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012-491	Tylan® 100 CAL Type A Medicated Article, Tylan® 40 CAL Type A Medicated Article
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013-076	Tylan® Soluble
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013-162	Tylan® Premix No.10
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015-166	Tylan® 100 Premix
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041-275	Tylan® 10 Sulfa-G Premix, Tylan® 40 Sulfa-G Premix
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106-964	Apralan® Soluble Powder
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126-050	Apralan® 75 Soluble Powder
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127-507	Tylan® 10 Sulfa-G, Tylan® 20 Sulfa-G, Tylan® 40 Sulfa-G, Tylan® 5 Sulfa-G
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Appendix 2

ANADAs for generic products or NADAs for 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
012-548	Tylosin® / Hygromix
013-388	Hygromix-Tylan® Premix
104-646	Rumensin® / Tylan®
140-947	Lincomix® / Maxiban®
140-955	Coban® / Flavomycin®
141-110	Coban® / Stafac®
141-164	Coban® / Tylan®
141-170	Monteban® / Tylan®
141-172	Paylean® / Tylan®
141-198	Tylan® / Bio-Cox®
141-224	Optaflexx™ / Rumensin® / Tylan®
141-233	Optaflexx™ / Rumensin® / Tylan® / MGA®
200-375	HeifermaX™ 500 / Rumensin® / Tylan®
200-424	Heifermax™ / Optaflexx® / Rumensin® / Tylan®
200-427	Heifermax™ 500 Liquid Premix and Tylan®
200-430	Heifermax™ 500 Liquid Premix, Bovatec®, Tylan®
200-480	Zilmax®, Heifermax® 500, Rumensin®, and Tylan®