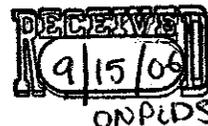




Innovative Dairy & Cheese Ingredients



September 12, 2006

Team Leader, Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS-822)
5100 Paint Brand Pkwy
College Park, MD 20740

Re: Letter dated January 4, 2006 requesting approval to participate in the Extended Temporary Marketing Test of Grated Parmesan Cheese under Docket No. 98P-1121

Dear Sir or Madam:

- I. Preface: DairiConcepts, LP, would like to amend the letter sent to FDA dated January 4, 2006, that requested approval for DairiConcepts to participate in the Extended Temporary Market Test for Parmesan Cheese that deviates from the standards set forth in 21 CFR 133.165 and 21 CFR 133.146 in that the cheese will be cured for 6 months instead of the 10 months called for in the standard. That letter and all of its attachments (excluding the actual labels sent in for approval) is incorporated with this letter and marked Exhibit 2 for September 12, 2006. The amendments we are requesting are delineated below.
- II. Description of Products to be Tested:
 - a. The products we propose to manufacture and market will be for foodservice and ingredients sales only. The retail business referred to in the letter dated January 4, 2006, is a co-packing business where the final retail labels are controlled by our customers. At this time, we would like to proceed with gaining approval for the products and labels that are controlled by DairiConcepts, which are limited to food service and ingredients sales in bulk pack form.
 - b. In addition to the Grated Parmesan Cheese that is produced at our Greenwood, WI, and Chili, WI, facilities (as indicated in our previous letter), we would like to now include Parmesan Cheese in block form that is produced at our Pollock, SD cheese plant. A make procedure for this cheese was attached to our previous letter (see Exhibit 2 for January 4, 2006) as we desire to use this cheese at Greenwood and Chili to produce Grated Parmesan cheese. We now desire to also market 6 month cheese in block form directly from our Pollock facility, for sale as Parmesan Cheese, per the Extended Temporary Market Test.
- III. Product Labels: Reflecting the changes mentioned above, a new set of labels is included with this request, along with a new list of the labels for easier referencing in our correspondence (marked as Exhibit 1 for September 12, 2006). These labels represent the various grated cheese products that will use the 6-month cured Parmesan Cheese. Also included is a pallet tag and block label for the Parmesan cheese produced at Pollock, SD. While these labels are DairiConcepts labels, there is a certain amount of information

DairiConcepts, L.P. 3253 E. Chestnut Expressway, Springfield, MO 65802-2584
Tel 417 829 3400, Fax 417 829 3401

Page 1 of 2



98P-1121

LET 9

DAIRICONCEPTS®

Innovative Dairy & Cheese Ingredients

Team Leader, Conventional Foods Team
September 12, 2006
Page 2 of 2

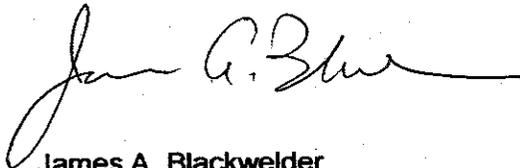
proprietary to our customers on many of these labels, and we request that the labels and the label list be considered as strictly confidential and not available for public access.

- IV. Amount to be Distributed: We seek approval for an additional 25 million pounds per annum for cheese to be marketed in block form as Parmesan Cheese.
- V. In Conclusion: In keeping with the above information and with the information presented in our previous letter of January 4, 2006, we request the FDA's approval to participate in the market test to evaluate the use of Parmesan Cheese cured for 6 months rather than 10 months on the same terms and conditions that have been granted to Kraft Foods, Inc., and other entities.

Because some of the particulars in the exhibits and attachments constitute trade secrets that are critical to the ability of DairiConcepts, its owners, its suppliers, and its customers to maintain a competitive position, we request that the FDA maintain the confidentiality of this material.

If any further information is required to assist in the evaluation of our request, please don't hesitate to contact me by telephone at 417-829-3450, or by e-mail at jblackwelder@dairiconcepts.com.

Sincerely,



James A. Blackwelder
Director, Technology Development

Attachments:

2 Documents

24 Labels

1 Pallet Tag

2006-818

DAIRICONCEPTS[®]

Innovative Dairy & Cheese Ingredients

January 4, 2006

Team Leader, Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS-822)
5100 Paint Brand Pkwy
College Park, MD 20740

Re: 21 CFR 130.17(i)—Participation in the Extended Temporary Marketing Test of “Grated Parmesan Cheese” under Docket No. 98P-1121

Dear Sir or Madam:

I. Preface

- a. This application is submitted in response to the notice (“Notice”) given in the Federal Register dated December 29, 2000 (Volume 65, Number 251) pertaining to parties seeking to participate in the test marketing of grated Parmesan cheese that deviated from the current standards of identity set forth in 21 CFR 133.165 and 21 CFR 133.146. The Notice relates to a petition submitted to the Food and Drug Administration (FDA) by Kraft Foods, Inc., to amend the previously mentioned standard of identity for Parmesan cheese by reducing the period required to cure the product from ten (10) months to six (6) months. We hereby request the FDA’s approval to participate in the market test conditions that have been granted to Kraft Foods, Inc.
- b. This application is also submitted in relation to a letter received by Greenwood Valley Cheese Company, LLC dated May 23, 2002, giving permission to Greenwood Valley to participate in the Temporary Market Test mentioned above. This letter is included for reference and is labeled Exhibit 1. Greenwood Valley Cheese Company, LLC is now fully owned by DairiConcepts, LP. We are hereby seeking to update the permission granted to Greenwood Valley Cheese so that it will now apply to DairiConcepts.
- c. Our grated Parmesan business still operates out of Greenwood, WI, where we continue to operate as a private label packer of grated Parmesan cheese. That is, we process aged Parmesan cheese into a grated format then pack it into packages of various sizes and configurations, and then label the packages with our customers’ brand names.
- d. In accordance with the Notice, the information below is submitted in support for our request to participate in the market test.

II. Description of Products to be Tested

- a. The product we propose to manufacture for retail, foodservice, and ingredient sales is grated Parmesan cheese produced from Parmesan that is cured for six (6) months rather than the ten (10) months specified in 21 CFR 133.165. With the exception for the difference in the length of curing, the products will meet all requirements of the standard of identity applicable to Parmesan cheese.
- b. Two exhibits are included in this communication in reference to the manufacturing procedure for our 6 month cured Parmesan cheese. One is a make instruction for Parmesan from our Pollock, SD, cheese plant and is marked 'Exhibit 2'. The other, marked 'Exhibit 3', is a more detailed report provided from our parent company, Fonterra, located in New Zealand. This is the same report that was included as part of communication sent to the FDA from Greenwood Valley Cheese in 2001 when requesting permission to participate in the market test. Both of these exhibits are marked "Confidential." We request your Department to treat these make procedures as strictly confidential and not available for public access.
- c. The make procedures involve the combined use of safe and suitable enzyme and culturing technology and storage temperature control to produce a fully cured Parmesan cheese within six (6) months. Otherwise, the manufacturing procedure is identical to make procedures that have conventionally been used for Parmesan production. In all respects other than curing time the product will meet the requirements described in 21 CFR 133.165.

III. Product Labels

- a. The labels of the products to be distributed use various product descriptions depending on what is being produced. Samples of 84 labels of various sizes and shapes are included with this request for approval. A list of the 84 labels is also enclosed and is described as Exhibit 4. We request that the sample labels and the list be considered as strictly confidential and not available for public access.
- b. The list includes the brand name or product ID, where applicable, and also the product description used on the label. This should allow for cross-referencing between the labels and the list. Included are products that are 100% Parmesan, that are blends of Parmesan with other cheeses, and that are blends of Parmesan with other safe and suitable food ingredients, as described in the ingredient statements.

DAIRICONCEPTS®

Innovative Dairy & Cheese Ingredients

Team Leader, Conventional Foods Team

January 4, 2006

Page 3 of 3

IV. Amount to be Distributed and Area of Distribution.

- a. We seek approval for nationwide distribution covering a quantity of 22 million pounds per annum of product in retail, foodservice, and ingredient packages.
- b. Nationwide distribution is needed to allow for evaluation of the cheese under different climatic conditions: high/low altitudes and environments with high/low extremes of temperature and humidity. In addition, we believe from a consumer marketing perspective that it is reasonable to test the product amongst different ethnic and geographic populations. Further, our market test includes the foodservice sector that uses Parmesan cheese as a topping and a vital ingredient in specialized sauces and other food preparations that are themselves subject to nationwide distribution.
- c. A quantity of 22 million pounds and nationwide distribution will permit us to obtain the needed acceptance data required to draw the appropriate market test conclusions for our products.

In Conclusion: In keeping with the above information and the exhibits enclosed, we request the FDA's approval to participate in the market test to evaluate the use of Parmesan cheese cured for six (6) months rather than ten (10) months on the same terms and conditions that have been granted to Kraft Foods, Inc.

Because some of the particulars in the exhibits and attachments constitute trade secrets that are critical to the ability of DairiConcepts, its owners, its suppliers, and its customers to maintain a competitive position, we request that the FDA maintain the confidentiality of this material.

If any further information is required to assist in the evaluation of our request, please feel free to contact me by telephone at 417-829-3450, or by e-mail at jblackwelder@dairiconcepts.com.

Sincerely,



James A. Blackwelder
Director, Technology Development.

Attachments:
4 documents
84 sample labels

DairiConcepts, L.P. 3253 E. Chestnut Expressway, Springfield, MO 65802-2584
Tel 417 829 3400, Fax 417 829 3401

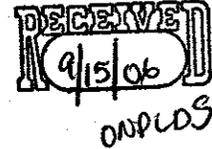




DairiConcepts Exhibit 2
September 12, 2006
Page 1 of 50

January 4, 2006

Team Leader, Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS-822)
5100 Paint Brand Pkwy
College Park, MD 20740



Re: 21 CFR 130.17(i)—Participation in the Extended Temporary Marketing Test of “Grated Parmesan Cheese” under Docket No. 98P-1121

Dear Sir or Madam:

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Team Leader, Conventional Foods Team

January 4, 2006

Page 3 of 3

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Because some of the particulars in the exhibits and attachments constitute trade secrets that are critical to the ability of DairiConcepts, its owners, its suppliers, and its customers to maintain a competitive position, we request that the FDA maintain the confidentiality of this material.

If any further information is required to assist in the evaluation of our request, please feel free to contact me by telephone at 417-829-3450, or by e-mail at jblackwelder@dairiconcepts.com.

Sincerely,

James A. Blackwelder
Director, Technology Development.

Attachments:
4 documents
84 sample labels

647

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE (ADDED TO PREVENT CAKING).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

676

FRESHLY GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-MILK, SALT, ENZYMES)

NET WT. 25 LBS. (11.35kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

810

FRESHLY GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (COW'S MILK, CHEESE CULTURED, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67 kg)

DISTRIBUTED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

536

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

554

GRATED PARMESAN CHEESE - WITHOUT ADDITIVES

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, AND ENZYMES).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

624

GRATED PARMESAN & ROMANO CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 25 LBS. (11.35kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ???? -

KEEP REFRIGERATED

50044

GRATED PARMESAN / ROMANO / ASIAGO CHEESE BLEND

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), ASIAGO CHEESE MADE FROM PASTURIZED MILK, CHEESE CULTURE, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING. POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

50065

GRATED PARMESAN / ROMANO CHEESE BLEND

INGREDIENTS: PARMESAN CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING. POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

50087

REDUCED FAT PARMESAN STYLE GRATED TOPPING

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, ENZYMES), IMITATION FAT FREE PARMESAN CHEESE (WATER, MODIFIED FOOD STARCH, CASEIN AND/OR CASEINATE, SALT, NATURAL FLAVOR, SODIUM PHOSPHATES, STABILIZERS (MONO AND DIGLYCERIDES, GUAR GUM, CARRAGEENAN)), LACTIC ACID, SORBIC ACID (PRESERVATIVE), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

876

GRATED PARMESAN CHEESE
LOW MOISTURE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L. P.
GREENWOOD, WI 54437

KEEP REFRIGERATED

LOT # ????????????

CASE # ????

50037

FRESHLY GRATED PARMESAN/ROMANO CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 25 LBS. (11.35 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L. P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

50038

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING, POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

69487

GRATED PARMESAN & ROMANO CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING. POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

STORE IN COOL DRY PLACE

50098

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 25 LBS. (11.33 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED

69832

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 25 LBS. (11.35 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED

69431

GRATED ITALIAN CHEESE BLEND

INGREDIENTS: HARD GRATING CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), PARMESAN CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), ROMANO CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING. POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED

69899

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED

69475

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART - SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING. POTASSIUM SORBATE (PRESERVATIVE).

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY: DAIRICONCEPTS, L.P. GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED

69916

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ?????

KEEP REFRIGERATED
STORE BELOW 23° C

69932

GRATED PARMESAN CHEESE

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), POWDERED CELLULOSE ADDED TO PREVENT CAKING.

NET WT. 50 LBS. (22.67 kg)

MANUFACTURED BY:
DAIRICONCEPTS, L.P.
GREENWOOD, WI 54437

LOT # ????????????

CASE # ????

KEEP REFRIGERATED

Product: PARMESAN
Plt: 46-237
Mfg Date: 08/31/06
Net Weight (lb)

40.35

Vat # 1
Pallet # 1
Block# 1
Item# 000280032

INGREDIENTS: Cultured
Pasteurized Part-Skim Milk,
Salt, and Enzymes.

Parmesan, Block, Unboxed

Item #

000280032

Item #



000280032

Lot #

Lot #

0250621201

0250621201

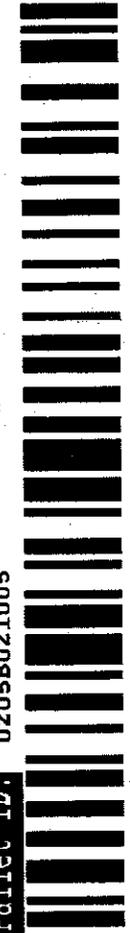
Unit #

03

Pallet ID:

0205B021005

Pallet #03



Net Weight:



July 31, 2006

DairiConcepts