



AUG 4 2003

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Mr. Roger Gibb
Bumble Bee Seafoods, Inc.
Post Office Box 85362
9655 Granite Ridge Drive
Suite 100
San Diego, California 92123

Re: Docket No. 2003P-0313

Dear Mr. Gibb:

This is in response to your application to the Food and Drug Administration (FDA) for a temporary permit to market test, in interstate commerce, canned tuna that will deviate from the standard of identity for canned tuna (Title 21 Code of Federal Regulations (CFR) 161.190) in that lemon juice and lemon oil will be used as flavoring ingredients instead of lemon oil and citric acid with safe and suitable carriers. Also, the product will be labeled "in water, with natural lemon flavor" rather than "lemon flavored chunk light tuna." In all other respects, the test product will conform to the standard for canned tuna.

For the purposes of this permit, the name of the test product will be "Bumble Bee Chunk Light Tuna 'Touch of Lemon' in water, with natural lemon flavor." The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9.

Relying on the representations made in the application, we are hereby granting permission to make interstate shipments, for market testing purposes, of approximately 20,000 tons (20,321,200 kg) of the test product packaged in 1.9 million cases. A finished label must be submitted to the Team Leader, Regulations and Review Team, Division of Food Labeling and Standards (HFS-820), Office of Nutritional Products, Labeling, and Dietary Supplements, before the product is shipped in interstate commerce. The test product will be manufactured at Bumble Bee Seafoods, Inc., 13100 Arctic Circle, Santa Fe Springs, California 90670, and at Bumble Bee International, Inc., Malecon Industrial Zone, Jose Gonzalez Clemente Ave., Road, 341 Km 4.5, Mayaguez, Puerto Rico 00680, and distributed nationwide. 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 will be effective for 15 months, 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. Before the permit becomes effective, 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 “Bumble Bee Chunk Light Tuna ‘Touch of Lemon’ in water, with natural lemon flavor” covered by this permit on the grounds that the food fails to comply with the standard of identity canned tuna (21 CFR 161.190) because of the deviation covered by the temporary permit.

Sincerely yours,

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

Christine L. Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition