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June 26, 2000

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VIA HAND DELIVERY

Alan M. Rulis, Ph.D.
HFS-200
Director
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street S.W.
Washington, DC 20204

Re: GRAS Notification for Whey Mineral Concentrate

Dear Dr. Rulis:

On behalf of our client, Glanbia Ingredients, Inc., we are hereby submitting, in triplicate, a Notification of a determination that whey mineral concentrate is generally recognized as safe (GRAS) for use as a source of milk-derived calcium in dietary supplements, fortified beverages and fortified foods, including nutrition bars, bakery products, sport beverages, isotonic beverages, and enriched dairy products. This Notification is submitted in accordance with proposed 21 C.F.R. § 170.36 ("Notice of a claim for exemption based on a GRAS determination"), 62 Fed. Reg. 18938, 18960 (Apr. 17, 1997). The basis for this Notification is scientific procedures.

* * *

We trust you will find the enclosed Notification acceptable. Should any questions arise during the review process, please do not hesitate to contact us, preferably by telephone, so that we may respond as quickly as possible.

2000 JUN 27 P 3:19
000002



Alan M. Rulis, Ph.D.
June 26, 2000
Page 2

KELLER AND HECKMAN LLP

Very truly yours,
KELLER AND HECKMAN LLP

Richard F. Mann
Counsel to Glanbia Ingredients, Inc.

Ann M. Boeckman
Counsel to Glanbia Ingredients, Inc.

Enclosures



000003

Before the
FOOD AND DRUG ADMINISTRATION
Department of Health and Human Services
Washington, D.C.

GRAS EXEMPTION CLAIM

Name of Notifier: Glanbia Ingredients, Inc.

Post Office Address: All communications on this matter are to be sent in care of Counsel for the Notifier, Richard F. Mann or Ann M. Boeckman, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4229
Facsimile: (202) 434-4646

Names of Substance and Intended Uses: Whey Mineral Concentrate for use in dietary supplements and fortified foods and beverages, including nutrition bars, bakery products, sport beverages, isotonic beverages, and enriched dairy products

Dated: June 26, 2000

Richard F. Mann
Ann M. Boeckman
Counsel to Glanbia Ingredients, Inc.

000004

NOTICE OF A CLAIM FOR EXEMPTION
BASED ON A GRAS DETERMINATION FOR
WHEY MINERAL CONCENTRATE

1. GRAS Exemption Claim for Whey Mineral Concentrate

(i) Name and Address of Notifier:

Glanbia Ingredients, Inc.
523 6th Street
Monroe, Wisconsin 53566.

All communications on this matter are to be sent in care of Washington
Counsel for the Notifier, Richard F. Mann or Ann M. Boeckman, Keller
and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C.
20001.

Telephone: (202) 434-4229 or (202) 434-4234

Facsimile: (202) 434-4646.

(ii) Common or usual name of the notified substance:

Whey mineral concentrate

(iii) Applicable conditions of use:

Whey mineral concentrate is used as a source of milk-derived calcium in dietary
supplements, fortified foods, and fortified beverages, including nutrition bars,
bakery products, sport beverages, isotonic beverages, and enriched dairy products.

000005

(iv) Basis for GRAS determination:

The described uses of whey mineral concentrate are generally recognized as safe (GRAS) based on scientific procedures, in accordance with 21 C.F.R. § 170.30, and as discussed more fully in the accompanying summary of the basis for the GRAS determination.

(v) Statement of availability of data

The data and information that are the basis for this GRAS determination are available for FDA's review and copying at reasonable times or will be sent to FDA upon request.

* * *

The foregoing information considered, it is respectfully submitted that the proposed and current uses of whey mineral concentrate are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because this substance is generally recognized as safe.

Respectfully submitted,

GLANBIA INGREDIENTS, INC.

By: _____

Richard F. Mann

Ann M. Boeckman

Keller and Heckman LLP
COUNSEL FOR THE NOTIFIER

000007

2. Identity of the Notified Substance

Quantitative Composition:

<i>Typical Composition of Whey Mineral Concentrate</i>	
<u>Total minerals</u>	79%
• Calcium	24.0%
• Phosphorus (as phosphate)	41.0%
• Organic Mineral (citrate)	9.0%
• Other ^{1/}	5.0%
<u>Lactose</u>	9.0%
<u>Protein</u>	5.0%
<u>Free Moisture</u>	4.0%
<u>Fat</u>	0.5%

Method of Manufacture: Whey mineral concentrate is produced by subjecting pasteurized whey to a proprietary precipitation and membrane separation process followed by purification and drying steps.

^{1/} The minerals found in whey mineral concentrate are those found naturally in milk and milk products. A mineral list of these is provided in Appendix A.

Characteristic Properties: Whey mineral concentrate occurs as a free-flowing, bland white powder. It is soluble in an acidic pH range.

Food-Grade Specifications: Whey mineral concentrate has a heavy metals content (as Pb) of not more than 10 parts per million (0.001%), as determined by the method described in the *Food Chemicals Codex*, 4th edition, 1996.

Residue on ignition: 70%

Microbial Limits:

Standard plate count	<10,000/g
Coliforms	Negative/0.1 g
Yeasts & Molds	<50 g
Coag. Pos. Staph	Negative/0.1 g
<i>Salmonella</i>	Negative/50 g
<i>Listeria</i>	Negative/50 g

3. Information on Self-Limiting Levels of Use:

The notifier has not identified self-limiting levels of use that are generally applicable to anticipated uses of whey mineral concentrate. Whey mineral concentrate is recommended for use, however, at levels that are consistent with current calcium supplementation guidelines. According to an expert panel of the National Academy of Sciences (NAS), adults should consume between 1,000 and 1,300 mg of calcium per day to promote optimal health and to prevent chronic disease. Standing Committee on the Scientific Evaluation of Dietary Reference Intakes, Institute of Medicine, Food and Nutrition Board, *Dietary Reference Intakes for Calcium, Phosphorus, Magnesium, Vitamin D, and Fluoride* 91-134 (1999) (providing adequate intake (AI) findings for calcium by age and gender group). A tolerable upper limit of 2,500 mg per day has been identified. *Id.* at 134-44.

4. Summary of Basis for GRAS Determination

A. Data and information relied on to establish safety

General recognition of safety in this instance is based on scientific procedures, in keeping with 21 C.F.R. § 170.30(b). This information is described more fully below.

Whey mineral concentrate is a dairy product manufactured by the physical removal—through well-understood precipitation and membrane separation processes—of certain constituents of a

GRAS-affirmed food ingredient. The source material for whey mineral concentrate is fluid whey, which FDA has affirmed as GRAS and has long been safely consumed by humans. 21 C.F.R. § 184.1979. Whey mineral concentrate is closely related to a number of whey-derived permeates, including reduced lactose whey, reduced minerals whey, and whey protein concentrate, all of which FDA has affirmed as GRAS. 21 C.F.R. §§ 184.1979a-184.1979c.

Whey mineral concentrate is also closely related to dairy product solids, a product that was the subject of GRAS Notice No. 000037, to which FDA did not object. Letter from Alan M. Rulis, Ph.D., Director, Office of Premarket Approval, FDA Center for Food Safety and Applied Nutrition, to Richard F. Mann, Keller and Heckman LLP (Apr. 21, 2000) (noting that FDA had “no questions” regarding the conclusion that dairy product solids is GRAS under the intended conditions of use set forth in GRN 000037). In its response to GRN 000037, FDA noted that “dairy product solids” has been defined to mean a modified dairy product produced from milk or whey through physical separation techniques such as precipitation, filtration, or dialysis. *Id.* The lactose content of the “dairy product solids” that was the subject of GRAS Notice No. 000037 was at least 59%. *Id.* Because whey mineral concentrate, as produced by the notifier, has a typical lactose content of 9%, it technically does not meet the definition of “dairy product solids” set forth in GRN 000037. The two products are related, however, in that the source material and the nature of the manufacturing processes for each present no safety concerns with respect to human consumption.

B. Information unfavorable to the GRAS determination

The notifier is not aware of any information unfavorable to the GRAS determination. In the 20 years of review of the safety of whey and modified whey products, the only safety issue that has been raised by FDA is the concern that the production of certain whey-derived ingredients might result in the concentration of potentially harmful constituents, such as lead or heavy metals, beyond what would be expected to be present in whey itself. In response to this concern, the notifier has implemented a specification for heavy metals (as Pb), which provides that heavy metals are limited to not more than 10 parts per million, which is consistent with heavy metal limitations set for other modified whey products. Moreover, the process for manufacturing the notified substance does not result in such potentially harmful concentrations.

C. Basis for concluding that the notified use of whey mineral concentrate is GRAS

FDA describes the criteria for determining GRAS status for a particular use of a substance through scientific procedures under 21 C.F.R. § 170.30(a) and (b). Section 170.30(a) states that general recognition of safety must be based on the views of experts qualified by scientific training and experience to assess the safety of substances added to food. GRAS status must also be based on common knowledge throughout the relevant scientific community that the substance is not harmful under the conditions of intended use.

In affirming the GRAS status of whey and certain modified whey products (reduced lactose whey, reduced minerals whey, and whey protein concentrate), FDA completed an exhaustive review of all available information on whey and whey products, as well as extensive public comments on the subject. 46 Fed. Reg. 44434 (Sept. 4, 1981). From initial petition to final promulgation of GRAS affirmation regulations, the process encompassed more than eight years. FDA received no comments that questioned the safety of whey or whey products. *Id.* at 44435.

Recognizing the likelihood of continuing improvements in whey processing, and not wishing to inhibit the development of more efficient practices, FDA did not attempt to list all methods used to prepare modified whey products in its GRAS regulations. The Agency stated that it would not object to the use of appropriate physical separation techniques:

The agency does not intend to limit the processing methods that may be used. Furthermore, the Agency has no objection to the use of newly developed physical separation techniques, if there are no new toxicants introduced as a result of these techniques, and if these techniques do not result in the concentration of natural toxicants in whey products. FDA believes that such results can be avoided by the use of good manufacturing practices and by the establishment of specifications for heavy metals.

Id. at 44437.

Applying these standards, whey mineral concentrate is deemed to be GRAS because it is obtained from a GRAS-affirmed ingredient—whey—using safe and suitable physical separation techniques. It is widely accepted that methods used for physically separating whey constituents from the whey source do not alter the chemical identity and characteristic properties of the resulting whey-derived permeate. *See, e.g.*, 46 Fed. Reg. at 44437. Out of an abundance of caution, and in response to concerns voiced previously by FDA, the notifier has set a specification for heavy metals (as Pb), which provides that heavy metals are limited to not more than 10 parts per million.

* * *

Considering the foregoing, we respectfully submit that all criteria for general recognition of safety based on scientific procedures are met and, thus, that whey mineral concentrate is generally recognized as safe for addition to dietary supplements, fortified foods, and fortified beverages, including nutrition bars, bakery products, sport beverages, isotonic beverages, and enriched dairy products.

Appendix A
GRAS NOTIFICATION
Whey Mineral Concentrate

Mineral Composition of Fluid Milk
Source: USDA Nutrient Database for
Standard Reference, Release 13 (Nov. 1999).

000015

Milk, fluid, 3.25% milkfat

Select weights to be reported. If you select 100 grams, then sample count and standard error will also be displayed. You may select up to 5 weights, or you may select 100 grams and up to 3 weights.

- 100 grams of edible portion = 100 grams
- 1 cup = 244.000 grams
- 1 tablespoon = 15.200 grams
- 1 fl oz = 30.500 grams
- 1 quart = 976.000 grams
- 1 school milk carton (1/2 pint) = 244.000 grams

000016

Milk, fluid, 3.25% milkfat

NDB No: 01077

Nutrient	Units	Value per 100 grams of edible portion	Sample Count	Std. Error
Proximates				
Water	g	87.990	1242	0.006
Energy	kcal	61.441	0	
Energy	kJ	257.000	0	
Protein	g	3.290	4209	0.003
Total lipid (fat)	g	3.340	1029	0.006
Carbohydrate, by difference	g	4.660	0	
Fiber, total dietary	g	0.000	0	
Ash	g	0.720	710	0.001
Minerals				
Calcium, Ca	mg	119.400	1054	0.251
Iron, Fe	mg	0.050	606	0.001
Magnesium, Mg	mg	13.440	1052	0.147
Phosphorus, P	mg	93.400	596	0.204
Potassium, K	mg	151.500	694	0.352
Sodium, Na	mg	49.000	53	1.147
Zinc, Zn	mg	0.380	48	0.009
Copper, Cu	mg	0.010	0	
Manganese, Mn	mg	0.004	0	
Selenium, Se	mcg	2.000	37	0.125
Vitamins				
Vitamin C, ascorbic acid	mg	0.940	115	0.044
Thiamin	mg	0.038	43	0.002
Riboflavin	mg	0.162	128	0.002
Niacin	mg	0.084	15	0.003
Pantothenic acid	mg	0.314	16	0.011
Vitamin B-6	mg	0.042	42	0.003
Folate	mcg	5.000	8	0.533
Vitamin B-12	mcg	0.357	75	0.012
Vitamin A, IU	IU	126.000	2800	
Vitamin A, RE	mcg_RE	31.000	2800	

000017

Vitamin D	IU	40.000	0	
Vitamin E	mg_ATE	0.100	0	
Lipids				
Fatty acids, saturated	g	2.079	0	
4:0	g	0.108	52	0.002
6:0	g	0.064	68	0.001
8:0	g	0.037	89	0.001
10:0	g	0.084	89	0.002
12:0	g	0.094	89	0.002
14:0	g	0.336	88	0.004
16:0	g	0.879	88	0.011
18:0	g	0.405	88	0.005
Fatty acids, monounsaturated	g	0.965	0	
16:1	g	0.075	71	0.002
18:1	g	0.840	78	0.011
20:1	g	0.000	0	
22:1	g	0.000	0	
Fatty acids, polyunsaturated	g	0.124	0	
18:2	g	0.075	74	0.003
18:3	g	0.049	65	0.003
18:4	g	0.000	0	
20:4	g	0.000	0	
20:5	g	0.000	0	
22:5	g	0.000	0	
22:6	g	0.000	0	
Cholesterol	mg	13.600	113	0.172
Phytosterols	mg	0.000	0	
Amino acids				
Tryptophan	g	0.046	0	
Threonine	g	0.149	0	
Isoleucine	g	0.199	0	
Leucine	g	0.322	0	
Lysine	g	0.261	0	
Methionine	g	0.083	0	
Cystine	g	0.030	0	
Phenylalanine	g	0.159	0	
Tyrosine	g	0.159	0	

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Valine	g	0.220	0	
Arginine	g	0.119	0	
Histidine	g	0.089	0	
Alanine	g	0.113	0	
Aspartic acid	g	0.250	0	
Glutamic acid	g	0.689	0	
Glycine	g	0.070	0	
Proline	g	0.319	0	
Serine	g	0.179	0	

USDA Nutrient Database for Standard Reference, Release 13 (November 1999)

[New Search](#)

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DATE: July 21, 2000

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CC:

FIRM/COMPANY: Food and Drug Administration

CITY/STATE/COUNTRY: Washington, D.C.

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CONFIRMATION NUMBER: (202) 418-3101

FROM: **NAME/ID NO:** Richard F. Mann

PHONE NO: 202/434-4229

MESSAGE:

IN HOUSE INFORMATION ONLY:

*CLIENT NO./NAME: GL11772
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July 21, 2000

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Via Facsimile

Linda Kahl, Ph.D.
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
1110 Vermont Avenue, N.W.
HFS-206
Washington, D.C. 20201

Re: GRAS Notification for Whey Mineral Concentrate

Dear Dr. Kahl:

Following up on your telephone conversation with Ann Boeckman today, this letter responds to your requests for clarification and/or additional information regarding the notification we submitted on behalf of Glanbia Ingredients, Inc. for whey mineral concentrate. Specifically, you asked that we address the (1) lead specification, (2) anticipated level of use, and (3) estimated dietary exposure for whey mineral concentrate.

As we discussed, whey mineral concentrate will meet a lead specification of 0.5 parts per million (ppm), as recommended by FDA.

Regarding the level of use, whey mineral concentrate will be used in food in accordance with good manufacturing practice (GMP), as defined in 21 C.F.R. § 184.1(b). Thus, as indicated in section 3, page 6 of the notification, the quantity of whey mineral concentrate added to food will not exceed the amount reasonably required to accomplish the intended nutritional effect.

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Linda Kahl, Ph.D.
July 21, 2000
Page 2

You also asked that we provide information regarding the estimated dietary exposure that will result from the intended uses of whey mineral concentrate. We are preparing the estimate for submission in future correspondence and will forward it to your attention as soon as possible.

Should you have any further questions, please do not hesitate to contact us.

Sincerely,

Keller and Heckman LLP

Richard F. Mann
Counsel for Glanbia Ingredients, Inc.

Ann. M. Boeckman
Counsel for Glanbia Ingredients, Inc.

cc: Stacey Goebel

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July 21, 2000

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Via Facsimile

Linda Kahl, Ph.D.
Office of Premarket Approval
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
1110 Vermont Avenue, N.W.
HFS-206
Washington, D.C. 20201

2000 AUG -8 A 8:02

Re: GRAS Notification for Whey Mineral Concentrate

Dear Dr. Kahl:

Following up on your telephone conversation with Ann Boeckman today, this letter responds to your requests for clarification and/or additional information regarding the notification we submitted on behalf of Glanbia Ingredients, Inc. for whey mineral concentrate. Specifically, you asked that we address the (1) lead specification, (2) anticipated level of use, and (3) estimated dietary exposure for whey mineral concentrate.

As we discussed, whey mineral concentrate will meet a lead specification of 0.5 parts per million (ppm), as recommended by FDA.

Regarding the level of use, whey mineral concentrate will be used in food in accordance with good manufacturing practice (GMP), as defined in 21 C.F.R. § 184.1(b). Thus, as indicated in section 3, page 6 of the notification, the quantity of whey mineral concentrate added to food will not exceed the amount reasonably required to accomplish the intended nutritional effect.

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Linda Kahl, Ph.D.
July 21, 2000
Page 2

You also asked that we provide information regarding the estimated dietary exposure that will result from the intended uses of whey mineral concentrate. We are preparing the estimate for submission in future correspondence and will forward it to your attention as soon as possible.

Should you have any further questions, please do not hesitate to contact us.

Sincerely,

Keller and Heckman LLP

Richard F. Mann
Counsel for Glanbia Ingredients, Inc.

Ann. M. Boeckman
Counsel for Glanbia Ingredients, Inc.

cc: Stacey Goebel

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October 25, 2000

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Via Facsimile

Martha D. Peiperl, Ph.D.
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Premarket Approval
200 C Street, S.W., HFS-215
Washington, D.C. 20204

Re: GRAS Notification for Whey Mineral Concentrate (GRN 000052)

Dear Dr. Peiperl:

Following up on your telephone conversation with Richard Mann of this office, this letter clarifies the specification for yeasts and molds in whey mineral concentrate, which is the subject of GRN 000052. As indicated in the attached revision to page 5 of GRN 000052, the correct specification for yeasts and molds in whey mineral concentrate is <50/g. Please refer to the attached page in place of the earlier version submitted on June 26, 2000.

Should you have any questions about this information, or should you otherwise wish to discuss GRN 000052, please give us a call.

Cordially yours,

Ann M. Boeckman

Enclosure

cc: Eric Bastian, Ph.D.
Richard Mann

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Characteristic Properties: Whey mineral concentrate occurs as a free-flowing, bland white powder. It is soluble in an acidic pH range.

Food-Grade Specifications: Whey mineral concentrate has a heavy metals content (as Pb) of not more than 10 parts per million (0.001%), as determined by the method described in the *Food Chemicals Codex*, 4th edition, 1996.

Residue on ignition: 70%

Microbial Limits:

Standard plate count	<10,000/g
Coliforms	Negative/0.1 g
Yeasts & Molds	<50/g
Coag. Pos. Staph	Negative/0.1 g
<i>Salmonella</i>	Negative/50 g
<i>Listeria</i>	Negative/50 g

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attachment

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DATE: January 19, 2001

TOTAL NO. OF PAGES: 2 + COVER

TO: NAME: Dr. Linda Kahl

FIRM/COMPANY: Food and Drug Administration

CITY/STATE: Washington, D.C.

FACSIMILE NUMBER: 202-418-3131

CONFIRMATION NUMBER: 202-418-3101

FROM: NAME/ID NO.: Richard F. Mann

PHONE NO.: 202/434-4229

MESSAGE: Please see attached.

IN HOUSE INFORMATION ONLY:

CLIENT NO./NAME: AM04917/01

FACSIMILE PREPARED BY: C. Tang-Kwok

RETURN TO: C. Tang-Kwok

TIME DEADLINE:

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January 19, 2001

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Re: GRAS Notice No. 000037
Whey Protein Isolate and Dairy Product Solids

Dear Dr. Kahl:

As Washington Counsel to the American Dairy Products Institute (ADPI), the organization that filed the referenced GRAS notification, we are writing to clear up some potential confusion that may be caused by the reference to "whey mineral concentrate" in the Food and Drug Administration's April 21, 2000, response to the notification.

As you know, ADPI filed a GRAS Affirmation Petition, No. 1G0371, in 1990, seeking affirmation of the GRAS status of "Lactose Product," "Whey Protein Isolate," and "Dairy Product Solids." At the time the initial petition was filed, "Dairy Product Solids" was defined as a permeate product with variable levels of protein, ash, lactose, and solids. As such, it was similar to "whey mineral concentrate," one of several modified whey products used as examples by FDA of ingredients for which additional GRAS affirmation petitions might be appropriate. See 46 Fed. Reg. 44438 (September 4, 1981)(Preamble to FDA GRAS Affirmation of Whey and Certain Modified Whey Products).

Subsequent to the filing of the initial petition, ADPI, at FDA's request, provided certain specifications for Dairy Product Solids, including a specification for minimum lactose of 59 percent, and ultimately narrowed the scope of its petition by eliminating the reference to "Lactose Product." FDA accepted the petition, as amended, for filing, including the specifications for

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January 19, 2001

Dr. Kahl
Page 2

Dairy Product Solids, on February 3, 1995. 60 Fed. Reg. 6713. Those same specifications were provided in the referenced GRAS notice for Dairy Product Solids, which was considered, and ultimately accepted, by FDA. Under these specifications, "whey mineral concentrate" and "dairy product solids" no longer necessarily accurately describe the same food ingredient. Accordingly, the reference to "whey mineral concentrate" in the response to ADPI's GRAS notification may cause some confusion and, perhaps, should be eliminated. We believe that this could be done without any other modifications to FDA's response.

Please give us a call, should you have any questions or otherwise wish to discuss this.

Sincerely,
KELLER AND HECKMAN LLP

Richard F. Mann
Washington Counsel to the
American Dairy Products Institute

c: Warren S. Clark, Jr., Ph.D.

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