



Bernadene Magnuson, Ph.D.
Health Science Consultants, Inc.
68-7105 Branigan Gate
Mississauga, Ontario L5N7S2
CANADA

Re: GRAS Notice No. GRN 000229

Dear Dr. Magnuson:

The Food and Drug Administration (FDA, we) completed our evaluation of Bergstrom Nutrition's supplement to GRN 000229. We received the supplement that you submitted on behalf of Bergstrom Nutrition on February 27, 2017. The supplement addresses removal of aluminum from the specifications.

We previously responded to GRN 000229 on February 18, 2008. We stated that we had no questions at that time regarding Bergstrom Nutrition's conclusion that methylsulfonylmethane (MSM) is GRAS for use as an ingredient in meal supplement and meal replacement foods, fruit smoothie-type drinks, and fruit-flavored thirst quencher-type beverages at levels up to 4,000 mg/kg and in food bars such as granola bars and energy-type bars at levels up to 30,000 mg/kg provided that food standards of identity do not preclude such use.

In the supplement dated February 17, 2017, Bergstrom Nutrition provides its rationale for removing the aluminum specification (less than 1 mg/kg) from the specifications described in GRN 000229.¹ Bergstrom Nutrition states that in the early 2000s there was public concern over the possible link between aluminum and Alzheimer's disease. Bergstrom Nutrition states that no such link has been established and references conclusions from public health organizations, including the World Health Organization, the National Institutes of Health, and the Environmental Protection Agency, that indicate aluminum is not a key risk factor in developing Alzheimer's disease.

Bergstrom Nutrition states that all other specifications, manufacturing procedures, and the intended use of MSM remain the same as in the original GRAS notice.

In addition, Bergstrom Nutrition provides an update on published safety studies of MSM through February 2017. Bergstrom Nutrition states that since the submission of GRN 000229 in 2007, there have been additional published studies on MSM administered orally to animals and humans. In the supplement, Bergstrom Nutrition

¹ Bergstrom Nutrition states that the potential source of aluminum in MSM is amorphous silicon dioxide added as a flow agent in MSM at a level of 0.5%. Bergstrom Nutrition states that amorphous silicon dioxide is used in the production of MSM is food grade and meets the specifications of the Food Chemicals Codex, 4th Edition (1996), which do not include a specified limit for aluminum.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

discusses nine animal studies published since 2007. Bergstrom Nutrition states that the results of these studies agree with the findings of the 90-day rat toxicology study described in GRN 000229 which showed a no observed effect level of 1500 mg MSM/kg bw/d. In addition, Bergstrom Nutrition reports that twelve human clinical trials investigating the biological effect of MSM have been published. None of these studies reported adverse effects at levels of MSM ranging from 56.6 mg/kg body weight (bw)/d to 100 mg/kg bw/d assuming a 60 kg bw individual. Bergstrom Nutrition states that the animal and human studies reported to date continue to provide evidence of the safety of the intended use of MSM.

Potential Labeling Issues

In citing published literature to support the safe use of MSM, Bergstrom Nutrition references studies that highlight health-related benefits. Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). The supplement raises a potential issue under these labeling provisions. If products containing MSM bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of the Office of Nutrition and Food Labeling (ONFL). The Office of Food Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Section 301(II) of the FD&C Act

Section 301(II) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, 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(II)(1)-(4) applies. In our evaluation of Bergstrom Nutrition's supplement, we did not consider whether section 301(II) or any of its exemptions apply to foods containing MSM. Accordingly, our response should not be construed to be a statement that foods containing MSM, if introduced or delivered for introduction into interstate commerce, would not violate section 301(II).

Conclusions


Based on the information that Bergstrom Nutrition provided, as well as other information available to FDA, we have no questions at this time regarding Bergstrom Nutrition's conclusion that MSM is GRAS under its intended conditions of use. This letter is not an affirmation that MSM is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient

manufacturers and food producers are responsible for ensuring marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to the supplement to GRN 000229 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

 Digitally signed by Susan J. Carlson -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=2000419015,
cn=Susan J. Carlson -S
Date: 2017.10.23 10:12:34 -04'00'

Susan J. Carlson, Ph.D.
Director
Division of Biotechnology
and GRAS Notice Review
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition