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To Stuart Shapiro	From Neal Forlaw	
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August 11, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: **Docket No. 96N-0417; Proposed Rule; "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements"**

Dear FDA:

OMYA, Inc. is a major supplier of food grade Ground Limestone and natural (ground) Calcium Carbonate to the food industry in general, including the dietary supplement sector. As such, our production processes/plants already are subject to the GMP requirements for general foods under 21 CFR Part 110, and our products must meet the specifications within their respective Food Chemicals Codex ("FCC") monographs.

As a member of the Council for Responsible Nutrition ("CRN"), OMYA would like to register its strong agreement with, and support of, the various comments submitted to FDA by CRN regarding this docket -- especially those comments contained within CRN's second in a series of comment letters, dated August 11, 2003, RE: "TOPIC: PURPOSE AND SCOPE OF THE RULE". More specifically, we draw your attention to the section titled "CRN PROPOSES THAT THE RULE APPLY ONLY TO MANUFACTURERS OF FINISHED PRODUCTS" beginning on page 11 of that document.

CRN noted that under DSHEA, a dietary supplement is a product intended to supplement the diet that contains one of more of the following "dietary ingredients:" a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of these. These "dietary ingredients" include a large number of ingredients that are also commonly used in conventional human foods, pet foods, and animal feeds. Such is the case with Ground Limestone and Calcium Carbonate, which are often used as a source of the essential mineral calcium in a multitude of conventional fortified foods such as breakfast cereals and snack bars, as well as in medical foods, pet foods, and animal feed. They are also used in other conventional human foods for functional purposes other than their nutrient value, for example as dough conditioners or firming agents, pH modifiers, and as a major constituent of chewing gum base.

As with other multiple-use dietary supplement ingredients, the use of Ground Limestone and Calcium Carbonate in the formulation of dietary supplements accounts for only a fraction of their total use in food and feed products in the United States. Consequently, they do not become "dietary ingredients" under DSHEA until they are purchased by a dietary supplement manufacturer specifically for the purpose of being included in the formulation of a dietary supplement product.

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In practical terms then, the proposed rule as written establishes an alternate set of standards to which a given multi-purpose food ingredient, such as Ground Limestone or Calcium Carbonate, may be subject to – with the deciding factor being whether or not the particular ingredient producer sells to a dietary supplement manufacturer. That would appear to be a bit ironic and likely confusing to consumers, considering that many conventional foods are now fortified with calcium at 100% of the Reference Daily Intakes – the same as many one-a-day type vitamin/mineral dietary supplement tablets. Yet the ingredient when used in conventional foods will be subject to the general food GMPs, while the very same ingredient when used in dietary supplements will be subject to the dietary supplement GMPs. Forget the irony and confusion to the consumers; what about the producers?

Given the apparently legitimate concerns surrounding certain "non-traditional/exotic" dietary supplement ingredients (at least as defined by modern Western standards) for which there are no expressly recognized U.S. food grade specifications, the FDA's desire to ensure adequate protective oversight is understandable. Acknowledging that concern, but also recognizing the fact that there are many traditional food/dietary supplement ingredients with longstanding records of consistent identity, purity, quality, strength, composition, and safety for which no additional regulation is necessary, a fairly simple and very workable compromise position would seem logical. Those dietary supplement ingredients already subject to an expressly recognized food quality standard such as a specific FDA direct food additive GRAS regulation and/or FCC monograph, will remain subject to the existing general food GMP rule. Those that are not will be subject to the new dietary supplement GMP rule. The line separating the two groups will be easy to draw and will be clear, and the FDA will not have to become embroiled in debates as to whether or not a particular ingredient is used primarily in traditional foods or in dietary supplements.

We appreciate the opportunity to submit information and comments on this issue and hope that they will be of value to the FDA as it further considers the various viewpoints.

Feel free to contact me at (802) 770-7261, or at neal.jordan@omya.com, if we can be of further assistance.

Sincerely,
OMYA, Inc.

Neal W. Jordan
Manager of Environmental
& Regulatory Affairs

cc: A. Dickinson, CRN