ORIGINAL SUBMISSION

GRAS Notice (GRN) No. 633
http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/default.htm

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Serving Business through Law and Science®

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Writer's Direct Access
Richard F. Mann
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February 18, 2016

Via FedEx

Antonia Mattia, Ph.D., Director
Division of Biotechnology and GRAS Notice Review (HFS-225)
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

Re: GRAS Notification for Native Whey Protein

Dear Dr. Mattia:

We respectfully submit the attached GRAS Notification on behalf of our client, Leprino Foods Company (Leprino), for native whey protein, including native whey protein concentrate (nWPC) and native whey protein isolate (nWPI), for use as a food ingredient for functional or nutritional purposes in multiple food applications. The attached GRAS Notification provides a review of the information related to the intended uses and manufacturing and safety of the ingredient. We have included three (3) hard copies of the GRAS Notification for your review.

Leprino has determined that native whey protein is generally recognized as safe (GRAS) based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and in conformance with the guidance issued by the Food and Drug Administration (FDA) under *proposed* 21 C.F.R. § 170.36, 62 Fed. Reg. 18938 (Apr. 17, 1997). Therefore, the use of the native whey protein in food as described in this GRAS Notification is exempt from the requirement of premarket approval as set forth in the Federal Food, Drug, and Cosmetic Act.

The analytical data, published studies, and information that are the basis for this GRAS determination are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001, or will be sent to FDA upon request.

We look forward to the Agency's review of this submission and would be happy to provide Agency officials with any information they may need to complete their assessment. Thank you for your attention to this matter.

Sincerely,

(b) (6)

Richard F. Mann

Enclosure

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

GENERALLY RECOGNIZED AS SAFE *(GRAS)* NOTICE

Form Approved: OMB No. 0910-0342; Expiration Date: 02/29/2016
(See last page for OMB Statement)

FDA USE ONLY

GRN NUMBER	DATE OF RECEIPT
ESTIMATED DAILY INTAKE	INTENDED USE FOR INTERNET
NAME FOR INTERNET	
KEYWORDS	

RECEIVED FEB 10 2016 OFFICE OF FOOD ADDITIVE SAFETY

Transmit completed form and attachments electronically via the Electronic Submission Gateway *(see Instructions)*; OR Transmit completed form and attachments in paper format or on physical media to: Office of Food Additive Safety *(HFS-200)*, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835.

PART I – INTRODUCTORY INFORMATION ABOUT THE SUBMISSION

1. Type of Submission *(Check one)*

☒ New ☐ Amendment to GRN No. _____ ☐ Supplement to GRN No. _____

2. ☐ All electronic files included in this submission have been checked and found to be virus free. *(Check box to verify)*

3a. For New Submissions Only: Most recent presubmission meeting *(if any)* with FDA on the subject substance *(yyyy/mm/dd)*: _____

3b. For Amendments or Supplements: Is your amendment or supplement submitted in response to a communication from FDA? *(Check one)* ☐ Yes ☐ No If yes, enter the date of communication *(yyyy/mm/dd)*: _____

PART II – INFORMATION ABOUT THE NOTIFIER

1a. Notifier

Name of Contact Person	Position
Larry Rasmussen	Director of International Regulatory Affairs

Company *(if applicable)*: Leprino Foods Company

Mailing Address *(number and street)*: 1830 West 38th Avenue

City	State or Province	Zip Code/Postal Code	Country
Denver	Colorado	80211	United States of America

Telephone Number	Fax Number	E-Mail Address
(303) 600-2514		lrasmussen@leprinofoods.com

1b. Agent or Attorney *(if applicable)*

Name of Contact Person	Position
Richard F. Mann	Partner

Company *(if applicable)*: Keller and Heckman LLP

Mailing Address *(number and street)*: 1001 G Street NW, Suite 500W

City	State or Province	Zip Code/Postal Code	Country
Washington	District of Columbia	20001	United States of America

Telephone Number	Fax Number	E-Mail Address
(202) 434-4229	(202) 434-4646	mann@khlaw.com

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PART III – GENERAL ADMINISTRATIVE INFORMATION

1. Name of Substance

Native whey protein

2. Submission Format: *(Check appropriate box(es))*

☐ Electronic Submission Gateway

☒ Paper

☐ Electronic files on physical media with paper signature page

If applicable give number and type of physical media

3. For paper submissions only:

Number of volumes 1

Total number of pages 22

4. Does this submission incorporate any information in FDA's files by reference? *(Check one)*

☒ Yes *(Proceed to Item 5)* ☐ No *(Proceed to Item 6)*

5. The submission incorporates by reference information from a previous submission to FDA as indicated below *(Check all that apply)*

☒ a) GRAS Notice No. GRN 504

☐ b) GRAS Affirmation Petition No. GRP

☐ c) Food Additive Petition No. FAP

☐ d) Food Master File No. FMF

☐ e) Other or Additional *(describe or enter information as above)*

6. Statutory basis for determination of GRAS status *(Check one)*

☒ Scientific Procedures *(21 CFR 170.30(b))* ☐ Experience based on common use in food *(21 CFR 170.30(c))*

7. Does the submission (including information that you are incorporating by reference) contain information that you view as trade secret or as confidential commercial or financial information?

☐ Yes *(Proceed to Item 8)*

☒ No *(Proceed to Part IV)*

8. Have you designated information in your submission that you view as trade secret or as confidential commercial or financial information *(Check all that apply)*

☐ Yes, see attached Designation of Confidential Information

☐ Yes, information is designated at the place where it occurs in the submission

☐ No

9. Have you attached a redacted copy of some or all of the submission? *(Check one)*

☐ Yes, a redacted copy of the complete submission

☐ Yes, a redacted copy of part(s) of the submission

☐ No

PART IV – INTENDED USE

1. Describe the intended use of the notified substance including the foods in which the substance will be used, the levels of use in such foods, the purpose for which the substance will be used, and any special population that will consume the substance *(e.g., when a substance would be an ingredient in infant formula, identify infants as a special population).*

Native whey protein will be used as a food ingredient in a variety of food categories.

The level of incorporation depends on the specific type of native whey protein (described with respect to protein content in the GRAS Notification), as well as the food in which the ingredient is used. Intended uses, applications, and levels of incorporation are detailed in Table 4 of the GRAS Notification.

Depending on the food category in which native whey protein is used, the ingredient is intended to serve as an emulsifier, flavor enhancer, flavoring agent, formulation aid, humectant, stabilizer and thickener, texturizer, and/or source of high-quality protein.

Foods containing native whey protein will be consumed by the general population, i.e., adults and children (1 year and older).

2. Does the intended use of the notified substance include any use in meat, meat food product, poultry product, or egg product? *(Check one)*

☐ Yes ☒ No

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PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
1	Native whey protein				
2					
3					

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (1- 3) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)*and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s))*, and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source), and include any known toxicants that* could be in the source.

Native whey protein is obtained by the microfiltration and subsequent separation of whey proteins from milk or skim milk. The identity of a specific native whey protein product is characterized by the product's total protein (dry basis) and by having a casein:whey protein ratio where casein is less than or equal to 40%. From a process standpoint, native whey protein differs from traditional whey protein in that it is not produced via the cheese making process. Native whey protein is identified by a number or a descriptor that represents the protein content of the product, e.g., "native whey protein XX" where XX refers to the percent total protein; "native whey protein concentrate" where total protein (dry basis) is greater than or equal to 79.5%; or "native whey protein isolate" where total protein (dry basis) is greater than or equal to 89.5%.

3. Synonyms

Provide as available or relevant:

1	Native whey protein concentrate (nWPC)
2	Native whey protein isolate (nWPI)
3	

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PART V – IDENTITY

1. Information about the Identity of the Substance

	Name of Substance[1]	Registry Used *(CAS, EC)*	Registry No.[2]	Biological Source *(if applicable)*	Substance Category *(FOR FDA USE ONLY)*
4					

[1] Include chemical name or common name. Put synonyms *(whether chemical name, other scientific name, or common name)* for each respective item (4- 6) in Item 3 of Part V *(synonyms)*

[2] Registry used e.g., CAS *(Chemical Abstracts Service)*and EC *(Refers to Enzyme Commission of the International Union of Biochemistry (IUB), now carried out by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (IUBMB))*

2. Description

Provide additional information to identify the notified substance*(s)*, which may include chemical formula*(s)*, empirical formula*(s)*, structural formula*(s)*, quantitative composition, characteristic properties *(such as molecular weight(s))*, and general composition of the substance. For substances from biological sources, you should include scientific information sufficient to identify the source *(e.g., genus, species, variety, strain, part of a plant source (such as roots or leaves), and organ or tissue of an animal source), and include any known toxicants that* could be in the source.

3. Synonyms

Provide as available or relevant:

4	

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PART VI – OTHER ELEMENTS IN YOUR GRAS NOTICE

(check list to help ensure your submission is complete – check all that apply)

- [x] Any additional information about identity not covered in Part V of this form
- [x] Method of Manufacture
- [x] Specifications for food-grade material
- [x] Information about dietary exposure
- [x] Information about any self-limiting levels of use *(which may include a statement that the intended use of the notified substance is not-self-limiting)*
- [ ] Use in food before 1958 *(which may include a statement that there is no information about use of the notified substance in food prior to 1958)*
- [x] Comprehensive discussion of the basis for the determination of GRAS status
- [ ] Bibliography

Other Information

Did you include any other information that you want FDA to consider in evaluating your GRAS notice?

[ ] Yes [x] No

Did you include this other information in the list of attachments?

[ ] Yes [ ] No

PART VII – SIGNATURE

1. The undersigned is informing FDA that Leprino Foods Company *(name of notifier)*

has concluded that the intended use*(s)*of Native whey protein *(name of notified substance)*

described on this form, as discussed in the attached notice, is (are) exempt from the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act because the intended use(s) is (are) generally recognized as safe.

2. [x] Leprino Foods Company *(name of notifier)* agrees to make the data and information that are the basis for the determination of GRAS status available to FDA if FDA asks to see them.

Leprino Foods Company *(name of notifier)* agrees to allow FDA to review and copy these data and information during customary business hours at the following location if FDA asks to do so.

Keller and Heckman LLP, 1001 G Street NW, Suite 500W, Washington, DC 20001 *(address of notifier or other location)*

Leprino Foods Company *(name of notifier)* agrees to send these data and information to FDA if FDA asks to do so.

OR

[ ] The complete record that supports the determination of GRAS status is available to FDA in the submitted notice and in GRP No. ---------- *(GRAS Affirmation Petition No.)*

3. Signature of Responsible Official, Agent, or Attorney	Printed Name and Title	Date (mm/dd/yyyy)
(b) (6)	Richard F. Mann, Partner	02/18/2016

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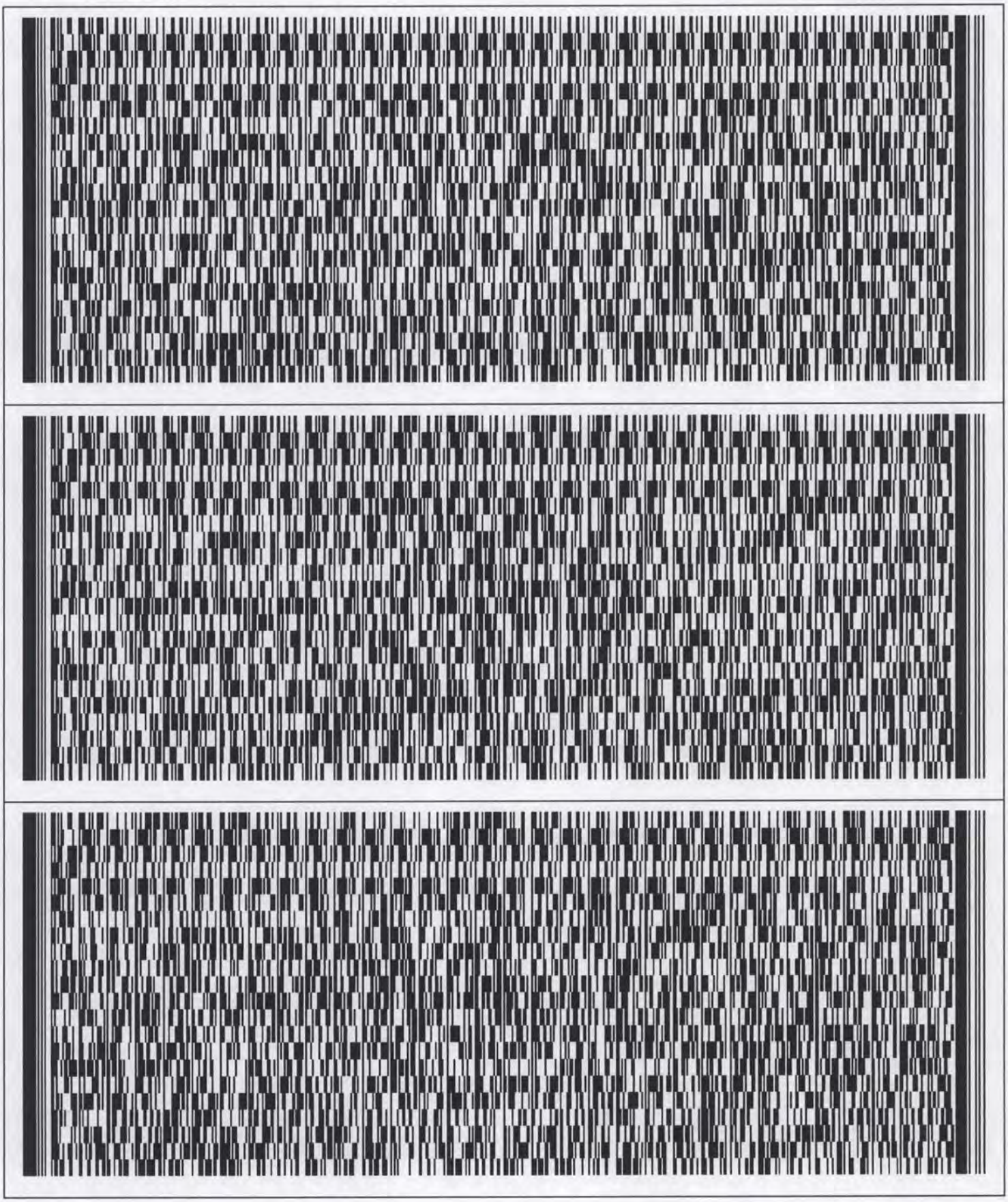
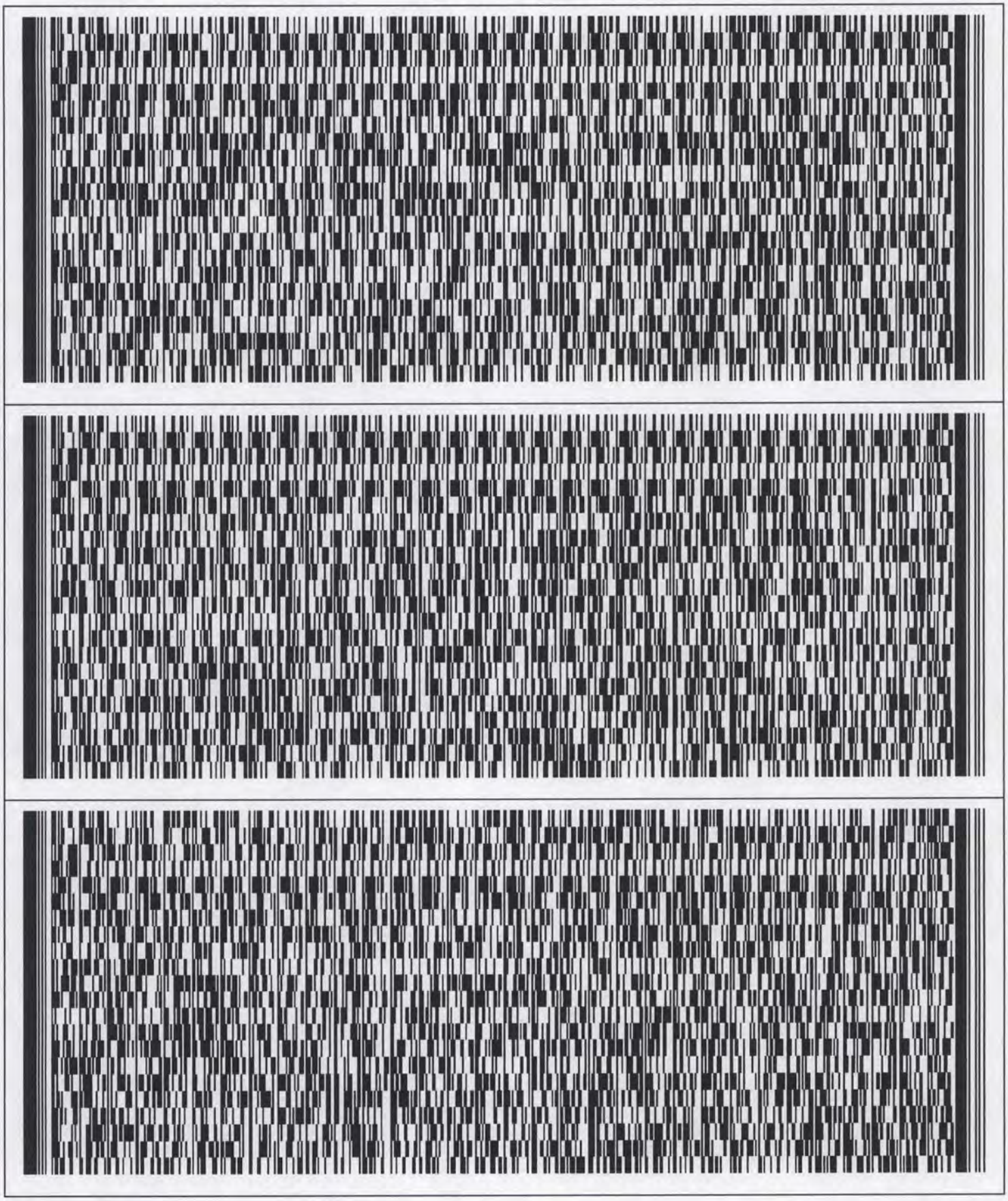
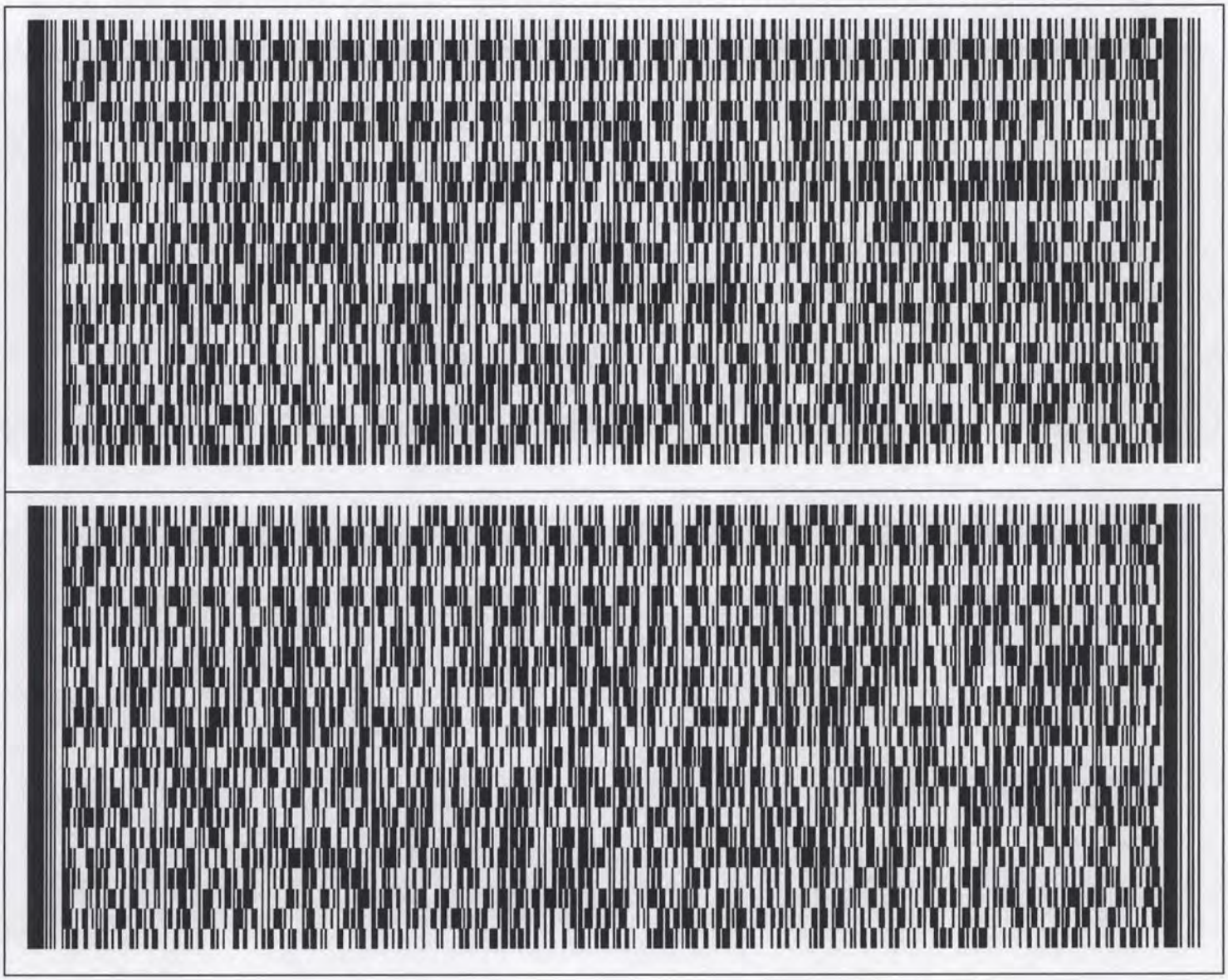
PART VIII – LIST OF ATTACHMENTS

List your attached files or documents containing your submission, forms, amendments or supplements, and other pertinent information. Clearly identify the attachment with appropriate descriptive file names (or titles for paper documents), preferably as suggested in the guidance associated with this form. Number your attachments consecutively. When submitting paper documents, enter the inclusive page numbers of each portion of the document below.

Attachment Number	Attachment Name	Folder Location (select from menu) (Page Number(s) for paper Copy Only)
	Cover Letter to Dr. Antonia Mattia	N/A
	GRAS Notification for Native Whey Protein	1-19







GRAS Notification for Native Whey Protein

Prepared for:

U.S. Food and Drug Administration
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by:

Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington, DC 20001

Date:

February 18, 2016

Table of Contents

Tables

Figures

Appendices

I. Introduction

Keller and Heckman LLP submits the enclosed information on behalf of our client, Leprino Foods Company, in support of this notification that native whey protein, including native whey protein concentrate (nWPC) and native whey protein isolate (nWPI), is generally recognized as safe (GRAS) for use in multiple food applications. As detailed below, these products are manufactured using the same process and differ primarily in terms of their protein content. We refer to these products collectively as "native whey protein" (nWP) throughout the document, unless otherwise specified.

Native whey protein is intended for use as a food ingredient for functional or nutritional purposes in the following foods, which are intended for consumption by adults and children (1 year and older): Meal Replacements and Meal Supplements; Powdered Nutritional Beverages; Nutritional Bars; Acidified Sports Beverages; Milk Products (including dairy beverages); Yogurt and Fermented Milk Products; Standardized and Non Standardized Cheese Products; Spreads, Dips, and Cream Substitutes; Coffee Creamers; Frozen Dairy Desserts and Mixes; Desserts and Mousses; Confections (including chocolate confections); Snack Foods; Coatings and Fillings; Salad Dressings; and Soups, Soup Mixes, and Sauces.[1] In each food category, the native whey protein will be used where permitted, and within limits permitted, by existing standards of identity or any other applicable regulations.

We submit information in the following areas:

- The identity and specifications for native whey protein;
- The manufacturing process for native whey protein;
- The intended uses and an estimation of consumption of native whey protein; and
- Supportive evidence from the long history of safe use of milk and milk protein as food.

Where applicable, we also incorporate by reference information from the successful GRAS Notice submitted for concentrated milk proteins, GRN No. 504.

It is our expectation that FDA will concur that the information presented fully supports the determination that the native whey protein as produced by Leprino Foods Company is GRAS for use as a food ingredient.

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[1] With the exception of acidified sports beverages, these product categories are the same as those described in the GRAS Notice submitted by the American Dairy Products Institute (ADPI) and the U.S. Dairy Export Council (USDEC) to cover the concentrated milk proteins, milk protein concentrate (MPC) and milk protein isolate (MPI). See GRN No. 504, available at: http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=504 (FDA "no questions" letter issued on Nov. 21, 2014).

II. Administrative Information

A. Claim Regarding GRAS Status

Leprino Foods Company has determined that native whey protein is GRAS for use in a variety of food categories based on scientific procedures in accordance with 21 C.F.R. § 170.30(b) and in conformance with the guidance issued by FDA under proposed 21 C.F.R. § 170.36, 62 Fed. Reg. 18938 (Apr. 17, 1997). The analytical data, published studies, and information that are the basis for this GRAS determination are available for FDA review and copying at reasonable times at Keller and Heckman LLP, 1001 G Street, NW, Suite 500W, Washington, DC 20001, or will be sent to FDA upon request.

B. Name and Address of the Notifier

Leprino Foods Company
1830 West 38th Avenue
Denver, CO 80211

All communications on this matter are to be sent to Counsel for the Notifier:

Richard F. Mann
Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington, DC 20001
Telephone: (202) 434-4229
Facsimile: (202) 434-4646
Email: mann@khlaw.com

C. Common or Usual Name of GRAS Substance

The common or usual names for the GRAS ingredient are:

- "native whey protein XX" where XX refers to the percent total protein; or
- "native whey protein concentrate (nWPC)" when total protein (dry basis) is ≥79.5%; and/or
- "native whey protein isolate (nWPI)" when total protein (dry basis) is ≥89.5%.

Collectively, these protein products are known as "native whey protein" (nWP).

D. Intended Use of GRAS Substance

Native whey protein will be used as a food ingredient in a variety of food categories at levels up to those outlined in **Table 4**.[2] Depending on the food category in which the native whey protein is used, this substance is intended to serve the following functions: emulsifier, flavor

[2] As noted previously, these food categories are the same as those described in GRN No. 504, with the addition of acidified sports beverages.

enhancer, flavoring agent, formulation aid, humectant, stabilizer and thickener, texturizer, and/or source of high-quality protein. Foods containing native whey protein will be consumed by the general population (adults and children > 1 year).

E. Self-Limiting Levels of Use

The use of native whey protein as a food ingredient is limited by the level that can technically be added to a given food without jeopardizing its quality and consumer acceptability.

III. Product Identity and Specifications

Native whey protein's identity is characterized by the product's total protein (dry basis) and by having a casein:whey protein ratio where casein is ≤ 40%. From a process standpoint, native whey protein differs from traditional whey protein in that it is not produced via the cheese making process.

Native whey protein products are substantially similar in composition, with the primary difference relating to total protein content. They differ to a lesser extent in terms of their levels of lactose and ash. The products have the same microbiological characteristics, and they are manufactured using the same process, as detailed further below.

A. Product Identification

Native whey protein is obtained by the microfiltration and subsequent separation of whey proteins from milk or skim milk. The milk source from which the native whey protein is derived is cow's milk. The whey protein is further concentrated by the partial removal of non-protein constituents (lactose and minerals) from the permeate fraction such that the finished dry product contains 79.5% or more protein by weight for native whey protein concentrate (nWPC) and 89.5% or more protein by weight for native whey protein isolate (nWPI). Native whey protein is produced by microfiltration, which may be preceded or followed by ultrafiltration, nanofiltration, evaporation, dialysis,[3] chromatography, or by any other safe and suitable process in which all or part of the lactose, minerals and moisture may be removed. A diafiltration step also may be used in native whey protein production. The native whey protein products are made available for commercial purposes as a free flowing, off-white to light tan colored powder.

B. Product Specifications

Tables 1 and 2 provide typical composition and microbiological and lead specifications for the native whey protein products and their test methods.

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[3] Dialysis is an example of a physical separation technique used to separate proteins that have close isoelectric points. It can be used in the production of whey protein concentrates as described in 21 C.F.R. § 184.1979c, and its safety has previously been established. Dialysis also may be used in the production of concentrated milk proteins, which are the subject of GRN No. 504. All dialysis membranes used meet applicable food contact regulations in 21 C.F.R. § 173.25.

Table 1. Product Specifications for Native Whey Protein

	nWPC80	nWPI90	Test method
Protein % (dry basis, N x 6.38)	79.5 min	89.5 min	SM 15.132 (Kjeldahl)
Fat %	3.00 max[4]	3.00 max	AOAC 989.05 (Mojonnier)
Ash %	5.0 max	4.5 max	AOAC 900.02 (Gravimetric)
Moisture %	5.50 max	5.50 max	AOAC 927.05 (Vacuum Oven)

Native whey protein products have an average casein:whey ratio of ≤ 40%.

Table 2. Microbiological and Lead Specifications for Native Whey Protein

Parameter	Standard	Test Method
Standard Plate Count	10,000 cfu/g max	FDA BAM
Coliform Bacteria	10 cfu/g max	AOAC 989.10 (Petrifilm)
Salmonella	Neg./375 g	FDA BAM
Yeast/Mold	50 max cfu/g	FDA BAM
Listeria monocytogenes	Neg./25 g	FDA BAM
Staphylococcus aureus	<10 cfu/g	AOAC 2003.08
E. coli	<10 cfu/g	AOAC 989.10
Lead	<1 ppm	FSNC (ICP-OES)

Five-batch analysis was performed on nWPI (Appendix 1) and nWPC (Appendix 2).

IV. Manufacturing Process

Figure 1 provides a step-by-step illustration of the manufacturing process, which we also describe in detail below. The various processes and steps described below are widely utilized in the dairy production industry, and much of the discussion below overlaps substantially with the manufacturing process described for concentrated milk proteins in GRN No. 504.

Native whey protein is manufactured from skim milk in accordance with current Good Manufacturing Practices (cGMP) for food (21 C.F.R. Part 110). The manufacture of native whey protein does not involve organic solvents.

[4] Fat content typically will not exceed 1%, but if the protein is instantized, the fat content may be up to 2% higher due to the application of oil and lecithin. We have included the highest possible fat content to account for instantization of the protein.

Manufacturers have significant flexibility with respect to the use of additives and ingredients in concentrated milk protein production. The food additives and ingredients that may be utilized in the manufacturing process for native whey protein are all either approved food additives or GRAS for their food applications and used in accordance with cGMP. Lecithin, potassium chloride, and sodium chloride are examples of three ingredients appropriately used in the production of commercial forms of native whey protein. For example, lecithin is used in the production of instantized ingredients. Lecithin is listed in 21 C.F.R. § 184.1400 as GRAS for use in food generally with no limitation other than cGMP. Sodium chloride (salt, NaCl) or potassium chloride (KCl) may be added in very small quantities during the diafiltration process to improve solubility of the final product. Salt is a common food ingredient and a GRAS substance (i.e., in 21 C.F.R. § 182.1). Potassium chloride is affirmed in 21 C.F.R. § 184.1622 as GRAS for use in food generally with no limitation other than cGMP.

To ensure pathogen control and compliance with regulatory limits in the finished product, the milk used to manufacture native whey protein is pasteurized in accordance with the provisions of the Pasteurized Milk Ordinance (PMO) at a minimum temperature of 145°F for a minimum time of 30 minutes or any other combination of time and temperature that satisfies PMO requirements. Alternatively, the native whey protein may be pasteurized in liquid form later in the manufacturing process, prior to spray drying.[5] Any other pasteurization process that is (or may come to be) recognized and accepted by FDA as being equally efficient as thermal pasteurization for the control of pathogens in milk may be employed for this purpose.

Table 3. Pasteurization Temperature vs. Time

Temperature	Time
63°C (145°F)	30 minutes
72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

The manufacturing techniques employed to concentrate protein and to remove non-protein constituents from milk are based primarily on the use of membrane filtration technologies, as listed in 21 C.F.R. § 177.2910 ("Ultra-filtration membranes"). All membrane materials employed in the production of native whey protein comply with applicable food-contact regulations, and the use of such technologies complies with cGMP for food. Semi-permeable membranes used in the production of native whey protein typically are rated at 0.1 to 10 microns. Based on the combination of this membrane pore size and the fluid dynamics of processing a dairy stream such as milk or skim milk, the effect is a concentration of fat, casein, small amounts of whey protein, and any other large particles in the stream (suspended solids,

[5] Figure 1 does not depict the pasteurization step.

extraneous material, bacteria, spores, etc.).[6] The components that freely pass through the membrane are water, whey proteins, lactose, ash, small amounts of casein, and non-protein nitrogen (NPN). Depending on the level of concentration (or alternatively, the extent of the removal of lactose and ash relative to protein), the higher the protein level of the native whey protein.

The raw material (milk or skim milk) is circulated along a semi-permeable membrane in a pressure-driven process. The membrane is permeable to lower molecular weight constituents (whey proteins, sugars, minerals, and other low molecular weight components) that pass through and form a permeate stream. Higher molecular weight constituents (casein protein and fat) are preferentially retained by the membrane and become components of the retentate stream. Two distinct semi-permeable membrane processes are now employed as core technologies in the manufacture of native whey protein. Microfiltration includes a fractionation step made possible through the physical partitioning of casein protein from whey protein.[7] Ultrafiltration facilitates the concentration of the native whey protein stream by the removal of lower molecular weight constituents, such as lactose, minerals, and non-protein nitrogen components.

Sufficient lactose and minerals are removed into the ultrafiltration permeate until the desired protein content is reached in the retentate stream. Diafiltration – a step wherein water is added to dilute the retentate in order to facilitate the removal of further quantities of minerals and lactose – may be used in the production of native whey protein.

As indicated above, microfiltration may be used to effect changes in the partition of protein components between the retentate and permeate streams, thereby facilitating adjustments to the ratio of casein to whey protein present in the finished product.

When the native whey retentate has reached its target protein content, it is removed from the filtration system. Further processing steps may include: ultrafiltration, chromatography, nanofiltration, and evaporative concentration stages in which additional solids and moisture are removed to increase the solids/protein content of the product stream. Following evaporation (or without this processing step, depending on the particular manufacturing circumstance), the product stream may be dried and packaged using normal dairy drying techniques.

The finished native whey protein may be obtained by removing the product stream from the process at the completion of various stages, such as the filtration stage, concentration stage, or drying stage. The resulting product may be identified as fluid, concentrate, or dried versions of native whey, respectively. For purposes of this GRAS Notice, the native whey protein is obtained after the drying stage, in dry form.

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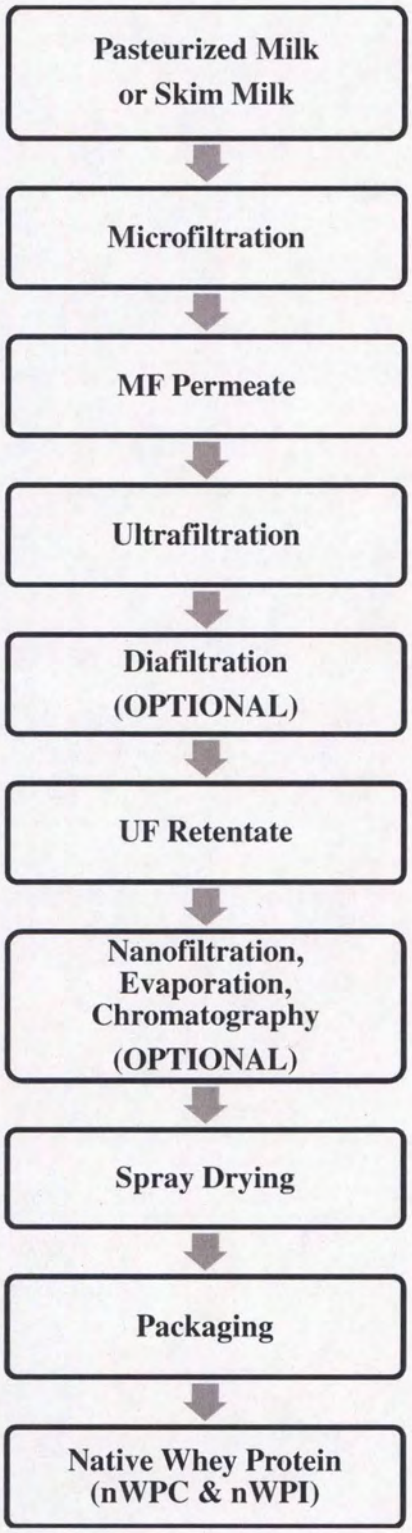
[6] The extraneous material is removed when the raw milk enters the plant. All raw milk is screened as it is pumped from the tanker truck to the plant's tank. The raw milk is tested for sediment where it must meet the state and federal levels for sediment. Because extraneous matter is removed at the outset, milk containing extraneous matter is not introduced into the membrane filtration system.

[7] The microfiltration process described in this GRAS Notice is the same process that FDA evaluated in its review of GRN No. 504 for concentrated milk proteins.

Figure 1. Manufacturing Process Flow Chart



V. Consideration of Potential Contaminating Materials

A. Pesticide Residues

Native whey protein is tested regularly for the presence of pesticides such as organophosphorous and organosulfur, carbamate, organonitrogen, halogenated pesticides, and phenylurea herbicides. The results show that no pesticides have been detected in the product. The raw milk used in the production of native whey protein is produced in accordance with good agricultural practices, and as such, meets applicable state and federal regulations. More specifically, the fluid cow's milk starting material meets regulatory limits on veterinary drug residues, polychlorinated biphenyls (PCBs), and pesticides. Neither the fluid milk starting material nor the finished native whey protein contains radionuclides in excess of FDA's Derived Intervention Levels (DILs).[8] The fluid milk starting material does not exceed FDA's limit of 0.5 ppb for aflatoxin M1.[9]

B. Melamine

Native whey protein is tested regularly to verify absence of melamine. The results show that melamine is not present in this product. All equipment used in the manufacture of this product and its packaging materials are melamine free. The analytical method for melamine detection follows FDA LIB 4421 Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS.[10]

C. Other Contaminants

The milk used in the production of native whey protein is tested regularly for any potential contaminants. Procedures for sampling, analysis, and reporting are presented in the PMO.[11] The document states "industry shall screen all bulk milk pickup tankers, regardless of final use, for Beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers when the Commissioner

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[8] FDA, CPG Sec. 560.750, Radionuclides in Imported Foods – Levels of Concern (Updated 11/29/05), available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074576 (last accessed on February 17, 2016).

[9] FDA, CPG Sec. 527.400, Whole Milk, Lowfat Milk, Skim Milk – Aflatoxin M1 (Updated 11/29/05), available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074482.htm (last accessed on February 17, 2016).

[10] FDA Laboratory Information Bulletin LIB No. 4421 Volume 24, October 2008 Determination of Melamine and Cyanuric Acid Residues in Infant Formula using LC-MS/MS, available at: http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071637.htm (last accessed on February 17, 2016).

[11] FDA, Grade "A" Pasteurized Milk Ordinance (2013 Revision), at Appendix N ("Drug Residue Testing and Farm Surveillance – Industry Responsibilities – Monitoring and Surveillance").

of the FDA determines that a potential problem exists as cited in [Section 6 of the PMO]. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. Samples collected under this random sampling program shall be analyzed as specified by FDA." The Notifier follows PMO guidelines with respect to monitoring for contaminants during the production of native whey protein. Finally, we note that the native whey protein covered by this GRAS Notice will be made solely from milk produced within the U.S.

VI. Nutrition – Protein Identification and Digestibility

Native whey protein products are essentially the same as traditional whey protein products, with the key distinction being that they are not derived from the cheese making process. In terms of nutritional composition, native whey protein provides substantially the same macronutrient profile as traditional whey protein. The native whey protein manufacturing process utilizes physical separation processes that simply concentrate the milk proteins and do not result in any substantive alteration to the chemical character of the milk constituents. Thus, the native whey protein is as nutritious as milk itself – and as nutritious as traditional whey protein – and the protein digestibility is essentially equivalent to that of other dairy proteins. The value of the protein digestibility-corrected amino acid score (PDCAAS) for whey protein derived from cheese making has been shown to be 1.14, higher than for beef (0.9), soy (0.93) or wheat (0.42).[12] Since native whey protein is derived from cow's milk using only physical separation processes, the PDCAAS for native whey protein is expected to be similar to, or better than, that of whey protein derived from cheese making.

The nutritional utilization of milk proteins has been studied in both animals and humans.[13] It has been shown that milk proteins are of particularly excellent nutritional value in humans with a true digestibility and a net postprandial protein utilization of 95-96% and 74%, respectively.[14]

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[12] Schaafsma G. The Protein Digestibility-Corrected Amino Acid Score. J Nutr 2000; 130:1865S-1867S (internal citations omitted).

[13] Cook BB, Morgan AF, Singer B, Parker J. The effect of heat treatment on the nutritive value of milk proteins. II. Rat growth studies with casein and lactalbumin and their lactose derivatives. J Nutr 1951;44:63–81; Gilani GS, Sepehr E. Protein digestibility and quality in products containing antinutritional factors are adversely affected by old age in rats. J Nutr 2003;133:220–5; Rutherfurd SM, Moughan PJ. The digestible amino acid composition of several milk proteins: application of a new bioassay. J Dairy Sci 1998; 81:909–17; Bos C, Gaudichon C, Tome D. Nutritional and physiological criteria in the assessment of milk protein quality for humans. J Am Coll Nutr 2000;19(suppl):191S–205S; Gaudichon C, Mahe S, Benamouzig R, et al. Net postprandial utilization of [15N]- labeled milk protein nitrogen is influenced by diet composition in humans. J Nutr 1999;129:890–5.

[14] Bos C, Mahe S, Gaudichon C, et al. Assessment of net postprandial protein utilization of 15N-labelled milk nitrogen in human subjects. Br J Nutr 1999;81:221–6; Bos C, Metges CC, Gaudichon C, et al. Postprandial kinetics of dietary amino acids are the main determinant of their metabolism after soy or milk protein ingestion in humans. J Nutr 2003;133:1308–15; Gausseres N, Mahe S, Benamouzig R, et al. [15N]-labeled pea flour protein nitrogen exhibits good ileal digestibility and postprandial retention in

VII. Basis for GRAS Determination

A. Regulatory Status of Milk Protein Products

As discussed further below, several substances that are similar to native whey protein have already been affirmed as GRAS or have been the subject of GRAS Notices. Milk proteins are classified under two major groups: whey proteins (20%) and caseins (80%).[15] Whey proteins, in particular, are the soluble proteins that remain when milk coagulates. Like the GRAS substances described below, the native whey protein that is the subject of the current GRAS Notice is manufactured through physical separation techniques. Therefore, the constituents of the final product are no different in substance than the other milk protein products described below. Due to the similarities between native whey protein and the substances described below, FDA's acceptance of the GRAS status of the following substances has direct implications for the GRAS status of native whey protein.

Whey protein concentrate is GRAS affirmed at 21 C.F.R. § 184.1979(c). The regulation states that whey protein concentrate is the substance obtained by the removal of sufficient non-protein constituents from whey so that the finished dry product contains not less than 25 percent total protein. Whey protein concentrate is produced by physical separation techniques such as precipitation, filtration, or dialysis. As with whey, whey protein concentrate can be used as a fluid, concentrate, or dry product form.

In GRAS Notice No. GRN000011, FDA had no questions regarding the GRAS determination of a "mixture of calcium casein peptone and calcium phosphate (CCP-CP)" for use as a texturizer in chewing gum at a level not to exceed 5%.[16] CCP-CP is produced by the enzymatic hydrolysis of casein to form casein peptone, which is then complexed with amorphous calcium phosphate to form a calcium casein peptone-calcium phosphate complex. Casein peptones have been GRAS affirmed for the direct addition to human foods at 21 C.F.R. § 184.1553.

In GRAS Notice No. GRN000037, FDA had no questions regarding the GRAS determination of "whey protein isolate" for use in high-energy food and beverage products such as yogurts, pudding, ice cream, margarine, and mayonnaise. Similarly, also in GRAS Notice No. GRN000037, FDA had no questions regarding the GRAS determination of "dairy product

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humans. J Nutr 1997;127:1160–5; Morens C, Bos C, Pueyo ME, et al. Increasing habitual protein intake accentuates differences in postprandial dietary nitrogen utilization between protein sources in humans. J Nutr 2003;133:2733–40.

[15] *See, e.g.,* Institute of Food Technologists, Food Chemistry Experiments, IFT Experiments in Food Science Series, at page 3-1, available at: http://www.ift.org/~/media/Knowledge%20Center/Learn%20Food%20Science/Experiments/TeacherGuidePROTEINS.pdf (last accessed on February 17, 2016).

[16] FDA Response to GRN000011, available at: http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154906.htm (last accessed on February 17, 2016).

solids" for use in a variety of foods and in the production of alcohol and organic chemicals, galactose and glucose syrups, and sugar and corn syrup replacers. Both whey protein isolate and dairy product solids are manufactured using physical separation techniques involving the application of membrane filtration systems and optional dialysis to process whey.[17]

In GRAS Notice No. GRN000052, FDA had no questions regarding the GRAS determination of "whey mineral concentrate" for use as a source of calcium in fortified beverages, fortified foods, and enriched dairy products. Whey mineral concentrate is produced by subjecting pasteurized fluid whey to a precipitation and membrane separation process, followed by purification and drying. The resulting concentrate is a free-flowing white powder that is soluble at acid pH.[18]

In GRAS Notice No. GRN 000196, FDA did not object to the determination that "bovine milk basic protein fraction (BMBPF)" is GRAS for use in cottage cheese, imitation milk (including rice and soy milk), juice, meal replacement bars and drinks, milk, processed cheese, salad dressing, and yogurt at levels of up to 40% in some of the applications. BMBPF is produced from pasteurized bovine skim milk that is applied to a cation exchange chromatographic column, removing acid milk proteins and lactose. The basic proteins remaining on the column are eluted from the resin using sodium chloride. The resulting eluate is concentrated and dialyzed to produce BMBPF solids. These BMBPF solids are then crushed and packaged.[19]

Finally, in GRAS Notice No. GRN000504, FDA had no questions regarding the GRAS determination related to "milk protein concentrate" containing 42 to 85 percent protein and "milk protein isolate" containing greater than 90 percent protein produced by ultrafiltration of skim milk. The concentrated milk proteins described in GRN000504 were determined to be GRAS for use as ingredients in: meal replacements and meal supplements, milk products including milk drinks, yogurt, fermented milks, spreads, dips; non-standardized cheese products; dairy product analogs; frozen dairy desserts and mixes; desserts and mousses; confections and frostings; snack foods; coatings and fillings; salad dressings; soups and soup mixes; and sauces.

The GRAS Affirmations and Notices above exhibit FDA's confidence in the safety of these milk-derived ingredients. Similar to the milk-derived ingredients above, native whey protein is produced using physical processes that do not present any safety concerns that have not already been addressed in the existing, favorably-reviewed GRAS Affirmations and Notices discussed above.

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[17] FDA Response to GRN000037, available at: http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154133.htm (last accessed on February 17, 2016).

[18] FDA Response to GRN000052, available at: http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm153729.htm (last accessed on February 17, 2016).

[19] FDA Response to GRN000196, available at: http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm154673.htm (last accessed on February 17, 2016).

B. Safety Overview

Due to the substantial similarities between native whey protein and traditional whey protein, as well as the substantial similarities between these products and the concentrated milk proteins that are the subject of GRN No. 504, the safety discussion related to the latter group of products is directly applicable to establishing the safety and GRAS status of native whey protein. We incorporate the safety overview provided in GRN No. 504 by reference and highlight the relevance of those safety data to our assessment of native whey protein below.

1. Human Consumption of Milk Protein

The raw material used in the manufacture of native whey protein is milk or skim milk. Milk and products derived from milk, such as whey, have a long history of safe consumption by humans at all ages in the form of fluid milk, in dried form (i.e., milk powder), or as milk-derived ingredients.

2. Purification of Native Whey Protein

Native whey protein is manufactured using safe and well-characterized physical separation techniques that are analogous to the processes employed in the manufacture of the whey protein concentrate and whey protein isolate products described above. Such physical separation processes do not cause substantive alterations to the chemical character and safety-related properties of the constituents. The food additives that may be utilized in the manufacturing process for native whey are all either approved food additives or GRAS food ingredients for these applications and are used in accordance with food cGMP. The manufacturing process does not generate, concentrate, or introduce any potential toxicants. As a result, the native whey protein is as safe as milk itself.

3. Safety Studies on Native Whey Protein

Given the long history of human consumption of milk, milk and milk proteins are of little toxicological concern to humans or animals. With the exception of particularly sensitive populations – namely milk-allergic and lactose-intolerant individuals, whom we address below – we are not aware of adverse effects associated with consumption of native whey protein. In addition, a literature search does not yield any reported adverse effects.

4. Allergenicity of Milk Protein

An allergy to milk is among the eight most common food allergies.[20] Because the substances are chemically identical, milk and concentrated milk proteins will produce similar incidences of protein allergy when consumed. All concentrated milk protein ingredients, including native whey protein, will clearly indicate that that the product is derived from milk protein and will inform those consumers who are allergic to milk and satisfy food allergen labeling requirements.

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[20] "Eight major foods or food groups – milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans– account for 90 percent of food allergies." Pub. L. 108-282, title II § 202(1)(2)(A) (Aug. 2, 2004).

5. Lactose Intolerance

Lactose intolerance is the inability or insufficient ability to digest lactose, a sugar found in milk and milk products. Lactose intolerance is caused by a deficiency of the enzyme lactase, which is produced by the cells lining the small intestine. Lactase breaks down lactose into two simpler forms of sugar called glucose and galactose, which are then absorbed into the bloodstream. People with lactose intolerance may feel uncomfortable 30 minutes to 2 hours after consuming milk and milk products. Symptoms range from mild to severe based on the amount of lactose consumed and the amount a person can tolerate. Common symptoms include abdominal pain, abdominal bloating, gas, diarrhea, and nausea.[21]

Research indicates that most people with lactose intolerance are able to consume the amount of lactose in up to 2 cups of milk a day if taken with meals, one at breakfast and the other at dinner. Other dairy foods, such as aged cheese and yogurts are also well-tolerated because lactose is converted to lactic acid by select microorganisms during the making of the products.[22]

The percentage of lactose is inversely related to the protein content of the concentrated milk protein. The percentage of lactose in native whey protein products is 13% and 4% for native whey protein concentrate and native whey protein isolate, respectively. These levels are lower than the level of lactose in Nonfat Dry Milk, which is around 49.0-52.3%.[23] Therefore, we do not anticipate any unique impact on lactose sensitive populations.[24]

C. Estimated Consumption of Native Whey Protein Derived From Proposed Food Uses

The typical proposed food uses of native whey protein in food are provided in **Table 4.**

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[21] Lactose Intolerance, National Digestive Diseases Information Clearinghouse (NDDIC), available at: http://digestive.niddk.nih.gov/ddiseases/pubs/lactoseintolerance/ (last accessed on February 17, 2016).

[22] National Dairy Council, Handbook of Dairy Foods and Nutrition 6 (3rd ed. 2006).

[23] The Really BIG List of Lactose Percentages, available at: http://www.stevecarper.com/li/list_of_lactose_percentages.htm (last accessed on February 17, 2016).

[24] Additional information on lactose intolerance can be found in the scientific status report from the National Dairy Council, available at: https://www.nationaldairycouncil.org/content/2015/science-summary-dairy-and-lactose-intolerance (last accessed on February 17, 2016).

Table 4. Proposed Food Uses of Native Whey Protein in Food

Food Category	Application	Function	Native Whey Protein Incorporation Level
Nutritional Products	Meal Replacements and Meal Supplements	Emulsification, heat stability, source of high quality protein, flavor	5-15%
	Powdered Nutritional Beverages	Source of high quality protein, organoleptic appeal	10-100%
	Nutritional Bars	Source of high quality protein, cohesiveness, flexibility, chewiness control	5-50%
	Acidified Sports Beverages	Heat stability, source of high quality protein	5-15%
Dairy and Dairy Based Products*	Milk Products (including dairy beverages and coffee creamer)	Sedimentation stability, protein enrichment, mouthfeel	1-15%
	Yogurt and Fermented Milk Products	Texturizing thickener	1-5%
	Non Standardized Cheese Products	Texturizing thickener, fat stabilization	1-10%
	Spreads, Dips and Cream Substitutes	Mouthfeel, fat replacement	1-15%
	Frozen Dairy Desserts and Mixes*	Stabilization, emulsification	1-10%

Sugar Based Products	Desserts and Mousses	Foaming, reduction of lactose content	<5%
	Confections (including chocolate confections) *	Source of lactose[25], mouthfeel, dairy flavor	1-10%
	Snack Foods	Flavor carrier, dairy flavor, texture	1-10%
	Coatings and Fillings	Flavor carrier, dairy flavor, texture	1-10%
Dressings	Salad Dressings	Emulsification, flavor	<5%
Other	Soups, Soup Mixes, and Sauces	Reduction of stabilizer,[26] dairy flavor, creaminess	2-10%

* Where, and within limits permitted by, existing standards of identity or any other regulations

Due to the relative novelty of native whey protein products, specific consumption data are not available at this time. However, because native whey protein products are equivalent to traditional whey protein products from the standpoint of nutritional properties and safety, and because native whey protein products effectively will substitute for traditional whey protein products in the marketplace, we anticipate no issues related to dietary exposure.

As a conservative numeric estimate, we have calculated dietary exposure using data available for an analogous dairy protein product, micellar casein. The total 2010 domestic market for micellar casein (all protein levels) was estimated to be 5,000 metric tons (5.0×10^6 kg).[27] The total population of the United States in 2010 was about 310 million people.[28] The mean daily consumption of micellar casein per capita is as follows:

5.0×10^6 (kg/year) x 10^3 (g/kg) ÷ 310 x 10^6 (persons) ÷ 365 (days/year) = 0.044 g/person/day

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[25] Where the technical effect is as a "source of lactose," native whey protein is added as a nutritive sweetener.

[26] The function listed as "reduction of stabilizer" refers to the emulsifying function performed by the native whey in soups, soup mixes, and sauces.

[27] DH Business Consulting and Associates, Micellar casein ingredients business & market analysis (2013).

[28] The 2016 population of the United States is slightly higher than this figure, but we have used a 2010 population estimate to remain conservative and consistent with the available market data for micellar casein.

We conservatively assume that the protein content of the micellar casein comprises 90% of the product. The mean daily protein intake from micellar casein per capita would thus be:

0.044 g/person/day x 90% = 0.040 g/person/day

If we assume that the entire amount of micellar casein produced in the United States is consumed by only 10% of the population ("eaters-only"), the daily consumption of micellar casein per capita for the eaters-only population would be 0.44 g/person/day and the daily protein intake from micellar casein per capita would thus be 0.40 g/person/day. **Table 5** provides recommendations for milk intake taken from GRN No. 504 for concentrated milk proteins:

Table 5. Recommendations for Milk Intake

Male and Female Age Groups	Number of 8 ounce cups per Day	Milk Protein Equivalent grams/daily
<1-3 years	1-2	8-16
4-8 years	2-3	16-24
9-18 years	4	32
19-50 years	3	24
51+ years	3	24

The recommended daily protein intake from milk for the general population, excluding infants, ranges between 8 and 32 grams per day, depending on age cohort. In addition, FDA has established a Daily Reference Value (DRV) of 50 g/day for protein for adults and children aged 4 or older.[29] The Institute of Medicine (IOM) has established a Recommended Dietary Allowance (RDA) for protein of 56 g/day for adult males and 46 g/day for adult females.[30] The estimated daily protein intake from micellar casein is approximately 0.040 g/person/day, which is a fraction of the recommended protein intake. Even considering the eaters-only population, which provides the most conservative estimate of consumption, the daily protein intake from micellar casein of 0.40 g/person/day is far less than the recommended protein intake described above. These data serve as a proxy for a native whey protein consumption estimate, and they indicate there is no safety concern at the intended use levels.

Most of the population's protein intake is derived from, and will continue to be

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[29] FDA Guidance for Industry: A Food Labeling Guide, Calculate the Percent Daily Value for the Appropriate Nutrients, available at: http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm064928.htm (last accessed on February 17, 2016).

[30] Dietary Reference Intakes (DRIs): Recommended Dietary Allowances and Adequate Intakes, Total Water and Macronutrients. Food and Nutrition Board, Institute of Medicine, National Academies, available at: http://www.iom.edu/Activities/Nutrition/SummaryDRIs/~/media/Files/Activity%20Files/Nutrition/DRIs/5_Summary%20Table%20Tables%201-4.pdf (last accessed on February 17, 2016).

derived from, unprocessed foods, including meat, poultry, fish, and legumes. Moreover, for those processed foods to which the native whey protein will be added, there are competitive products on the market. Thus, the addition of native whey protein simply will serve as a replacement for these other competitive protein sources and will not increase consumer exposure to protein. Therefore, we do not realistically expect that the actual consumption of foods containing native whey protein will contribute to a significant portion of total protein intake.

D. Directions for Labeling

For any food containing native whey protein, the label will bear a statement indicating that the product has been derived from a milk source to satisfy allergen labeling requirements. A food containing native whey protein will have an ingredient statement stating "Native Whey Protein Concentrate" if the protein content is greater than 79.5% on a dry weight basis or "Native Whey Protein Isolate" if the protein content is greater than 89.5% on a dry weight basis.

VIII. Summary of Basis for GRAS Determination

Leprino Foods Company has determined that native whey protein, including native whey protein concentrate (nWPC) and native whey protein isolate (nWPI), is Generally Recognized as Safe (GRAS) based on the following:

- The fact that native whey protein is manufactured under current good manufacturing practices (cGMP) for food (21 C.F.R. Part 110) and meets appropriate food grade specifications;
- That potential contaminants such as pesticides and heavy metals are either absent (not detected) or below toxicological and regulatory limits;
- The digestibility and nutritional quality of native whey protein;
- The intended uses and the estimated consumption of native whey protein;
- The proper labeling of the products;
- Supportive evidence from the long history of safe use of milk and milk protein as food; and
- Supportive evidence from the successful GRAS Notice for concentrated milk proteins, GRN No. 504.

IX. Conclusion

Based on the documentation provided in this GRAS Notice, and as discussed above, Leprino Foods Company has concluded that native whey protein is GRAS via scientific procedures for use in a variety of foods and beverages.

Appendix 1

Batch Analysis for nWPI

Parameter	Batch 1 (05/17/14)	Batch 2 (06/13/14)	Batch 3 (10/08/14)	Batch 4 (11/12/14)	Batch 5 (5/14/15)
% Water	4.62	5.02	5.01	4.15	4.51
% Protein (dry basis)	92.63	93.47	92.51	94.47	93.19
% Fat	0.74	0.08	0.34	0.14	0.52
% Minerals	2.97	2.14	3.26	1.33	2.11
% Carbohydrate	3.32	3.98	3.51	3.83	3.87
Standard Plate Count, cfu/g	8400	2300	6000	990	2000
Coliform, cfu/g	<10	<10	<10	<10	<10
E coli, cfu/g	<10	<10	<10	<10	<10
Salmonella, /375 g	NEG	NEG	NEG	NEG	NEG
Yeast and Molds, cfu/g	<10	<10	<10	<10	<10
Listeria monocytogenes, /25 g	NEG	NEG	NEG	NEG	NEG
Staphylococcus aureus, cfu/g	<10	<10	<10	<10	<10

Unless otherwise specified, all composition is based on an "as is" basis.

Appendix 2

Batch Analysis for nWPC

Parameter	Batch 1 (7/14/15)	Batch 2 (8/25/15)	Batch 3 (9/14/15)	Batch 4 (9/28/15)	Batch 5 (10/13/15)
% Water	5.05	4.82	4.98	5.21	5.08
% Protein (dry basis)	81.32	80.78	80.74	81.57	80.32
% Fat	0.69	0.26	0.59	0.33	0.12
% Minerals	3.12	2.89	2.09	1.26	1.76
% Carbohydrate	13.93	15.14	15.62	15.88	16.8
Standard Plate Count, cfu/g	7600	1900	5850	790	1750
Coliform, cfu/g	<10	<10	<10	<10	<10
E coli, cfu/g	<10	<10	<10	<10	<10
Salmonella, /375g	NEG	NEG	NEG	NEG	NEG
Yeast and Molds, cfu/g	<10	<10	<10	<10	<10
Listeria Monocytogenes, /25g	NEG	NEG	NEG	NEG	NEG
Staphylococcus Aureus, cfu/g	<10	<10	<10	<10	<10

Unless otherwise specified, all composition is on an "as is" basis.

SUBMISSION END