DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 12 2013

REGISTERED MAIL
RETURN RECEIPT REQUESTED

Paul W. Carr, President, Shotwell & Carr, Inc.
Huvepharma AD
1415 Halsey Way
Suite 304
Carrollton, Texas 75007

RE: FDA Guidance for Industry #213

Dear Mr. Carr:

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 the sponsors of pioneer new animal drug applications (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. FDA is asking sponsors of affected products to notify the Agency within 3 months from the date of publication of this final guidance to inform us in writing whether they intend to engage in the voluntary process.

Our records indicate that you are the sponsor of abbreviated new animal drug applications (ANADAs) for generic copies of products and/or NADAs/ANADAs for combination drug medicated feeds containing medically important antimicrobial new animal drugs for use in medicated feed or drinking water for food-producing animals, as described in GFI #213 (*see* Appendix 1).

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 provide us with the file or (A)NADA numbers for these additional applications.

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 contact me at 240-276-9062 for any questions or clarifications.

Please send any 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.
Directory, Division of Surveillance
Office of Surveillance and Compliance
Center for Veterinary Medicine

Appendix 1

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
046-209	Coyden 25® / CTC®
139-473	Stafac® / Stenorol®
140-340	Lincomix® / Stenorol®
141-090	Clinacox™ / Stafac®
200-090	3-Nitro® / Lincomix® / Sacox®
200-091	3-Nitro® / Aureomycin® / Sacox®
200-092	Sacox® / Stafac®
200-093	Sacox® / Lincomix®
200-094	3-Nitro® / Sacox® / Stafac®
200-095	Aureomycin® / Sacox®
200-096	Sacox® / Terramycin®
200-473	Oxytetracycline HCl Soluble Powder-343
200-484	Tylovet® 100
200-531	Rumensin® plus Tylovet® 100
200-532	MGA® plus Tylovet® 100
200-533	Deccox®/ Rumensin®/ Tylovet® 100
200-534	MGA® plus Rumensin® plus Tylovet® 100
200-535	MGA®/ Bovatec®/ Tylovet® 100
200-544	Zilmax®/Rumensin®/Tylovet® 100/MGA®
200-547	Zilmax®/Rumensin®/Tylovet® 100