



FEB 26 2003

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

Re: 21 CFR 130.17(e) – Temporary Marketing Test of canned tomato products under  
Docket No. 02N-0178

Dear Mr. Drozen:

This letter is in response to your labels submission for the following Del Monte Brand products: “Stewed Tomatoes, Original Recipe,” “Chunky Diced Tomatoes, Pasta Style,” “Diced Tomatoes, basil, garlic & oregano,” “Diced Tomatoes, garlic & onion,” “Diced Tomatoes, green pepper & onion,” “Tomato Wedges,” “Chunky Diced Tomatoes, Zesty 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 final labels, which will be used for market test purposes under the temporary market permit (TMP) for canned tomato products that was announced in the Federal Register of June 27, 2002 (Docket No. 02N-0178) have been reviewed and are acceptable for their intended use, with the exception of the final labels for two of the products, namely, “Chunky Diced Tomatoes, Pasta Style” and “Chunky Diced Tomatoes, Zesty Chili Style.”

Note that the products identified as “Chunky Diced Tomatoes, Pasta Style” and “Chunky Diced Tomatoes, Zesty Chili Style” in the final labels were previously identified as “Chunky Tomatoes, Pasta Style” and “Zesty Chunky Tomatoes, Chili Style,” respectively, in the labels that you submitted to us on March 25, 2002. The TMP granted on June 27, 2002 provided for the use of the term “chunky” in lieu of style declarations (for example, diced) required by the current standard of identity for canned tomatoes (See Title 21 Code of Federal Regulations

02N-0178

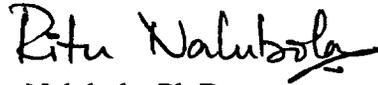
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Page 2 – Mr. Melvin S. Drozen

Section 155.190). Therefore, the manner in which the term “chunky” is used in your final labels is not consistent with the provisions of the TMP granted on June 27, 2002.

If you have further questions, please do not hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink that reads "Ritu Nalubola". The signature is written in a cursive style with a long horizontal stroke at the end of the name.

Ritu Nalubola, Ph.D.  
Division of Food Labeling  
and Standards  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

**KELLER AND HECKMAN LLP**  
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WRITER'S DIRECT ACCESS

**Melvin S. Drozen**  
(202) 434-4222  
drozen@khlaw.com

January 16, 2003

**Via Hand Delivery**

Geraldine June  
Team Leader, Conventional Foods Team  
Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling, and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Room 4D-014  
Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Labels for Products to be Marketed Under Del Monte's Temporary  
Marketing Permit**

Dear Ms. June:

Enclosed you will find one original set and one copy of the labels for the products that Del Monte is marketing under its Temporary Marketing Permit (TMP) that was granted by the Agency on June 27, 2002. 67 Fed. Reg. 43325 (June 27, 2002). In addition, we have been informed by our client that they began introducing the TMP products into interstate commerce on August 1, 2002.

Please let us know if you have any questions or concerns regarding the labels or Del Monte's marketing of these products.

Best regards,

  
Melvin S. Drozen

cc: Tim Ernst  
Bill Spain

Enclosures

WRITER'S DIRECT ACCESS

March 25, 2002

**Melvin S. Drozen**  
(202) 434-4222  
drozen@khlaw.com

**Via Hand Delivery**

Geraldine June  
Team Leader, Conventional Foods Team  
Division of Standards and Labeling Regulations  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition  
Room 4D-014  
Harvey W. Wiley Federal Building  
5100 Paint Branch Parkway  
College Park, MD 20740

**Re: Del Monte Temporary Marketing Permit Application**

Dear Ms. June:

Following up on our March 21, 2002 phone call with Dr. Ritu Nalubola, enclosed are the labels for all of the Del Monte brand products covered by the company's temporary marketing permit (TMP) as listed in the attachment to our December 21, 2001 letter. We have provided you with one set of color copies of the labels, along with two photocopied sets. We understand from Dr. Nalubola that you will take care of sending these labels to her via Federal Express.

As we mentioned to Dr. Nalubola, at this time, for the 2002 packing season, Del Monte would like to move forward with the TMP for the Del Monte brand products only, although the Company would like to market the S&W and Contadina brand products during the 2003 packing season. As you know, under 21 C.F.R. § 130.17, a TMP is generally granted for 15 months and marketing is to begin within 3 months after notice of TMP issuance is published in the Federal Register. Since the S&W and Contadina products would not be marketed until later next year, and to avoid any undue delay in the granting of the TMP, we enclose the labels for the Del Monte brand products only. Once this TMP is granted, the Company plans to submit an amended or new TMP application for the S&W and Contadina products. Because this would essentially be a "me too application," we would expect that CFSAN would need to expend few resources on processing it which could be done fairly quickly.

Additionally, Dr. Nalubola indicated that you would like information on the tomato solids levels in the finished food products in order to assist you in deciding the proper approach for establishing the upper limits for the maximum amount of high fructose corn syrup (HFCS) liquid sweetener that may be added to products under the TMP. We requested that Del Monte provide

Geraldine June  
March 25, 2002  
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KELLER AND HECKMAN LLP

us with this information, and they have informed us that they do not have or maintain information on the tomato solids levels contained in their finished products. Thus, they will not be able to provide this information which we assume will not be a problem at this point.

In the meantime however, we continue to believe that the best and most efficient approach regarding the issue of setting a maximum liquid sweetener level for this TMP is to set the limit at not more than 10% of the HFCS levels provided in the table attached to our December 21, 2001 letter. This is a trivial difference, but one that allows Del Monte a small amount of recipe flexibility.

\* \* \*

We trust that the information provided in this letter along with the enclosed labels will further assist you in approving Del Monte's TMP application. Should you have any additional questions or require any clarification regarding the issues discussed above, please do not hesitate to contact me, preferably by telephone so that we may respond expeditiously.

Sincerely,



Melvin S. Drozen

Enclosures

cc: William J. Spain  
Timothy S. Ernst

Memorandum of Telephone Conversation

April 30, 2002

Between

Ritu Nalubola  
Division of Standards and Labeling Regulations  
ONPLDS, CFSAN

and

Melvin Drozen  
Keller and Heckman LLP  
representing Del Monte Corporation

Subject: TMP for canned tomatoes; "chunky" style deviation

I spoke with Melvin Drozen to inform him that two of Del Monte's canned tomato products labels, submitted along with their TMP application, use the word "chunky" to describe the products. This term is not provided in the standard of identity for canned tomatoes and, therefore, its use would be considered a deviation from the canned tomatoes standard. Mr. Drozen stated that Del Monte is requesting that FDA approve the use of the word "chunky" in the TMP. I informed him that Del Monte must provide FDA with the necessary information required by section 130.17(c), as Del Monte provided for the other deviation it seeks. Mr. Drozen asked if he could provide this information electronically, and I agreed.



Ritu Nalubola

R/D:HFS-822:RNalubola:4/30/02  
Init:HFS-822:GAJune:5/01/02

**June; Geraldine A**

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**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)

202-434-4222 (Fax-4646)



MAY 6 2002

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

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

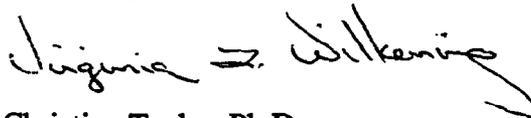
Page 2 – Mr. Melvin S. Drozen

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