



FEB 27 2004

6710 04 102-4 1073

Gale Prince
Director of Corporate Regulatory Affairs
The Kroger Company
1014 Vine Street
Cincinnati, Ohio 45202-1100

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

Dear Mr. Prince:

This is to acknowledge your letter of October 28, 2003, 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, Incorporated (65 FR 83040, December 29, 2000). The test products will bear the names “100% Grated Parmesan Cheese,” and “Classic Shredded Parmesan Cheese.”

The test product designated as “Parmesan Cheese” will deviate from the United States (U.S.) standards of identity for Parmesan cheese (Title 21 of the Code of Federal Regulations (CFR) section 133.165) and Grated cheeses (CFR section 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.

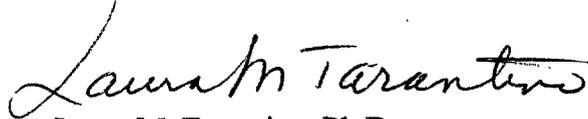
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 3.5 million pounds (1,583,710 kg) of the new test product. The product will be manufactured at Melrose Dairy Products LLC, 1000 East Kraft Drive, Melrose, Minnesota 56352 and Antigo Cheese Company, 907 9th Avenue, Antigo, Wisconsin 54409. The product 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, Regulations and Review Team, Food Labeling and Standard Staff, 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

ANS 7

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 section 133.165) and Grated cheeses (21 CFR section 133.146).

Sincerely yours,

A handwritten signature in cursive script that reads "Laura M. Tarantino". The signature is written in black ink and is positioned above the printed name and title.

Laura M. Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



The Kroger Co.
Gale Prince
Director, Corporate Regulatory Affairs

1014 Vine Street

Cincinnati, Ohio 45202-1100

513/762-4209
Fax: 513/762-4372

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

October 28, 2003

Loretta A. Carey
Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition (HFS-820)
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

Re: Notification pursuant to 21 CFR 130.17 of participation in Extended Market Test of Parmesan Cheese deviating from the Standard of Identity in 21 CFR 133.165.

Dear Ms. Carey:

In accordance with 21 CFR 130.17 (i), and the notice appearing in the FEDERAL REGISTER of December 29, 2000, vol. 65 no. 251 (Docket No. 98P-1121), pertaining to an extension of a temporary permit to Kraft Foods for market testing Parmesan Cheese, The Kroger Co. hereby notifies the Food and Drug Administration that the Company accepts the invitation to participate in the extended market test of Parmesan Cheese.

- (1) The name and address of the applicant is: The Kroger Co., 1014 Vine Street, Cincinnati, OH 45202
- (2) The grated Parmesan Cheese will be manufactured by Melrose Dairy Products, LLC, 1000 East Kraft Drive, Melrose, MN 56352 under the make procedure of Land O' Lakes, Inc. dated July 25, 2002. The resulting Parmesan Cheese will be sold to Rochester Cheese, P.O. Box 6997, Rochester, MN 55901 and ship to Rochester Cheese, 5115 Hwy 47 NW, Dalbo, MN 55017 where the Parmesan is dehydrated and packaged in Kroger labeled canisters. A copy of the FDA approval letter to Land O' Lakes is enclosed (Exhibit A) identifying Melrose Dairy Products as the manufacturer.
- (3) The shredded Parmesan Cheese will be produced by Antigo Cheese Company, 907 9th Avenue, Antigo, WI 54409 under the make procedure of Antigo Cheese dated January 23, 2001. The resulting Parmesan Cheese will be sold to Pace Dairy Foods, 2700 Valley High Drive N.W., Rochester, MN 55903 where the product will be shredded and packaged in Kroger labeled packages. A copy of the FDA approval letter to Antigo Cheese is enclosed (Exhibit B).
- (4) The probable amount of test product to be distributed annually is 3.5 million pounds under the Kroger brand name in 3, 8, and 16-ounce consumer size containers of grated Parmesan and also in 6-ounce packages of shredded Parmesan Cheese. The amount of test product requested is based upon

distribution of the test product to various parts of our trade area that reflects a wide range of demographics and environmental conditions that are essential in evaluating consumer preferences.

- (5) The area of distribution will be throughout the United States.
- (6) The Parmesan Cheese referred to above deviates from the U.S. Standard of Identity for Parmesan cheese (21 CFR 133.165) and Grated cheese (21 CFR 133.146) in that the cheese is aged for six months, rather than ten months. In all other respects, the test product will conform to the standards for Parmesan cheese and Grated cheese. The make procedures have been previously filed by the manufacturers indicated in points 2 and 3 above. Copies of their FDA approvals for temporary marketing permits are enclosed (Exhibit A & B).
- (7) Copies of the proposed labels for each container size to be market tested are attached. Before the product is shipped in interstate commerce, finished labels, complying with the applicable food labeling requirements in 21 CFR part 101 and 130, will be submitted to the Office of Food Labeling address above.

The Kroger Co. understands that any permit to market test Parmesan Cheese expires either on the effective date of a final rule for any proposal to establish a new Standard of Identity for Parmesan Cheese, which may result from the petition, or 30 days after termination of such proposal.

Sincerely yours,



Gale Prince
Director of Corporate Regulatory Affairs
GP/jf

Enclosures: Federal Register notice - Kraft extension
Labels
Exhibits A & B

Kroger

QUALITY GUARANTEED

100%

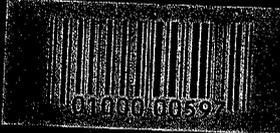
PARMESAN
CHEESE

Sprinkle on the Flavor!

Guaranteed by the Kroger Co.
with every sale and return.

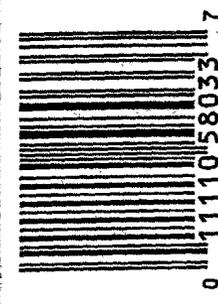
QUALITY GUARANTEED

REFRIGERATE
AFTER
OPENING



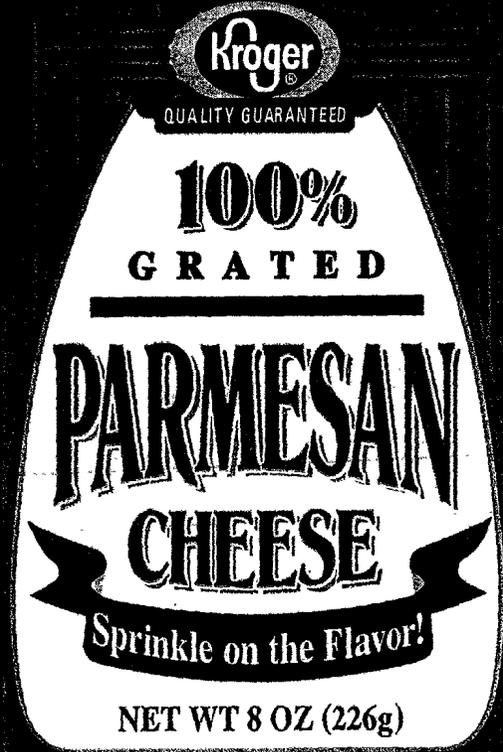
INGREDIENTS
 PARMESAN CHEESE (CHEESE
 ONLY, PART SKIM MILK
 SALT, LIZYMS, SODIUM
 SEYUO, CALCIUM LACTATE, SODIUM
 TO PREVENT CLUMMING, SUGAR
 AND A PRESERVATIVE)
 DISTRIBUTED BY
 THE KROGER CO.
 CINCINNATI, OHIO 45202
 U.S.A.

QUALITY GUARANTEED
 We guarantee the quality
 of this product. If for any
 reason you are not satisfied,
 please return the product to
 the store for a full refund or
 replacement. If you have
 comments or questions,
 please call 1-800-632-6900.



**Buttered
 Parmesan Bread**
 1/2 cup Kroger Grated
 Parmesan Cheese
 1/2 cup (1stick) Kroger
 Butter (or Margarine)
 1/4 tsp. Kroger Italian
 Seasoning
 1 loaf Kroger Italian or
 French bread
 1. Cut bread in half length-
 wise.
 2. Mix cheese, butter (or
 margarine), and seasoning
 until uniform. Spread on the
 bread and place the bread on
 a cookie sheet.
 3. Bake at 400°F for 8 to 10
 minutes or until lightly
 browned. Allow to cool and
 serve. Makes 10-12 servings.

REFRIGERATE AFTER OPENING
 Best when purchased
 by date shown
 Product will settle during
 shipping and handling



Nutrition Facts
 Serving Size 2 tsp (5g)
 Servings Per Container about 45

Amount Per Serving	
Calories 25	Calories from Fat 15
% Daily Value*	
Total Fat 1.5g	2%
Saturated Fat 1g	5%
Cholesterol 5mg	2%
Sodium 100mg	4%
Total Carbohydrate 0g	0%
Dietary Fiber 0g	0%
Sugars 0g	
Protein 2g	4%
Vitamin A 0%	Vitamin C 0%
Calcium 6%	Iron 0%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g
Protein	50g	65g



QUALITY GUARANTEED

100%
G R A T E D

PARMESAN
CHEESE

Sprinkle on the Flavor!

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), SODIUM SILICO ALUMINATE (ADDED TO PREVENT CAKING), SORBIC ACID (A PRESERVATIVE).

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), SODIUM SILICO ALUMINATE (ADDED TO PREVENT CAKING), SORBIC ACID (A PRESERVATIVE).

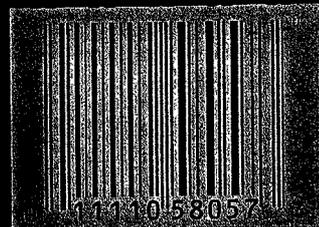
DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202 U.S.A.

REFRIGERATE AFTER OPENING

Best when purchased
by date on bottom.

INGREDIENTS: PARMESAN CHEESE (CULTURED PART-SKIM MILK, SALT, ENZYMES), SODIUM SILICO ALUMINATE (ADDED TO PREVENT CAKING), SORBIC ACID (A PRESERVATIVE).

QUALITY GUARANTEED



RESEALABLE PACKAGING

YEAR LONG

Kroger

QUALITY GUARANTEED



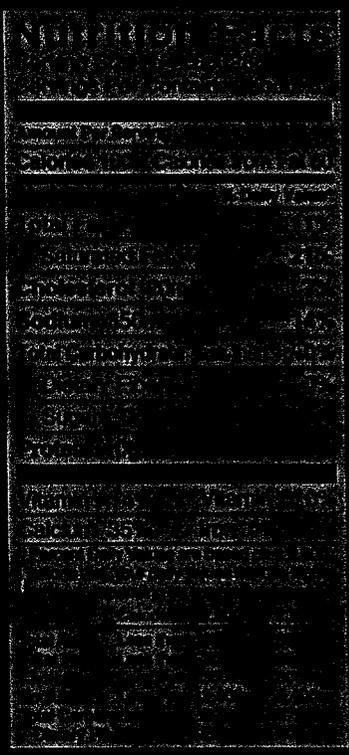
Tear along dotted line.



Pull zipper apart to open.



Press to close.



INGREDIENTS: PASTEURIZED PART-SKIM MILK, CHEESE CULTURE, SALT, ENZYMES, POWDERED CELLULOSE (TO PREVENT CAKING), NATAMYCIN (A NATURAL MOLD INHIBITOR).

This resealable package is a convenient way to store unused cheese. For best quality keep refrigerated and use within 3 to 5 days after opening.

DISTRIBUTED BY THE KROGER CO. CINCINNATI, OHIO 45262



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-1121]

Grated Parmesan Cheese Deviating From Identity Standard; Temporary Permit for Market Testing; Extension of Temporary Permit

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of temporary permit.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Kraft Foods, Inc., to market test products designated as "100% Grated Parmesan Cheese" that deviate from the U.S. standards of identity for parmesan cheese and grated cheese. The extension will allow the permit holder to continue to collect data on consumer acceptance of the products while the agency takes action on a petition to amend the standard of identity for parmesan cheese that was submitted by the permit holder.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for parmesan cheese that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4168.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17, FDA issued a temporary permit to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093-2753, to market test products identified as "parmesan cheese" that deviate from the U.S. standards of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) (see 64 FR 16743, April 6, 1999). The agency issued the permit to facilitate market testing of foods deviating from the requirements of the standard of identity for parmesan cheese issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate market testing of products identified as "parmesan cheese" that deviate from the standardized parmesan cheese products described in 21 CFR part 133 in that the product is formulated by using a different enzyme technology that fully cures the cheese in 6 months rather than 10 months. The

test product meets all the requirements of the standard with the exception of this deviation.

On August 28, 2000, Kraft Foods, Inc. requested that its temporary permit be extended to allow for additional time for the market testing of its products under the permit in order to gain additional information in support of its petition. The petition requests FDA to amend the standard of identity for parmesan cheese to change the curing time from 10 months to 6 months.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified as parmesan cheese to gain information on consumer expectation and acceptance. FDA is inviting interested persons to participate in the market test under the conditions that apply to Kraft Foods (e.g., the composition of the test product), except that a different condition for the designated area of distribution may apply. Any person who wishes to participate in the extended market test must notify, in writing, the Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. The notification must include a description of the test products to be distributed, a justification statement for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. 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.

Therefore, under the provisions of 21 CFR 130.17(i), FDA is extending the temporary permit granted to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093-2753 to provide for continued market testing on an annual basis of 86 million pounds. The test products will bear the name "100% Grated Parmesan Cheese." FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule amending the standard of identity for parmesan cheese that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be. All other conditions and terms of this permit remain the same.

Dated: December 12, 2000.

Christine J. Lewis,

Director, Office of Nutritional Products Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition.

[FR Doc. 00-33373 Filed 12-28-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Veterinary Antimicrobial Decision Support System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) announces that funds may be available to support an unsolicited grant application submitted by Iowa State University. The applicant has requested funds to develop a web-based, peer-reviewed antimicrobial decision support system centered on therapeutic applications that will allow food animal veterinary practitioners to utilize all available information in the construction of antimicrobial regimens.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Peggy L. Jones, Division of Contracts and Procurement Management (HFA-520), Food and Drug Administration, 5600 Fishers Lane, rm. 2129, Rockville, MD 20857, 301-827-7160.

Correspondence hand-carried or commercially delivered should be addressed to 5630 Fishers Lane (HFA-520), rm. 2129, Rockville, MD 20857.

Regarding the programmatic aspects of this notice: David B. Batson, Office of Research, Center for Veterinary Medicine (HFV-502), Food and Drug Administration, 8401 Muirkirk Rd., Laurel, MD 20708, 301-827-8021.

SUPPLEMENTARY INFORMATION:

I. Purpose of the Project

The specific aims of the project are as follows: (1) Perform extensive literature searches to identify pharmacokinetic, pharmacodynamic, clinical trial, antimicrobial pathogen susceptibility, regulatory, food safety, and approval process information pertinent to the veterinary antimicrobial decision support system (VADS); (2) develop and apply standard operating procedures for

Dated: March 22, 1999.

Laura M. Tarantino,
Acting Director, Office of Premarket
Approval, Center for Food Safety and Applied
Nutrition.

[FR Doc. 99-8442 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P-1121]

Grated Parmesan Cheese Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kraft Foods, Inc., to market test a product designated as "100% Grated Parmesan Cheese" that deviates from the U.S. standards of identity for parmesan cheese and grated cheeses. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the product, identify mass production problems, and assess commercial feasibility, in support of a petition to amend the standard of identity for parmesan cheese.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 6, 1999.

FOR FURTHER INFORMATION CONTACT:

Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Kraft Foods, Inc., Three Lakes Dr., Northfield, IL 60093.

The permit covers 86 million pounds of interstate marketing tests products identified as "grated parmesan cheese" that deviate from the U.S. standard of identity for parmesan cheese (21 CFR 133.165) and grated cheeses (21 CFR 133.146) in that the product is formulated by using a different enzyme technology that fully cures the cheese in 6 months rather than 10 months. The

test product meets all the requirements of the standards with the exception of this deviation. Because test preferences vary by area, along with social and environmental differences, the purpose of this permit is to test the product throughout the United States.

Under this temporary permit, the parmesan cheese will be test marketed as grated parmesan cheese. The test product will bear the name "100% Grated Parmesan Cheese."

This permit provides for the temporary marketing of 86 million pounds of grated parmesan cheese in retail containers of various sizes. The test product will be manufactured at Kraft Foods, Inc., 10800 Avenue 184, Tulare, CA 93274. The product will then be shipped to Kraft Foods Inc., 1007 Town Line Rd., Wausau, WI 54401, where it is aged, grated, and packaged for distribution. The product will be distributed throughout the United States.

The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of 21 CFR part 101.

This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but not later than July 6, 1999.

Dated: March 29, 1999.

Kenneth J. Falci,
Acting Director, Office of Food Labeling,
Center for Food Safety and Applied Nutrition.
[FR Doc. 99-8440 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96G-0096]

The Flax Council of Canada; Withdrawal of GRAS Affirmation Petition

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a petition (GRASP 5G0416) proposing to affirm that the use of low linolenic acid flaxseed oil is generally recognized as safe (GRAS) as a food oil.

FOR FURTHER INFORMATION CONTACT:
Lawrence J. Lin, Center for Food Safety

and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3103.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of March 27, 1996 (61 FR 13505), FDA announced that a petition (GRASP 5G0416) had been filed by the Flax Council of Canada, 465-167 Lombard Ave., Winnipeg, MB R3B 0T6, Canada. This petition proposed that the use of low linolenic acid flaxseed oil as a food oil be affirmed as GRAS.

The Flax Council of Canada has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: March 17, 1999.

Eugene C. Coleman,
Acting Director, Office of Premarket
Approval, Center for Food Safety and Applied
Nutrition.

[FR Doc. 99-8443 Filed 4-5-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0557]

"Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans;" Availability

AGENCY: Food and Drug Administration,
HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled "Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans." The guidance document is being issued in response to public comments and recent interest among clinical investigators in using nonhuman primate xenografts in the near future. The document is intended to provide guidance on nonhuman primate xenotransplantation in humans.

DATES: Written comments may be submitted at any time, however, comments should be submitted by July 6, 1999, to ensure adequate consideration in preparation of a revised document, if warranted. The agency is soliciting public comment but is implementing this guidance document immediately because of the public health concerns related to the use of live cells, tissues, and organs from nonhuman primate xenografts in humans.



Exhibit A

Food and Drug Administration
College Park, MD

JUL 25 2002

**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.

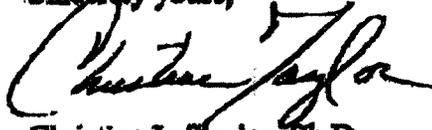
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 20 million pounds of bulk (9,070,294 kg) (500 pound barrels) new test product. The product will be manufactured at Melrose Dairy Proteins facility located 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.

Post-It® Fax Note	7871	Date	5/5/03	# of pages	2
To	Gray Anderson	From	Case Enck King		
Co./Dept.		Co.			
Phone #		Phone #			
Fax #		Fax #			

Page 2 -- Peter S. Janzen

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,



Christine L. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Exhibit B

Food and Drug Administration
Washington, DC

JAN 23 2001

Mr. Leo Malone
Sales/Marketing Manager
The Antigo Cheese Company
907 9th Avenue
P.O. Box 503
Antigo, Wisconsin 54409-0503

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

Dear Mr. Malone:

This is to acknowledge your letters of May 25, 2000, and January 11, 2001, 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, Inc. (65 FR 251, December 29, 2000). The test product will bear the name "Parmesan Cheese."

The test product designated as "Parmesan Cheese" will deviate from the 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.

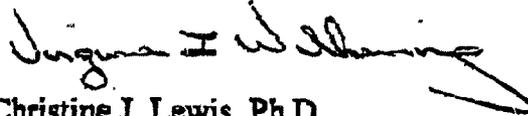
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 20 million pounds (9,070,294 kg) of the new test product. The product will be manufactured at The Antigo Cheese Company, 907 9th Avenue, Antigo, Wisconsin 54409 and will be distributed throughout the United States.

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 Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), 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.

Page 2 - Mr. Leo Malone

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,



f Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition



Exhibit A

Food and Drug Administration
College Park, MD

JUL 25 2002

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.

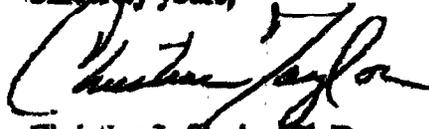
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 20 million pounds of bulk (9,070,294 kg) (500 pound barrels) new test product. The product will be manufactured at Melrose Dairy Proteins facility located 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.

Post-It® Fax Note	7871	Date	5/5/03	# of pages	2
To	Gray Anderson	From	Case Enabling		
Co./Dept.		Co.			
Phone #		Phone #			
Fax #		Fax #			

Page 2 – Peter S. Janzen

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,



Christine L. Taylor, Ph.D.

Director

**Office of Nutritional Products, Labeling
and Dietary Supplements**

**Center for Food Safety
and Applied Nutrition**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Exhibit B

Food and Drug Administration
Washington, DC

JAN 23 2001

Mr. Leo Malone
Sales/Marketing Manager
The Antigo Cheese Company
907 9th Avenue
P.O. Box 503
Antigo, Wisconsin 54409-0503

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

Dear Mr. Malone:

This is to acknowledge your letters of May 25, 2000, and January 11, 2001, 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 251, December 29, 2000). The test product will bear the name "Parmesan Cheese."

The test product designated as "Parmesan Cheese" will deviate from the 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.

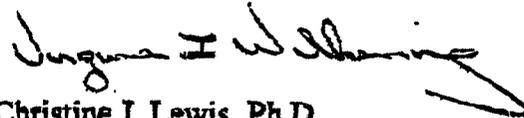
Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes of 20 million pounds (9,070,294 kg) of the new test product. The product will be manufactured at The Antigo Cheese Company, 907 9th Avenue, Antigo, Wisconsin 54409 and will be distributed throughout the United States.

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 Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), 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.

Page 2 - Mr. Leo Malone

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,



f Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition