

GR



Original Submission

000001

LAW OFFICES  
**KELLER AND HECKMAN LLP**

1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001  
TELEPHONE (202) 434-4100  
FACSIMILE (202) 434-4646

25 RUE BLANCHE  
B-1060 BRUSSELS  
TELEPHONE 32(2) 541 05 70  
FACSIMILE 32(2) 541 05 80

WWW.KHLAW.COM

JOSEPH E. KELLER (1907-1994)  
JEROME H. HECKMAN  
WILLIAM H. BORGHESE, JR.  
MALCOLM D. MACARTHUR  
WAYNE V. BLACK  
TERRENCE D. JONES  
MARTIN W. BERCOVICI  
JOHN S. ELDRED  
RICHARD J. LEIGHTON  
ALFRED S. REGNERY  
DOUGLAS J. BEHR  
RAYMOND A. KOWALSKI\*  
MICHAEL F. MORRONE  
JOHN B. RICHARDS  
JEAN SAVIGNY\*  
JOHN B. DUBECK  
PETER L. DE LA CRUZ  
MELVIN S. DROZEN  
LAWRENCE P. HALPRIN  
RALPH A. SIMMONS  
RICHARD F. MANN

C. DOUGLAS JARRETT  
SHEILA A. MILLAR  
GEORGE G. MISKO  
PATRICK J. HURD  
DAVID G. SARVADI  
CATHERINE R. NIELSEN  
MARK MANSOUR\*  
ELLIOT BELILOS  
JEAN-PHILIPPE MONTFORT\*  
JOAN C. SYLVAIN\*  
JUSTIN C. POWELL  
GEORGE BRENT MICKUM, IV  
COLETTE FERRIS-SHOTTON  
ARTHUR S. GARRETT III  
ROBBIE S. PITT  
ELIZABETH N. HARRISON  
JOHN B. RODGERS  
MARTINE MARRAPESE  
PETER A. SAARI\*  
NEGIN MONTADI  
NICOLE B. DONATH  
DAVID R. JOY  
FREDERICK A. STEARNS

TODD A. HARRISON\*  
JOHN F. FOLEY  
TONYE RUSSELL EPPS  
THOMAS C. BERGER  
RACHIDA SEMAIL\*  
JOHN DOBSON\*  
DANIEL QUINTART\*  
KOMAL J. HERSHBERG  
PAULA DEZA  
JOHN B. O'LOUGHLIN, JR.  
DEVON W. HILL  
N. A. JOY MATHEW  
JOANNA R. SOFFA  
AMY E. FORTENBERRY  
PAMELA L. GAUTHIER  
COLLEEN M. EVALE  
ANN W. BOECKMAN\*  
SANA D. COLEMAN  
DEBORAH W. ZIFFER\*  
JEFFREY A. KEITHLINE\*  
MICHAEL D. OLSEN\*  
MICHELLE L. DAUPHINAIS\*  
FRANK J. VITOLO\*

\*NOT ADMITTED IN D.C.  
\*RESIDENT BRUSSELS

SCIENTIFIC STAFF  
DANIEL S. DIXLER, Ph.D.  
CHARLES V. BREDER, Ph.D.  
ROBERT A. MATHEWS, Ph.D., D.A.B.T.  
JOHN P. MODDERMAN, Ph.D.  
(1944-1998)  
HOLLY HUTMIRE FOLEY  
JANETTE HOUK, Ph.D.  
LESTER BORODINSKY, Ph.D.  
THOMAS C. BROWN  
MICHAEL T. FLOOD, Ph.D.  
ANNA GERGELY, Ph.D.  
STEFANIE M. CORBITT  
JUSTIN J. FREDERICO, Ph.D.  
ROBERT J. SCHEUPLEIN, Ph.D.  
RACHEL F. JOYNER  
ELIZABETH A. HEGER  
TELECOMMUNICATIONS  
ENGINEER  
RANDALL D. YOUNG  
WRITER'S DIRECT ACCESS

January 13, 2000

**Via Hand Delivery**

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

**Re: Conversion of GRAS Petition No. 1G0371 to a GRAS Notification for Whey Protein Isolate and Dairy Product Solids**

Dear Dr. Rulis:

On behalf of our client, the American Dairy Products Institute (ADPI), enclosed please find one original and two copies of an amendment to the referenced GRAS affirmation petition. In accordance with proposed 21 C.F.R. § 170.36(g) ("Notice of a claim for exemption based on a GRAS determination"), 62 *Fed. Reg.* 18938, 18961 (Apr. 17, 1997), the purpose of this amendment is to convert the pending GRAS affirmation petition for whey protein isolate and dairy product solids into a GRAS Notification. The attached amendment provides a GRAS exemption claim, which is required to effect such a conversion. 62 *Fed. Reg.* at 18954, 18961 (proposed 21 C.F.R. § 170.36(g)(2)).

(202) 434-4229  
mann@khlaw.com

2000 JAN 14 P 3: 09

000002

Alan M. Rulis, Ph.D.  
January 13, 2000  
Page 2

We trust you will find the enclosed amendment acceptable. Should any questions arise during the review process, please do not hesitate to contact us.

Very truly yours,  
KELLER AND HECKMAN LLP

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

Enclosures

000003

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

**GRAS EXEMPTION CLAIM**

**Amending GRAS Petition No. 1G0371**

Name of Notifier: American Dairy Products Institute  
(ADPI)

Post Office Address: All communications on this matter are to  
be sent in care of Washington Counsel  
for the Notifier, Richard F. Mann, 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 Substances and  
and Intended Use: Whey Protein Isolate and Dairy Product  
Solids for use as direct human food  
ingredients.

Dated: January 13, 2000

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

**000004**

NOTICE OF A CLAIM FOR EXEMPTION  
BASED ON A GRAS DETERMINATION FOR  
WHEY PROTEIN ISOLATE AND DAIRY PRODUCT SOLIDS

**A. GRAS Exemption Claim for Whey Protein Isolate (WPI)**

**(i) Name and Address of Notifier:**

American Dairy Product Institute (ADPI)

300 West Washington Street # 400

Chicago, Illinois 60606.

All communications on this matter are to be sent in care of Washington

Counsel for the Notifier, Richard F. Mann, Keller and Heckman LLP, 1001

G Street, N.W., Suite 500 West, Washington, D.C. 20001.

Telephone: (202) 434-4229

Facsimile: (202) 434-4646.

**(ii) Applicable GRAS affirmation petition number:**

GRAS Petition No. 1G0371.

**(iii) Common or usual name of the notified substance:**

Whey protein isolate (WPI).

**(iv) Applicable conditions of use:**

There are two major applications for WPI—nutritional and functional. WPI is used for nutritional purposes as a source of high quality protein in a wide variety of high-energy food and beverage products. WPI also provides excellent protein functionality, and may be used to facilitate gelation (yogurts, pudding), foaming

**000005**

and whipping (toppings and fillings), water binding (meat, sausage), and emulsification (ice cream, margarine, mayonnaise). It has been used in soups and sauces, low calorie spreads, beverages, and egg white replacers. Proposed uses include edible coatings to be used as moisture barriers in prepared foods.

**(v) Basis for GRAS determination**

The described uses of WPI are generally recognized as safe (GRAS) based on experience through common use in food, as discussed more fully in GRAS Petition No. 1G0371. This petition was accepted for filing by the Food and Drug Administration in 1995. See 60 *Fed. Reg.* 6713 (February 3, 1995).

**(vi) Statement of availability of data**

The complete record that supports this GRAS determination has been submitted to FDA in GRAS Petition No. 1G0371.

**B. GRAS Exemption Claim for Dairy Product Solids**

**(i) Name and Address of Notifier:**

American Dairy Product Institute (ADPI)

300 West Washington Street # 400

Chicago, Illinois 60606.

All communications on this matter are to be sent in care of Washington

Counsel for the Notifier, Richard F. Mann, Keller and Heckman LLP, 1001

G Street, N.W., Suite 500 West, Washington, D.C. 20001.

Telephone: (202) 434-4229

Facsimile (202) 434-4646

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

Dairy Product Solids.

**(iii) Applicable GRAS affirmation petition number:**

GRAS Petition No. 1G0371.

**(iv) Applicable conditions of use:**

"Dairy product solids" are used in a wide variety of foods in fluid, concentrate, or in dry product form. In addition, the product may be used in alcohol production, fermentation to organic chemicals, hydrolysis to galactose and glucose syrups, and sugar and corn syrup replacers.

**000007**

**(v) Basis for GRAS determination**

The described uses of dairy product solids have been shown to be generally recognized as safe (GRAS) based on experience through common use in food, as discussed more fully in GRAS Petition No. 1G0371. This petition was accepted for filing by the Food and Drug Administration in 1995. See 60 *Fed. Reg.* 6713 (February 3, 1995).

**(vi) Statement of availability of data**

The complete record that supports this GRAS determination has been submitted to FDA in GRAS Petition No. 1G0371.

\* \* \*

The foregoing information considered, it is respectfully submitted that the proposed and current uses of WPI and dairy product solids are exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because these substances are generally recognized as safe.

Respectfully submitted,

AMERICAN DAIRY PRODUCTS INSTITUTE

By: \_\_\_\_\_  
Richard F. Mann  
Keller and Heckman LLP  
COUNSEL FOR THE NOTIFIER

**000008**

End Submission

000009



LAW OFFICES

**KELLER AND HECKMAN LLP**

1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001  
TELEPHONE (202) 434-4100  
FACSIMILE (202) 434-4646

25 RUE BLANCHE  
B-1060 BRUSSELS  
TELEPHONE 32(2) 541 05 70  
FACSIMILE 32(2) 541 05 80

WWW.KHLAW.COM

JOSEPH E KELLER (1907-1994)  
JEROME H HECKMAN  
WILLIAM H. BORGHESE, JR.  
MALCOLM D. MACARTHUR  
WAYNE V. BLACK  
TERRENCE D. JONES  
MARTIN W. BERCOVICI  
JOHN S. ELDRED  
RICHARD J. LEIGHTON  
ALFRED S. RESNERY  
DOUGLAS J. BEHR  
RAYMOND A. KOWALSKI\*  
MICHAEL F. MORRONE  
JOHN B. RICHARDS  
JEAN SAVIGNY\*  
JOHN B. DUBECK  
PETER L. DE LA CRUZ  
MELVIN S. DROZEN  
LAWRENCE P. HALPRIN  
RALPH A. SIMMONS  
RICHARD F. MANN

C. DOUGLAS JARRETT  
SHEILA A. MILLAR  
GEORGE G. MISKO  
PATRICK J. HURD  
DAVID G. SARVADI  
CATHERINE R. NIELSEN  
MARK MANSOUR\*  
ELIJOT BELLIOS  
JEAN-PHILIPPE MONTFORT\*  
JOAN C. SYLVAIN\*  
JUSTIN C. POWELL  
GEORGE BRENT MICKUM, IV  
COLETTE FERRIS-SHOTTON  
ARTHUR S. GARRETT III  
ROBBIE S. PITT  
ELIZABETH N. HARRISON  
JOHN B. RODGERS  
MARTHA F. MARRAPESE  
PETER A. SAARI\*  
NEGIN MOHTADI  
NICOLE B. DONATH  
DAVID R. JOY  
FREDERICK A. STEARNS

TODD A. HARRISON\*  
JOHN F. FOLEY  
TONYE RUSSELL EPPS  
THOMAS C. BERGER  
RACHIDA SEMAIL\*  
JOHN DOBINSON\*  
DANIEL QUINTART\*  
KOMAL J. HERSHBERG  
PAULA DEZA  
JOHN B. O'LOUGHLIN, JR.  
DEVON W. HILL  
N. AJOY MATHEW  
JOANNA R. SOFFA  
AMY E. FORTENBERRY  
PAMELA L. GAUTHIER  
COLLEEN M. EVALE  
ANN M. BOECKMAN\*  
SANA D. COLEMAN  
DEBORAH W. ZIFFER\*  
JEFFREY A. KEITHLINE\*  
MICHAEL D. OLSEN\*  
MICHELLE L. DAUPHINAIS\*  
FRANK J. VITOLLO\*

\*NOT ADMITTED IN D.C.  
\*RESIDENT BRUSSELS

SCIENTIFIC STAFF  
DANIEL S. DIXLER, Ph.D.  
CHARLES V. BREDER, Ph.D.  
ROBERT A. MATHEWS, Ph.D., D.A.B.T.  
JOHN P. MODDERMAN, Ph.D.  
(1944-1998)  
HOLLY HUTMIRE FOLEY  
JANETTE HOUK, Ph.D.  
LESTER BORODINSKY, Ph.D.  
THOMAS C. BROWN  
MICHAEL T. FLOOD, Ph.D.  
ANNA GERGELY, Ph.D.  
STEFANIE M. CORBITT  
JUSTIN J. FREDERICO, Ph.D.  
ROBERT J. SCHEUPLEIN, Ph.D.  
RACHEL F. JOYNER  
ELIZABETH A. HEGER  
TELECOMMUNICATIONS  
ENGINEER  
RANDALL D. YOUNG  
WRITER'S DIRECT ACCESS

April 4, 2000

(202) 434-4229  
mann@khlaw.com

Linda S. Kahl, Ph.D.  
Division of Product Policy, HFS-206  
Office of Premarket Approval  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Washington, D.C. 20204

Re: GRAS Notice (GRN) No. 000037--Whey Protein Isolate and Dairy Product Solids

Dear Dr. Kahl:

This confirms our telephone conference of March 29, 2000, concerning the statutory basis for the referenced GRAS determination. We agreed that Whey Protein Isolate and Dairy Product Solids should be evaluated for safety on the basis of scientific procedures. We believe that the fact that these food ingredients are components of commonly consumed foods that have been affirmed as Generally Recognized as Safe by the Food and Drug Administration is evidence of their safety.

:Please give us a call, should you have any questions.

Sincerely,  
KELLER AND HECKMAN LLP

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

2000 APR 11 PM 4:44



LAW OFFICES

# KELLER AND HECKMAN LLP

1001 G STREET, N.W.  
SUITE 500 WEST  
WASHINGTON, D.C. 20001  
TELEPHONE (202) 434-4100  
FACSIMILE (202) 434-4848

25 RUE BLANCHE  
B-1060 BRUSSELS  
TELEPHONE 32(2) 541 05 70  
FACSIMILE 32(2) 541 05 80

WWW.KHLAW.COM

JOSEPH E KELLER (1907-1994)  
JEROME H HECKMAN  
WILLIAM H BORGHESE, JR.  
WAYNE V BLACK  
TERRENCE D JONES  
MARTIN W BERCOVICI  
JOHN S ELDRED  
RICHARD J LEIGHTON  
ALFRED S REGNERY  
DOUGLAS J BEHR  
RAYMOND A KOWALSKI  
MICHAEL F MORRONE  
JOHN B RICHARDS  
JEAN SAVIGNY\*  
JOHN B DUBECK  
PETER L DE LA CRUZ  
MELVIN S DROZEN  
LAWRENCE P HALPRIN  
RALPH A SIMMONS  
RICHARD F MANN  
C DOUGLAS JARRETT  
SHEILA A MILLAR  
GEORGE G MISKO

DAVID I READER  
DAVID G SARVADI  
CATHERINE R NIELSEN  
MARK MANSOUR\*  
ELLIOT BELILOS  
JEAN-PHILIPPE MONTFORT\*  
ARTHUR S GARRETT III  
JOAN SYLVAIN BAUGHAN\*  
MARTHA E MARRAPESE  
JUSTIN C POWELL  
GEORGE BRENT MICKUM IV  
ELIZABETH H HARRISON  
LESA L BYRUM  
PETER A SAARI\*  
NEGIN MOHTADI  
NICOLE B DONATH  
DAVID R JOY  
DAVID J ETTINGER  
FREDERICK A STEARNS  
TODD A HARRISON  
JOHN F FOLEY  
TONYE RUSSELL EPPS  
THOMAS C BERGER

RACHIDA SEMAIL\*  
R HOLLAND CAMPBELL  
JOHN DOBSONSON\*  
DANIEL QUINTART\*  
KOMAL J HERSHBERG  
MANESH K RATH  
LYNN LORIS OWENS\*  
DEVON WH HILL  
N AJAY MATHEW  
JOANNA R SOFFA  
PAMELA L GAUTHIER  
ERIC H SINGER\*  
COLLEEN M EVALE  
ANN M BOECKMAN  
DEBORAH W ZIFFER  
JEFFREY A KEITHLINE  
MICHELLE L DAUPHINAIS\*  
FRANK J VITOLO  
JENNIFER B BENNETT\*  
CAREN A C GRAU  
LUTHER L HAJEK\*  
SHANNON M HEIM\*  
CHRISTIAN C SEMONSEN\*

\*NOT ADMITTED IN DC  
◊ RESIDENT BRUSSELS

SCIENTIFIC STAFF  
DANIEL S DIXLER, Ph D  
HOLLY HUTMIRE FOLEY  
CHARLES V BREDER, Ph D  
ROBERT A MATHEWS, Ph D, D ABT  
JANETTE HOUK, Ph D  
LESTER BORODINSKY, Ph D  
THOMAS C BROWN  
MICHAEL T FLOOD, Ph D  
ANNA GERGELY, Ph D  
STEFANIE M CORBITT  
RACHEL F JOYNER  
ELIZABETH A HEGER  
ROBERT J SCHEUPLEIN, Ph D  
ANDREW P JOVANOVIH, Ph D, MBA  
KAREN R OBENSHAIN

TELECOMMUNICATIONS  
ENGINEER  
RANDALL D YOUNG

WRITERS DIRECT ACCESS

January 19, 2001

(202) 434-4229  
mann@khlaw.com

Linda S. Kahl, Ph.D.  
Division of Product Policy, HFS-206  
Office of Premarket Approval  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
Washington, D.C. 20204

**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

000024

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.

000025