DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

DEC 12 2013

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Christine Nostrom, Associate II, Pharmaceutical Regulatory Affairs
Boehringer Ingelheim Vetmedica, Inc.
800 5th Street North West
Fort Dodge, Iowa 50501

RE: FDA Guidance for Industry #213

Dear Ms. Nostrom:

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.

If you are the sponsor of any additional NADAs or abbreviated new animal drug applications (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.

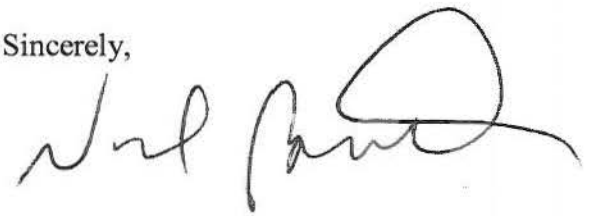
Copies of GFI #213 may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm 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

If you have any questions regarding this letter, you can contact me at (240) 276-9062.

Sincerely,



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
006-084	Sulmet® Drinking Water Solution
033-373	Vetisulid®
040-181	Prinzone Oral Suspension; Pyradan Oral Suspension; Vetisulid® Oral Suspension
055-012	Chloronex® Sulmet® Soluble Powder
065-071	Aureomycin® Soluble Powder
065-269	Polyotic® Soluble Powder
065-440	Chloronex® Soluble Powder
122-272	Sulmet® Soluble Powder