



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JUL 22 1998

Mr. Neal W. Jordan
Manager of Environmental & Regulatory Affairs
OMYA, Incorporated
61 Main Street
Proctor, Vermont 05765

Dear Mr. Jordan:

This is in reply to your letters, dated May 8, 1998, and May 28, 1998, regarding use of the name "calcium carbonate" to designate the food ingredient "ground limestone" in the list of ingredients declared on the food label.

We further acknowledge receipt of the letters, dated February 20, 1998, and April 23, 1998, from the law firm of Keller & Heckman on your behalf. We also acknowledge receipt of the letter, dated May 26, 1998, from The Biscuit and Cracker Manufacturers' Association (B&CMA), the May 27, 1998, letter from the Council of Responsible Nutrition, and the letter, dated June 26, 1998, from the American Bakers Association concerning use of "calcium carbonate" as the common or usual name for both calcium carbonate and food-grade ground limestone.

Your requests concern the food-grade ingredients calcium carbonate and ground limestone. Calcium carbonate and ground limestone are listed as Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS) under 21 CFR § 184.1191 and 21 CFR § 184.1409, respectively. Each of these ingredients is also the subject of a separate monograph (i.e., "Limestone, Ground" and "Calcium Carbonate") in the Food Chemicals Codex (FCC). The GRAS regulation for each ingredient requires it to meet the specifications in the appropriate FCC monograph.

We replied on April 20, 1998, to the February 20, 1998, letter from John S. Eldred, Keller and Heckman LLP, Washington, D.C., on your firm's behalf, regarding the appropriate common or usual name for high-purity ground limestone when used as a food ingredient. The Keller and Heckman letter requested an informal opinion regarding the common or usual name, for ingredient listing purposes in finished foods, of a 98 percent pure calcium carbonate product produced by grinding limestone. At that time we stated our opinion that the term "calcium carbonate" may be used as the common or usual name for a food ingredient that meets

all the requirements specified in the FCC monograph for calcium carbonate.

The Keller and Heckman letter requested the agency's opinion on the common or usual name of ground limestone containing not less than 98 percent pure calcium carbonate. However, in your May 28, 1998, letter you revised your request to include ground limestone that contains not less than 94 percent calcium carbonate.

In general, a food ingredient must be declared by its common or usual name on a food label, 21 U.S.C. 343(i); 21 CFR § 101.4. The common or usual name of a food must accurately identify or describe the basic nature of the food or its characterizing properties or ingredients in accordance with 21 CFR § 102.5. Additionally, the name must be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food must be given its own common or usual name that communicates, in clear terms, what it is in a way that distinguishes it from different foods.

Ordinarily, we would consider the identification of a food (which has its own specifications), by the name of another food that has different specifications to misbrand the food within the meaning of 21 U.S.C. § 343(a)(1). In this case, however, the ground limestone FCC monograph states that ground limestone consists essentially of calcium carbonate. In addition, letters we have received from trade associations and food manufacturing firms, including two letters submitted more than fifteen years ago as comments in FDA's rulemaking affirming calcium carbonate as GRAS, state that it is common practice in the food industry to use the two products interchangeably as a calcium source for fabricated foods and to declare both ground limestone and calcium carbonate as "calcium carbonate." Because calcium carbonate accurately identifies the basic nature of ground limestone and the two ingredients are regarded as interchangeable by industry, we do not believe that it would be misleading to declare ground limestone that meets the FCC monograph for ground limestone as "calcium carbonate" in the ingredient list of a finished food. Therefore, we would not object to the use of the term "calcium carbonate" in the ingredient list of a finished food to describe either precipitated calcium carbonate that meets FCC specifications for calcium carbonate or ground limestone that meets FCC specifications for ground limestone.

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We hope that this information is helpful.

Sincerely yours,



Elizabeth J. Campbell
Acting Director
Office of Food Labeling
Center for Food Safety
and Applied Nutrition

cc: John S. Eldred, Esquire
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