

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier R. LEDESMA

DDM

Cottage 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 Wells' Dairy, Inc., to market test cottage cheese that deviates from the U.S. standard of identity for cottage cheese. 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.

DATES: This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the test product into interstate commerce, but not later than *[insert date 3 months after date of publication in the Federal Register]*.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

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 Wells' Dairy, Inc., 1 Blue Bunny Dr., P.O. Box 1310, Le Mars, IA 51031.

The permit covers limited interstate marketing tests of these products:

1. Blue Bunny Brand

- "Cottage cheese, 4% milkfat, homestyle, large curd" 24 ounces (oz);
- "Cottage cheese, 4% milkfat, original, small curd" 32 oz;
- "Cottage cheese, 4% milkfat, original, small curd" 24 oz;
- "Cottage cheese, 4% milkfat, original, small curd" 12 oz;
- "Cottage cheese, 2% milkfat, reduced fat" 24 oz;
- "Cottage cheese, 2% milkfat, reduced fat" 12 oz;
- "Cottage cheese, 1% milkfat, lowfat" 24 oz;
- "Cottage cheese, 1% milkfat, lowfat" 12 oz; and
- "Cottage cheese, Health Smart, fat free" 24 oz.

2. Great Value Brand

- "Cottage cheese, 4% milkfat, large curd" 24 oz;
- "Cottage cheese, 4% milkfat, large curd" 16 oz;
- "Cottage cheese, 4% milkfat, small curd" 24 oz;
- "Cottage cheese, 4% milkfat, small curd" 16 oz;
- "Cottage cheese, 1% milkfat, lowfat, small curd" 24 oz;
- "Cottage cheese, 1% milkfat, lowfat, small curd" 16 oz; and
- "Cottage cheese, fat free, small curd" 24 oz.

3. ShurFresh Brand

- "Cottage cheese, 4% milkfat, small curd" 24 oz.

These cottage cheese products may deviate from the U.S. standard of identity for cottage cheese (21 CFR 133.128) in that the products are formulated using fluid ultrafiltered (UF) skim milk. Fluid UF skim milk is obtained by

subjecting skim milk to a physical separation process called ultrafiltration using a membrane with a pore size of 10,000 Daltons molecular weight cutoff, resulting in the partial loss of lactose, minerals, water-soluble vitamins, and water present in skim milk. The casein-to-whey protein ratio of skim milk is not altered during the ultrafiltration process. The moisture content of fluid UF skim milk so obtained is about 80 percent. Fluid UF skim milk is added to skim milk at a level needed to increase the total solids of the cheese milk by 5 to 25 percent. The physical, chemical, and sensory properties characteristic of cottage cheese are not altered in the test product. The fluid UF skim milk will be declared in the ingredient statement of the finished cottage cheese as “ultrafiltered skim milk.” The test product meets all the requirements of the standard with the exception of the use of fluid UF skim milk. 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.

This permit provides for the temporary marketing of a total of 15 million pounds (6.8 million kilograms) of the test product. The test products will be manufactured by Wells’ Dairy, Inc., at 12th and Lincoln Sts. SW., Le Mars, IA 51031. The test products will be distributed by Wells’ Dairy, Inc., throughout the States of Iowa, Minnesota, Wisconsin, Missouri, Nebraska, Oklahoma, Kansas, South Dakota, North Dakota, Arkansas, and Colorado. Each of the ingredients used in the food must be declared on the labels as required by the applicable sections of part 101 (21 CFR part 101). The information panel of the labels will bear nutrition labeling in accordance with § 101.9. This permit is effective for 15 months, beginning on the date the permit holder introduces or causes the introduction of the product into interstate commerce,

but not later than [insert date 3 months after date of publication in the **Federal Register**].

Dated: 29 Nov 2004

November 29, 2004.

Barbara Schneeman

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

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