February 29, 2012

Mr. Devon Wm. Hill
Keller and Heckman, LLP
1001 G Street NW
Washington, DC 20001

Re: GRAS Notice No. AGRN 000-007

Dear Mr. Hill:

The Food and Drug Administration (FDA) is responding to the notice, dated April 8, 2011 that you submitted on behalf of Emerald Carolina Chemicals, LLC ("the notifier") under FDA's Center for Veterinary Medicine (CVM) Pilot Program for substances generally recognized as safe (GRAS) added to food for animals (See 75 FR 31800; June 4, 2011). FDA's Center for Veterinary Medicine received the notice on April 12, 2011, filed it on May 12, 2011, and designated it as GRAS Notice No. AGRN 000-007.

The subject of your notice is polyoxyethylene (20) sorbitan monostearate. The notice informs FDA of the view of Emerald Carolina Chemicals, LLC that polyoxyethylene (20) sorbitan monostearate is GRAS, through scientific procedures, as an incidental additive in animal feed as a result of its use as an emulsifier in the production of wet and dried distillers grains with added solubles. Polyoxyethylene (20) sorbitan monostearate may be present at levels up to 20 ppm in the condensed distiller solubles, which are typically incorporated into distillers grain products, resulting in a maximum level of 13.9 ppm in distillers grains on a dry weight basis. The substance serves no technical function in the final animal feed. The intended food-producing target animal species are beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goat, and swine.

Emerald Carolina Chemicals, LLC provides information about the identity, characterizing properties, specifications, method of manufacture, and conditions of use of polyoxyethylene (20) sorbitan monostearate (CAS No. 9005-67-8). The substance is also referred to as Polysorbate 60.

Emerald Carolina Chemicals, LLC provides information about the manufacture of polyoxyethylene (20) sorbitan monostearate. Stearic acid and sorbitol react to form sorbitan monostearate. Sorbitan monostearate then reacts with ethylene oxide to yield polyoxyethylene (20) sorbitan monostearate.

Emerald Carolina Chemicals, LLC provides information about the specifications for polyoxyethylene (20) sorbitan monostearate, which is obtained from a supplier. The supplier states that the polyoxyethylene (20) sorbitan monostearate meets the criteria outlined in 21 CFR 172.836(b) which include: saponification number (45-55), acid number (0-2), hydroxyl number (81-96), and oxyethylene content (65-69.5%). Additionally, the notifier provides specifications for residual ethylene oxide (5 ppm maximum), 1,4-dioxane (5 ppm maximum), heavy metals (10 ppm maximum), Gardner color (6 ppm maximum), appearance at 25 °C (off-white paste), and KF moisture (3% maximum).

Emerald Carolina Chemicals, LLC describes the intended use of polyoxyethylene (20) sorbitan monostearate as one component of a defoamer. Polyoxyethylene (20) sorbitan monostearate is considered to be a surface active agent and is an approved food additive in animal feed for specified uses: as an emulsifier to be used alone or in combination with sorbitan monostearate in mineral premixes and dietary supplements for animal feeds and as an emulsifier in milk-replacer formulations for calves (21 CFR 573.840). It also is an approved direct food additive for multiple human food uses, alone and in conjunction with other emulsifiers (21 CFR 172.836) and an approved secondary direct food additive for use as a defoamer in human food (21 CFR 173.340).

The notifier addresses human food safety issues associated with polyoxyethylene (20) sorbitan monostearate. Published toxicology studies as well as decisions by FDA, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the European Food Safety Authority (EFSA) were discussed pertaining to the safety evaluation of the notified substance and structurally related substances. To address residue chemistry, the notifier provided a dietary exposure assessment for food animals and for humans, an estimation of daily intake, and information about the metabolism of polyoxyethylene (20) sorbitan monostearate in rats.

Emerald Carolina Chemicals, LLC discusses published and unpublished information on the absorption, distribution, metabolism and elimination of the substance, acute and chronic toxicity data, mutagenicity, and studies on developmental and reproductive effects pertinent to the intended target animal species. The notifier discusses information on the dietary exposure of beef cattle, dairy cattle, poultry, sheep, and swine to polyoxyethylene (20) sorbitan monostearate and cites information to support their exposure assessment from JECFA, the Scientific Committee for Food, the Japan Food Safety Commission, and FDA.

Based on the information provided by Emerald Carolina Chemicals, LLC, as well as other information available to FDA, the agency has no questions at this time regarding Emerald Carolina Chemicals, LLC's conclusion that polyoxyethylene (20) sorbitan monostearate is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of polyoxyethylene (20) sorbitan monostearate. As always, it is the continuing responsibility of Emerald Carolina Chemicals, LLC to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

The Association of American Feed Control Officials (AAFCO) publishes a list of names and definitions for accepted feed ingredients. FDA recognizes these names as being the "common and usual" names for feed ingredients. FDA recognizes the name "Polysorbate 60" as the common and usual name for polyoxyethylene (20) sorbitan monostearate when included in animal food.

In addition, in our review of Emerald Carolina Chemicals LLC's notice that polyoxyethylene (20) sorbitan monostearate is GRAS for use as a component of a defoamer, FDA did not review whether food containing polyoxyethylene (20) sorbitan monostearate would violate section 301(ll) of the Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. 331(ll)], or whether any of the exemptions in section 301(ll) apply to foods containing polyoxyethylene (20) sorbitan monostearate. Section 301(ll) of the FDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section

505 of the FDCA, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll) (1)-(4) applies. *See* section 301(ll) of the FDCA.

In accordance with the proposed 21 CFR § 570.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in the proposed GRAS exemption claim (21 CFR 570.36(c)(1)), is available for public review and copying on the Center for Veterinary Medicine's internet website (http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm).

If you have any questions about this letter, please contact Dr. Andrea Krause at 240-276-9768 or by email at andrea.krause@fda.hhs.gov. Please reference AGRN 000-007 in any future correspondence regarding this submission.

Sincerely,

Daniel G. McChesney, Ph.D.
Director
Office of Surveillance and Compliance
Center for Veterinary Medicine