



AUG 4 2003

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John F. Lemker
Bell, Boyd & Lloyd LLC
Three First National Plaza
70 West Madison Street, Suite 3300
Chicago, Illinois 60602-4207

Re: Docket Number 2003P-0296

Dear Mr. Lemker:

This is in response to your application on behalf of Kerry, Inc., Eau Galle Cheese Factory, and First District Association, to the Food and Drug Administration (FDA) for a temporary permit to market test, in interstate commerce, romano cheese for manufacturing that will deviate from the United States standard of identity for romano cheese Title 21 Code of Federal Regulations 133.183 in that the product is formulated using an enzyme technology that fully cures the cheese in 2 months, rather than 5 months, and that the product is intended only for further manufacturing into food ingredients. In all other respects, the test product will conform to the standard for romano cheese.

For the purposes of this permit, the name of the test product will be "Romano cheese for manufacturing made from cow's milk." The test product will be further manufactured into food ingredients such as cheese sauces, seasonings, and cheese powders, the labels of which will identify the test product as "Romano cheese."

Relying on the representations made in your application, we are hereby granting your request to make interstate shipments for test marketing purposes of a total of 9 million pounds (4.1 million kilograms) of the test product. You must submit finished labels to the Team Leader, Regulations and Review Team, Division of Food Labeling and Standards, Office of Nutritional Products, Labeling, and Dietary Supplements, before the test product is shipped in interstate commerce. The test product will be manufactured by Eau Galle Cheese Factory at N6765 State Highway, Durand, Wisconsin 54736, and by First District Association at 101 South Swift Avenue, Litchfield, Minnesota 55355. The test product will then be shipped to Kerry, Inc., plants in Wisconsin and Minnesota, where it will be further manufactured into food ingredients. The food ingredients will be distributed by Kerry, Inc., throughout the U. S. Each of the ingredients used in the test product must be declared on the labels as required by the applicable sections of 21 CFR part 101.

This permit will be effective for 15 months, beginning on the date the test products are introduced into interstate commerce, but not later than 90 days after notice of issuance of the permit is published in the Federal Register. Before you test market the product, you must notify FDA, in writing, of the date the 15-month period will begin.

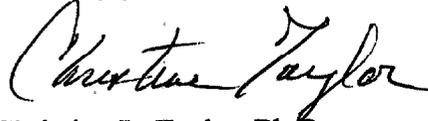
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While this permit is in effect, FDA will refrain from recommending regulatory action against shipments of romano cheese for further manufacturing covered by this permit on the grounds that the food fails to comply with 21 CFR 133.183 because of the above described deviations from the standard.

Sincerely yours,

A handwritten signature in cursive script that reads "Christine Taylor".

Christine L. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition