

August 23, 2018

Dear Phibro Animal Health Corporation Customer:

In response to the requirements enacted by the Food and Drug Administration (FDA) to comply with the Food Safety Modernization Act (FSMA), Phibro Animal Health Corporation (Phibro) provides this letter to you, our customer, to serve as notification of Phibro's compliance with the FSMA regulations for the categories of products marketed and sold by Phibro.

#### **TYPE A MEDICATED ARTICLES**

Phibro's Type A Medicated Articles (MFAs), distributed in the United States, are registered with the United States Food & Drug Administration under *21 CFR Part 558* "New Animal Drugs For Use In Animal Feeds," as safe and effective for use in animal feed and are manufactured in compliance with *21 CFR Part 226* "Current Good Manufacturing Practices for Type A Medicated Articles." Pharmaceuticals are not "food" as defined in Section 201(f) of the Food, Drug and Cosmetic Act. Phibro's MFA products are regulated as pharmaceuticals and therefore, the FSMA new rules DO NOT apply to MFAs. Examples of Phibro MFA products include, but are not limited to: Stafac® 20, Terramycin® 100, and Nicarb® 25%.

Over the last 15 years, Phibro has developed a comprehensive Quality Management System (QMS) that is aligned with applicable Current Good Manufacturing Practices (CGMP) and regulatory requirements for manufacturing of Veterinary Drugs, Type A MFAs, and Active Pharmaceutical Ingredients (APIs) for animal drug products. Phibro employees are committed to maintaining Phibro's QMS which allows our company to operate robust systems that are fully compliant with applicable regulatory requirements and industry standards.

#### **NON-MEDICATED ANIMAL FOOD**

Phibro's facilities that manufacture, process, package and/or hold Mineral Nutrition and Nutritional Specialty Products used in animal food and distributed within the United States, are registered with the FDA as part of the Bioterrorism and Preparedness Act of 2002. The registrations are renewed every two years. For non-medicated animal food, Phibro's compliance dates for the FSMA rules applicable to animal food are listed below:

- **CGMPs** (Current Good Manufacturing Practices) – Compliant as of 9/17/2016
- **Sanitary Transportation** – Compliant as of 4/7/2017
- **FSVP** (Foreign Supplier Verification Program) – Compliant as of 5/30/2017
- **Hazard Analysis & Risk Based Preventive Controls** – Will be fully compliant by the deadline of March 31, 2019

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Examples of Phibro non-medicated animal feed/food products include but are not limited to: Trace Mineral Ingredients, Trace Mineral Premixes, AB20®, Animate®, Cellerate Yeast Solutions™, GemStone®, Magni-Phi® and OmniGen-AF®.

For more than three decades, through the ongoing development of our Dynamic Quality Assurance® (DQA®) Program and supporting QMS, many of the elements of the FSMA regulations have already been put in place and validated at Phibro facilities. Validation has taken place through both customer audits as well as third party certifications including AFIA's International Safe Feed/Safe Food, FAMI-QS and GMP+. Phibro's professional staff actively participates in professional, industry and regulatory organizations and committees including training to obtain and maintain certifications and competencies necessary to remain at the forefront of ongoing animal food safety developments in our industry.

If you have any questions about FSMA compliance for Phibro products please feel free to reach out to your Phibro representative or the contact the individuals noted below with any questions.

Contact Information:

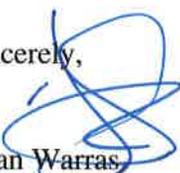
**For Non-Medicated Animal Food**

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**For Type A Medicated Articles**

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Melissa.Echeverria@pahc.com

Sincerely,



Dean Warras  
President, Phibro Animal Health and Nutrition, North America

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