



APR 12 2001

Sheryl A. Marcouiller
Senior Food Law Counsel
Kraft Foods
Three Lakes Drive
Northfield, Illinois 60093-2753

Re: Docket No. 01P-0150

Dear Ms. Marcouiller:

This is to acknowledge your letter of October 4, 2000, in which you request a modification of a temporary marketing permit (TMP) on behalf of Kraft Foods, Inc. ("Kraft Foods"). The TMP that you seek to modify permitted Kraft Foods to market test products identified as "salad dressing" in interstate commerce (64 FR 24408, May 6, 1999). As you concede in your letter, the product you now intend to market differs in a number of respects from the product covered by the original permit. Furthermore, the petition to amend the food standard for salad dressing to which you refer in your letter would not permit the marketing of the proposed test product, even if such petition were granted. The termination dates established by 21 CFR 130.17(i) would thus have no application. Therefore, FDA has decided to construe your letter requesting a modification of the original TMP as a request for issuance of a new TMP. Inasmuch as FDA is not granting you an extension on the original TMP, the TMP notice in the Federal Register of May 6, 1999, is no longer in effect.

Relying on the representations made in your letter, we are hereby granting your present request for a TMP. Under the new TMP, you may test market a product that is identified as "salad dressing" but that deviates from the standard of identity for salad dressing under 21 CFR 169.150. The product may so deviate only in that it contains potassium sorbate, at levels not to exceed 1%, and in that it contains not less yolk-containing ingredient than is equivalent to 2% by weight of liquid egg yolks, as opposed to the 4% required by the food standard. In all other respects, the test product must conform to the standard for salad dressing under 21 CFR 169.150.

For purposes of market testing, you may make interstate shipments of 150 million pounds of the product covered by the TMP. The distribution area for the product permitted by the TMP is the United States. The following plants may manufacture the product: Kraft Foods, 2340 Forest Lane, Garland, TX 75040; Kraft Foods, 1701 W. Bradley Ave., Champaign, IL 61821; and Kraft Foods, 7352 Industrial Blvd., Allentown, PA 18106.

DIP-0150

ACKI

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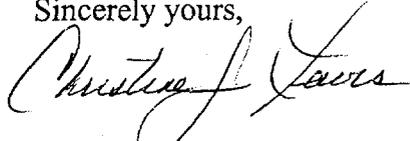
Page 2 – Ms. Sheryl A. Marcouiller

Before the product is shipped in interstate commerce, you must submit finished labels to 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). The information panel of the labels must bear nutrition labeling in accordance with 21 CFR 101.9. Furthermore, the labels on the product must declare each of the ingredients used in the product in accordance with the applicable sections of 21 CFR part 101.

Absent an extension granted in accordance with 21 CFR 130.17(i), the TMP will be effective for a 15-month period, beginning on the date the test product is introduced into interstate commerce but not later than 90 days after notice of issuance of the permit is published in the Federal Register. You must notify FDA, in writing, of the date the 15-month period will begin, as soon as it is determined.

While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of products identified as “salad dressing” that conform with this permit on the ground that the food fails to comply with 21 CFR 169.150.

Sincerely yours,

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

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****Docket No.**

Salad Dressing 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 "salad dressing" that deviates from the U.S. standard of identity for salad dressing. 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 salad dressing.

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 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity issued 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 Drive, Northfield, IL 60093-2753.

The permit covers limited interstate marketing tests of products identified as "salad dressing" that deviate from the U.S. standard of identity for salad dressing (21 CFR 169.150) by adding

potassium sorbate, which is not permitted under the current standard, and by reducing the amount of egg below the amount required by the current standard. In all other respects, the test product will conform to the standard for salad dressing. The test product meets all the requirements of the standard with the exception of the reduced amount of egg level in the product and the addition of potassium sorbate. 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 salad dressing will be test marketed as "salad dressing."

This permit provides for the temporary marketing of 150 million pounds of product during the entire 15-month period. The test product will be manufactured by Kraft Foods, at 2340 Forest Lane, Garland, TX 75040; 1701 West Bradley Ave., Champaign, IL 61821; and 7352 Industrial Blvd., Allentown, PA 18106. 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 [90 days after publication].

Date _____

R/D:HFS-822:LCarey:1/24/01

Init:HFS-822:GAJune:1/26/01

GCF-1: *J. Allen*



OFFICE OF THE CHIEF COUNSEL
U.S. FOOD AND DRUG ADMINISTRATION
MAILCODE GCF-1
5600 FISHERS LANE
ROCKVILLE, MARYLAND 20857

FAX TRANSMISSION COVER SHEET

DATE: February 2, 2001

To: Loretta Carey, HFS-822

FAX: (202) 205-4168

PHONE: (202) 205-5295

FROM: Matt Warren

FAX: 301-480-2255

PHONE: 301-827-2724

PAGES (INCLUDING THIS COVER SHEET): ~~6~~ Five (5)

MESSAGE:

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Kraft Foods

Sheryl A. Marcouiller
Senior Food Law Counsel

October 4, 2000

Loretta A. Carey
Food Standards Branch (HFS-158)
Division of Programs and Enforcement Policy
Office of Food Labeling
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

Re: Petition for Modification of Temporary Marketing Permit
Originally Granted April 27, 1999, 64 FR 24408
For Salad Dressing, 21 C.F.R. 169.150

Dear Ms. Carey:

Kraft Foods, Inc. (Kraft) requests a temporary permit to market test salad dressing deviating from the applicable standard of identity. Specifically, we request that the Food and Drug Administration (FDA) modify the permit granted to Kraft on April 27, 1999, 64 FR 24408 and grant Kraft time to test the modified product. The 1999 permit allows the addition of three safe and suitable preservatives to salad dressing and sanctions the use of 2% less egg than required by the current standard. The permit also allows the use of emulsifiers.

Our testing to date has been promising, but the combinations of formulas and processes tried and tested have not proved entirely satisfactory to consumers in sensory evaluations. Through the work done to date, we have determined not to proceed with the use of emulsifiers at this time and have narrowed our focus to the single preservative potassium sorbate. Thus, we request a modification of the existing permit, so that the modified permit will cover the new formula and associated labels. Of course, we then will need time to make the product in a plant setting, rather than a laboratory environment, to conduct sensory tests, and to complete home use evaluations, in which consumers examine a full range of product characteristics. Our goal is to show that the test product is just as acceptable to consumer as the current product, which does meet the standard of identity.

Therefore, we now request permission to test salad dressing made with one of the preservatives approved previously, potassium sorbate, and the same reduction in egg content allowed before. In particular, Kraft seeks a permit to test salad dressing made with the added preservative potassium sorbate at levels of 1% or less, consistent with Good Manufacturing Practice, and with the egg yolk solids content reduced from the 4% presently required to as low as 2% by weight.

Our request is consistent with the attached petition dated January 13, 1998 filed by The Association for Dressings and Sauces (ADS). In that petition, ADS asked the Food and Drug Administration to revise, simplify, and modernize the standard of identity for salad dressing.

The information required by the regulation governing temporary marketing permits, 21 CFR 130.17, is provided below.

1. The applicant is Kraft Foods, Inc., Three Lakes Drive, Northfield, IL 60093.
2. Kraft is regularly engaged in the business of marketing salad dressing made at several facilities throughout the United States.
3. The applicable standard of identity for salad dressing is 21 C.F.R. 169.150.
4. The product Kraft proposes to market is salad dressing containing less vegetable oil than the salad dressing Kraft sells today, but containing as much oil as is required by the current standard. To accomplish this reduction in vegetable oil content, Kraft needs to use techniques that are well accepted throughout the food industry, but not contemplated by the salad dressing standard. These techniques assure that the quality, flavor, and texture of the product are maintained.

The salad dressing Kraft proposes to market would contain the safe and suitable preservative potassium sorbate at levels not to exceed 1%, consistent with Good Manufacturing Practice and the permit issued in April of 1999. The preservative is needed because moisture content increases as the oil level is reduced and the acid and salt to moisture ratios, therefore, decrease. As a result, a preservative is needed to prevent spoilage due to yeast or mold growth.

The salad dressing Kraft proposes to market also would contain 2% by weight less egg than required by the current standard, but no less egg

than allowed under the April, 1999 permit. As the oil content of salad dressing is reduced, the flavor system changes and the egg levels in the current standard become too strong. The texture also changes due to the change in oil content. Therefore, the egg content of the emulsification system needs to be adjusted, from 4% egg yolk solids to as low as 2% egg yolk solids by weight, to accommodate the lower oil level without changing the organoleptic characteristics of the salad dressing.

5. The salad dressing that is the subject of this application is just as wholesome and non-deleterious as other salad dressing available to consumers under the existing standard of identity. No novel ingredients or processes are used in making the product.
6. The existing standard for salad dressing does not include preservatives in the list of permitted optional ingredients, although preservatives are commonly used in other dressing products in accordance with good manufacturing practice, typically at levels of 1% or less.

The standard currently requires egg yolk containing ingredients equivalent in egg yolk solids content to 4% by weight of liquid egg yolks, but lower egg levels produce more optimum emulsification and flavor systems, when the oil level is reduced.

Therefore, Kraft seeks permission to market test salad dressing made with the preservative potassium sorbate at levels not to exceed 1%, consistent with Good Manufacturing Practice, and an egg yolk solids content as low as 2% by weight.

7. The purpose of these variations is to facilitate the market testing of salad dressing containing less vegetable oil than the salad dressing Kraft sells today, but containing as much oil as is required by the current standard. Lowering the oil in the formula is consistent with current dietary guidelines and with the petition dated January 13, 1998 filed by The Association for Dressings and Sauces (ADS), in which ADS asked the Food and Drug Administration to revise, simplify, and modernize the standard of identity for salad dressing. The use of a safe and suitable preservative as well as a reduced egg yolk level are necessary to maintain product quality, texture and flavor.

Additionally, the temporary permit will facilitate the collection of data on consumer acceptance of the product to support the ADS petition for a revised standard of identity for salad dressing already on file.

8. The variation from existing standards would benefit consumers by making lower oil formulations available. Additionally, the variation will allow more efficient production, enabling manufacturers to provide better value for consumers.
9. Proposed labels for the products to be market tested under the requested temporary marketing permit modification were provided with our correspondence dated August 17, 2000. The packet of black and white labels, with some hand written corrections, contains the labels that will be used during the temporary market test. The color label, which is for product Kraft currently sells, is included for reference and to show the color scheme that will be used for the test labels, if this market test request is granted.

From our recent telephone conversation, I understood that the labels were still available at FDA and that resubmission of the same package of labels would not be necessary. Therefore, I respectfully request that you attach the previously submitted labels to this letter. Thank you for your cooperation in expediting the processing of this request.

When compared with our salad dressing made under the current standard of identity, the nutrition on a per serving basis for the proposed labels shows 10 fewer total calories, calories from fat lowered from 60 to 40, and total fat lowered from 7 grams to 5 grams.

The ingredient line for the proposed labels shows "water, soybean oil," rather than "soybean oil, water." The ingredient line also reflects the addition of eggs as well as egg yolks and adds the preservative potassium sorbate. When compared with the current labels for Miracle Whip salad dressing, the proposed labels also reflect the addition of high fructose corn syrup, corn syrup, and xanthan gum, all of which are permitted under the current standard of identity for salad dressing.

10. The time period requested for the temporary permit is October 30, 2000 through January 31, 2002. This period is needed for proper evaluation of production characteristics, sensory attributes, product stability, and overall consumer acceptance nation-wide through one complete change of seasons.
11. During the market test period we expect to distribute approximately 10 million pounds of product a month. Thus, during the entire fifteen month period we expect to distribute a total of roughly 150 million pounds of product. This amount of product is needed to assure manufacturing

consistency and efficiency as well as to provide for proper evaluation of sensory attributes, product stability, and overall consumer acceptance nation-wide through one complete change of seasons.

12. The product will be distributed throughout the United States.
13. The product will be manufactured by Kraft in Garland, Texas; Champaign, Illinois; and Allentown, Pennsylvania. The addresses, telephone numbers, and a contact person for each plant are listed below.

Robert Lloyd
Kraft Foods
2340 Forest Lane
Garland, TX 75040
972-485-6701

Mike Devlin
Kraft Foods
1701 W. Bradley Ave.
Champaign, IL 61821
217-378-2502

Raymond Harlin
Kraft Foods
7352 Industrial Blvd.
Allentown, PA 181106
610-398-0311, extension 3704

14. The product will be distributed in the state in which it is manufactured.
15. The product will be distributed in the state in which it is manufactured, so no additional explanation is necessary.
16. Nation-wide distribution is needed to assure manufacturing consistency and efficiency as well as to provide for proper evaluation of sensory attributes, product stability, and overall consumer acceptance through one complete change of seasons.

Loretta A. Carey
October 4, 2000
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Please do not hesitate to contact me at 847-646-4206, if you need additional information. Thank you for your consideration.

Respectfully submitted,

A handwritten signature in cursive script, reading "Sheryl A. Marcouiller".

Kraft Foods, Inc.
Sheryl A. Marcouiller
Senior Food Law Counsel

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