

September 10, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

SUBMITTED ELECTRONICALLY VIA [www.regulations.gov](http://www.regulations.gov)

Re: Comments on “Draft Guidance for Industry on Use of Nanomaterials in Food for Animals”; Docket No. FDA-2013-D-1009

To Whom It May Concern:

The Nanotechnology Panel of the American Chemistry Council<sup>1</sup> appreciates the opportunity to submit comments on the Food and Drug Administration’s (FDA) draft guidance for industry titled “Draft Guidance for Industry on Use of Nanomaterials in Food for Animals.”<sup>2</sup> The draft guidance largely builds upon previous FDA guidance on the use of nanomaterials in FDA-regulated products and would be consistent with the case-by-case evaluation process the agency has established for such products, including those that may contain nanomaterials.

The Panel appreciates that FDA makes clear that the draft guidance would not apply to animal food ingredients that have been determined to be generally recognized as safe (GRAS) and may naturally or incidentally contain nanomaterials.<sup>3</sup> Such clarification would be helpful for entities using, or wishing to use, materials that, through no additional processing, may contain naturally occurring or incidental nanomaterials.

While the guidance is generally clear in terms of instructions to industry, the Panel questions the assertion that FDA is “not aware of any animal food ingredient on the nanometer scale for which there is generally available safety data sufficient to serve as the foundation for a determination that the use of such an animal food ingredient is GRAS”.<sup>4</sup> The Panel is aware of at least one GRAS determination that clearly

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<sup>1</sup> Members of the ACC Nanotechnology Panel are 3M, BASF Corporation, Bayer MaterialScience, Cabot Corporation, The Dow Chemical Company, DuPont, Evonik Industries, Ferro Corporation, Lockheed Martin Corporation, and Procter & Gamble.

<sup>2</sup> 79 Fed. Reg. 36,530 (June 27, 2014).

<sup>3</sup> See *Draft Guidance for Industry on Use of Nanomaterials in Food for Animals* (GF #220) at 3.

<sup>4</sup> *Id.* at 7.

*The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is an \$812 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for twelve percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.*



indicates particle sizes at the nanoscale (GRN No. 321, synthetic amorphous silica<sup>5</sup>), and there may be others. Moreover, there are particulate materials listed at 21 CFR Part 184<sup>6</sup> that may normally include fractions of their particle size distributions in the nanometer range<sup>7</sup> and have likely included these fractions since their use began decades ago. The Panel would argue that sufficient safety data are available and, more importantly, were used, to make GRAS determinations for these substances. **In finalizing the guidance, the Panel requests that FDA clarify the statement in paragraph 7 concerning GRAS determinations, particularly the criteria and evidence used to reach the statement in question.**

If you have any questions, please contact me at [Jay.West@americanchemistry.com](mailto:Jay.West@americanchemistry.com) or 202-249-6407.

Sincerely,

Jay West  
Senior Director, Chemical Products and Technology Division  
ACC Nanotechnology Panel

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<sup>5</sup> GRN No. 321, Synthetic amorphous silica (Aug. 18, 2010), available at <http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=graslisting&id=321>.

<sup>6</sup> Code of Federal Regulation Title 21. Chapter 21—Food and Drug Administration, Department of Health and Human Services. Subchapter B—Food for Human Consumption (Continued). Part 184—Direct Food Substances Affirmed as Generally Recognized as Safe.

<sup>7</sup> See e.g., the material specifications in the European Food Safety Authority opinion on calcium silicate and silicon dioxide/silicic acid gel. *The EFSA Journal* (2009) 1132, 1-24. These substances clearly have particle size distributions at the nanoscale.