



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD

MAY 6 2002

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Melvin S. Drozen
Keller and Heckman LLP
1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001

0254 02 MAY 17 P1:25

Re: Docket No. 02N-0178

Dear Mr. Drozen:

This is in response to your application on behalf of the Del Monte Corporation to the Food and Drug Administration (FDA) for a temporary permit to market test, in interstate commerce, canned tomato products that will deviate from the United States standard of identity for canned tomatoes (21 CFR 155.190) in that a liquid carbohydrate sweetener, either corn syrup or high fructose corn syrup, is used as an optional ingredient in lieu of dry nutritive carbohydrate sweeteners. The liquid carbohydrate sweetener, corn syrup or high fructose corn syrup, is used in a quantity reasonably necessary to compensate for the tartness resulting from added organic acids, except that such addition of the liquid sweetener, in no case, may result in a finished canned tomato product with a tomato soluble solids content of less than 5.0 percent by weight as defined in 21 CFR 155.3(e) (which accounts for any added salt) and accounting for the soluble solids of the liquid sweetener. The feasibility of this tomato soluble solids requirement will be assessed during the temporary marketing of the test products. Additionally, this temporary marketing permit provides for use of the term "chunky" in lieu of the styles (i.e., whole, sliced, diced, and wedges) required by the standard. The test products meet all the requirements of the standard with the exception of the use of a liquid sweetener and the use of the alternative term "chunky" in lieu of style declarations required by the standard. In all other respects, the test product will conform to the standard for canned tomatoes.

For the purposes of this permit, the names of the test products will be Del Monte Brand "Stewed Tomatoes, Original Recipe," "Chunky Tomatoes, Pasta Style," "Diced Tomatoes, basil, garlic & oregano," "Diced Tomatoes, garlic & onion," "Diced Tomatoes, green pepper & onion," "Tomato Wedges," "Zesty Chunky Tomatoes, Chili Style," "Stewed Tomatoes, Cajun Recipe with pepper, garlic, and Cajun spices," "Stewed Tomatoes, Italian Recipe with basil, garlic & oregano," "Stewed Tomatoes, Mexican Recipe with garlic, cumin, and jalapeños," and "Stewed Tomatoes, no salt added." The information panel of the labels will bear nutrition labeling in accordance with 21 CFR 101.9.

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 5.6 million cases of the above mentioned canned tomato products. The total weight of the test products will be 5.0

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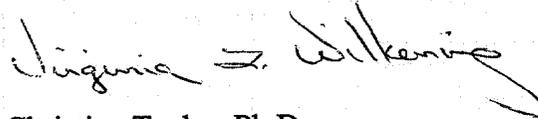
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million pounds (2.3 million kilograms). Finished labels must be submitted to the Director, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling, and Dietary Supplements, before the products are shipped in interstate commerce. The test products will be manufactured by Del Monte Corporation at 10652 Jackson Avenue, Hanford, CA 93230. The products will be distributed by Del Monte Corporation throughout the United States. 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 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. You will 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 canned tomato products covered by this permit on the grounds that the food fails to comply with 21 CFR 155.190.

Sincerely yours,



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

June, Geraldine A

From: Nalubola, Ritu
Sent: Thursday, May 02, 2002 1:02 PM
To: June, Geraldine A
Subject: FW: Del Monte TMP

-----Original Message-----

From: Melvin Drozen [mailto:Drozen@khlaw.com]
Sent: Wednesday, May 01, 2002 5:20 PM
To: Nalubola, Ritu
Cc: Tim.Ernst@delmonte.com; Sarah Key
Subject: Del Monte TMP

Dear Dr. Nalubola:

Following up on our telephone discussion of April 30, we provide below the questions you raised and our responses which we trust will now allow the Agency to issue a TMP to Del Monte that can include the "chunky" style deviation.

1) Why is the deviation needed?

The deviation is needed to provide consumers with an additional style option other than the whole, diced, sliced, and wedge styles currently prescribed by the standard of identity for canned tomatoes at 21 C.F.R. 155.190(a)(4).

2) How is the deviation in the interest of the consumer?

The deviation adds to the diversity of canned tomato products currently available to consumers, offering consumers an additional choice in the style of canned tomatoes beyond those styles that are currently available.

3) Why does the deviation not affect the finished food?

The deviation merely provides the consumer with an additional style of canned tomato product. The actual style, or shape of the tomato in the product, does not have any affect on the finished canned tomato product which will otherwise comply with the standard of identity except for the permitted us of liquid sweetener.

4) How would the consumer be able to distinguish the new product from the standard of identity products?

Consumers will be able to distinguish the products being marketed under the TMP from other canned tomato products because the principal display panel of product labels for the chunky style canned tomatoes will describe the product as "chunky tomatoes."

We trust that these responses are adequate and that the TMP can be issued forthwith.

Thank you again for all of your help.

Mel Drozen
Melvin S. Drozen
Keller and Heckman LLP
Washington, D.C. and Brussels
Serving Business Through Law and Science (SM)

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