March 5, 2012

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

Re: GRAS Notice No. AGRN 000-005

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 000-005.

The subject of your notice is hydrophobic silica. The notice informs FDA of the view of Emerald Carolina Chemicals, LLC that hydrophobic silica is GRAS, through scientific procedures, as an incidental additive in animal feed as a result of its use as a defoamer during the removal of oil from condensed distillers solubles. Hydrophobic silica 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 distillers grains products or the animal feed containing distillers products. The intended 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 hydrophobic silica (CAS No. 67762-90-7). Emerald Carolina Chemicals, LLC incorporates by reference the GRAS affirmation of hydrophobic silica and listed in Title 21 Code of Federal Regulations, Part 584.700.[1] The notifier states that the subject of this notice is chemically identical to the hydrophobic silica (CAS No. 68611-44-9) that FDA affirmed as GRAS in 1996 for use as an anticaking free-flow agent in vitamin preparations for animal feed.

Emerald Carolina Chemicals, LLC provides information about the manufacture of hydrophobic silica. Precipitated silicas are formed when sodium silicate and sulfuric acid are combined in water under alkaline conditions. The precipitated silica is filtered, washed to remove soluble salts, and dried. Following this, it is reacted with polydimethylsiloxane (PDMS) silicone oil in a fluidized bed reactor at 205-240 °C. Water is released during the condensation reaction and the result is the formation of silica coated with silicone oil which exhibits hydrophobic properties.

[1] 21 CFR 584.700, 61 Federal Register 43453 August 23, 1996 (Docket No. 95G-0039)

Emerald Carolina Chemicals, LLC provides information about the specifications for hydrophobic silica, which is obtained from a supplier. The specifications for hydrophobic silica are consistent with hydrophobic silica affirmed GRAS in 21 CFR § 584.700 (ii) and are as follows for precipitated hydrophobic silica: not less than 94.0% silicon dioxide after ignition, not more than 3 ppm arsenic, not more than 0.003% heavy metals (as lead), not more than 10 ppm lead, less than 7% loss on drying, not more than 8.5% loss on ignition after drying, not more than 5% soluble ionizable salts (as sodium sulfate), and not more than 1% insoluble substances. Additionally, the notifier provides specifications for hydrophobicity (less than or equal to 2), appearance (white powder), naphtha residue (less than or equal to 10 black specks), and pH (8-11).

Emerald Carolina Chemicals, LLC describes the intended use of hydrophobic silica as one component of a defoamer. Hydrophobic silica is a common active component of defoamers and interacts with the surface of a film to create a defect via dewetting to result in the rupture of the foam.

Emerald Carolina Chemicals, LLC addresses human food safety issues associated with hydrophobic silica. Published and unpublished toxicology studies, decisions by FDA, and evaluations by a number of scientific panels are discussed by the notifier. The notifier discusses the safety and toxicology information pertaining to hydrophobic silica and silicon dioxide. To address residue chemistry, the notifier provides an estimated dietary intake for the food-producing target animals and an estimated daily intake for humans using publicly available information.

To address target animal safety, Emerald Carolina Chemicals, LLC discusses information contained in the hydrophobic silica GRAS affirmation final rule to support the applicability of toxicity data for other silicates. The notifier concludes that the interchangeable use of toxicity information for other silicates is appropriate. The publicly available toxicity data for other silicates support the toxicity profile for hydrophobic silica in the intended target animal species. The notifier discusses safety reviews of silicates by authoritative bodies including the U.S. Environmental Protection Agency, the Select Committee on GRAS Substances (SCOGS), and FDA, to conclude that silicates are safe for consumption at their intended use levels for the target animal species.

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 hydrophobic silica 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 hydrophobic silica. 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" name for feed ingredients. FDA recognizes the name "hydrophobic silica" as the common and usual name for hydrophobic silica when included in animal food.

In addition, in our review of Emerald Carolina Chemicals LLC's notice that hydrophobic silica is GRAS for use as a component of a defoamer, FDA did not review whether food containing hydrophobic silica 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 hydrophobic silica. 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 000-005 in any future correspondence regarding this submission.

Sincerely,

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