



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Docket
Public Health Service

Food and Drug Administration
College Park, MD

JUL 25 2002

4155 '02 JUL 29 A9:29

Peter S. Janzen
Associate General Counsel
Law Department
Land O'Lakes, Inc.
Post Office Box 64101
St. Paul, Minnesota 55164-0101

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

Dear Mr. Janzen:

This is to acknowledge your letter of February 18, 2002, to the Food and Drug Administration (FDA), accepting the agency's invitation to participate in the extended temporary market testing of “Grated Parmesan Cheese” that was granted to Kraft Foods, Incorporation (65 FR 83040, December 29, 2000). The test product will bear the name “Parmesan Cheese.”

The test product designated as “Parmesan Cheese” will deviate from the United States (U.S.) standards of identity for Parmesan cheese (21 CFR 133.165) and Grated cheeses (21 CFR 133.146) in that the curing period will be six months rather than ten months. In all other respects, the test product will conform to the standards for parmesan cheese and grated cheeses.

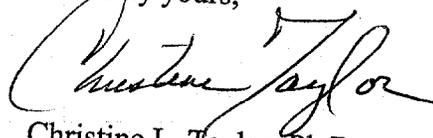
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 20 million pounds of bulk (9,070,294 kg) (500 pound barrels) new test product. The product will be manufactured at Melrose Dairy Proteins facility located at Melrose Dairy Products, LLC, 1000 East Kraft Drive, Melrose, Minnesota 56352 and will be distributed throughout the U.S. The draft labels that you submitted for the test food are acceptable for the purpose of this market test. Finished labels must be submitted to the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-822), before the product is shipped in interstate commerce. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR Part 101.

98P-1121

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While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of "Parmesan Cheese" covered by this permit on the grounds that the food fails to comply with the standards of identity for Parmesan cheese (21 CFR 133.165) and Grated cheeses (21 CFR 133.146).

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Christine Taylor".

Christine L. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Land O'Lakes, Inc.

4001 LEXINGTON AVE. N., ARDEN HILLS, MINNESOTA

Mailing Address: P.O. Box 64101, St. Paul, MN 55164-0101
Telephone: (651) 481-2222

LAW DEPARTMENT

Writer's Direct Number: 651-481-2827

Facsimile: 651-481-2832

E-Mail: pjanz@landolakes.com

February 18, 2002

Team Leader
Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-822)
200 C Street SW
Washington DC 20204

RE: Temporary Marketing Permit

Dear Team Leader:

Land O'Lakes, Inc. and Melrose Dairy Products, LLC, a limited liability company in which Land O'Lakes owns a 50 percent interest (hereinafter collectively referred to as Land O'Lakes) desires to apply for a temporary marketing permit for a product to be labeled, pursuant to 21 CFR Section 133.165, as Parmesan Cheese. A temporary marketing permit is necessary because Land O'Lakes desires to age the cheese for only six (6) months rather than the ten (10) months aging period required in the standard of identity for Parmesan Cheese. Such a temporary marketing permit has already been granted for grated Parmesan Cheese.

1. The applicants are Land O'Lakes, Inc., 4001 Lexington Avenue North, Arden Hills, Minnesota 55126 and Melrose Dairy Products, LLC, 1000 East Kraft Drive, Melrose, Minnesota 56352.
2. Both companies are regularly engaged in processing dairy products, including cheese products.
3. The proposed Parmesan Cheese product is a variation of Parmesan Cheese as provided for in 21 CFR Section 133.165.
4. The proposed Parmesan Cheese deviates from the standard for Parmesan Cheese in that it is cured, either at the manufacturing facility or some other facility before the product is sold for consumption or further processed, for six (6) months rather than the ten (10) months provided for in the standard of identity.
5. The proposed Parmesan Cheese is made from pasteurized milk and follows the same make procedure as is utilized to make standardized Parmesan Cheese. The length of cure time does not effect the wholesomeness of the product.
6. There are no new ingredients added to the proposed Parmesan Cheese.

February 18, 2002

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7. The purpose of effecting the variation is simply to shorten the cure period and the costs associated with such cure period.
8. By shortening the required cure period, the costs of storing the cheese during the cure period are reduced and such cost reduction results in a potential benefit to consumers.
9. A proposed label is attached hereto.
10. Land O'Lakes requests a temporary marketing permit for a 24 month period. Land O'Lakes would like such period to commence in April 2002. The 24 month period is needed in order to gather and analyze sufficient data relating to customer and consumer acceptance of the proposed Parmesan Cheese.
11. The probably annual amount of such food that would be distributed is 20 million pounds of bulk (500 pound barrels) Parmesan Cheese. This amount is necessary in order to allow Land O'Lakes to conduct research with its customers and consumers throughout the continental United States.
12. The area of distribution would be the continental United States.
13. The proposed Parmesan Cheese would be manufactured at the Melrose Dairy Proteins facility whose address is set forth above.
14. The product would be distributed in the state in which it is manufactured.
15. Not applicable.
16. Distribution through normal marketing channels inherently includes interstate distribution.

Land O'Lakes appreciates your prompt attention to this application. Should you have any questions or require additional information, please contact at the address or telephone/fax numbers noted above.

Very truly yours,


Peter S. Janzen
Associate General Counsel



TARE 63.5 NET 560.8
GROSS 624.3 DRUM #000
MAKE DATE: 12-19-2001
1:56 PM LOT # 05422

MDP PARMESAN (27-630)

Uncured Parmesan Cheese
for the completion of curing and
proper labeling. Part-skim milk,
Cheese Cultures, Salt, Enzymes.

10, Factory No.
Malrose, Mn.

Land O'Lakes, Inc.

4001 LEXINGTON AVE. N., ARDEN HILLS, MINNESOTA

Mailing Address: P.O. Box 64101, St. Paul, MN 55164-0101
Telephone: (651) 481-2222

LAW DEPARTMENT
Writer's Direct Number: (651) 481-2827
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July 15, 2002

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

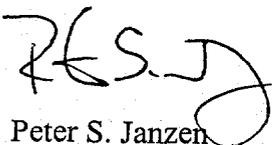
Re: Temporary Marketing Permit

Dear Team Leader:

By way of a letter dated February 18, 2002, Land O'Lakes applied for a Temporary Marketing Permit for a revised type of Parmesan Cheese. It is now July and we are responding to our third request for information regarding our label and process. We are very hopeful that this process will be brought to conclusion in the near future. We know that there are others who already are processing similar products under a TMP.

Please find attached hereto a copy of the label showing the net weight amounts. Given that we are not running this type of product at this time, we were not able to generate an actual label. Hopefully the actual label that we previously generated together with this revised label showing the net weight together will work to resolve all of the label issues.

Very truly yours,



Peter S. Janzen
Associate General Counsel
Law Department



TARE	13.0 lbs.	NET 520.8 lbs.
GROSS	533.8 lbs.	DRUM # 256
MAKE DATE		07-01-2002
11:34AM		LOT # 5889

MDP PARMESAN

Uncured Parmesan Cheese
for the completion of curing and
proper labeling. Part-skim milk,
Cheese Cultures, Salt, Enzymes.
10, Factory NO. 27-630
Melrose, MN

Land O'Lakes, Inc.

4001 LEXINGTON AVE. N., ARDEN HILLS, MINNESOTA

Mailing Address: P.O. Box 64101, St. Paul, MN 55164-0101
Telephone: (651) 481-2222

LAW DEPARTMENT

Writer's Direct Number: (651) 481-2827

Facsimile Number: (651) 481-2832

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April 19, 2002

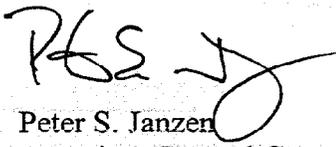
Team Leader
Conventional Foods Team
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling and Dietary Supplements
Food and Drug Administration
Center for Food Safety and Applied Nutrition (HFS-822)
200 C Street SW
Washington DC 20204

Re: Temporary Marketing Permit

Dear Team Leader:

By way of a letter dated February 18, 2002, Land O'Lakes applied for a Temporary Marketing Permit for a revised type of Parmesan Cheese. We received a verbal request for actual labels for the product. Please find attached hereto an actual tag that is applied to the barrel of cheese. Please do not hesitate to contact me if you have any further questions or need any additional information regarding this application.

Very truly yours,



Peter S. Janzen
Associate General Counsel
Law Department

Rec'd 6/11/02

Land O'Lakes, Inc.

4001 LEXINGTON AVE. N., ARDEN HILLS, MINNESOTA

Mailing Address: P.O. Box 64101, St. Paul, MN 55164-0101
Telephone: (651) 481-2222

LAW DEPARTMENT
Writer's Direct Number: (651) 481-2827
Facsimile Number: (651) 481-2832
E-mail: pjanz@landolakes.com

May 23, 2002

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

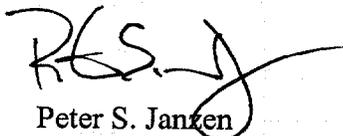
Re: Temporary Marketing Permit

Dear Team Leader:

By way of a letter dated February 18, 2002, Land O'Lakes applied for a Temporary Marketing Permit for a revised type of Parmesan Cheese. We received a verbal request for actual labels for the product, which we have provided to the agency. About one month later we received a second request for the make procedure for the product. A copy of such **Highly Confidential** procedure is attached hereto and is stamped Confidential. Hopefully the request for Temporary Marketing Permit can now be processed.

Please do not hesitate to contact me if you have any questions or comments regarding this matter.

Very truly yours,



Peter S. Janzen
Associate General Counsel
Law Department



TARE	63.5	NET	560.8
GROSS	624.3	DRUM	#000

MAKE DATE: 04-01-2002

10:00AM

LOT # 05422

MDP PARMESAN

Uncured Parmesan Cheese
for the completion of curing and
proper labeling. Part-skim milk,
Cheese Cultures, Salt, Enzymes.
10, Factory NO. 27-630
Melrose, MN