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WRITER'S DIRECT ACCESS

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

April 23, 2003

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: Renewal of Del Monte Temporary Marketing Permit

Dear Ms. June:

On behalf of the Del Monte Corporation ("Del Monte"), pursuant to 21 C.F.R. §§ 130.17(f) and (i), we respectfully submit this request for an extension of Del Monte's temporary marketing permit ("TMP") for Del Monte brand canned tomatoes deviating from the Agency's Standard of Identity at 21 C.F.R. § 155.190. See 67 Fed. Reg. 43325 (June 27, 2002). The existing TMP is scheduled to expire on October 31, 2003. As required by the regulation, enclosed is a copy of the Citizen Petition we have submitted on behalf of Del Monte to amend the Standard of Identity for canned tomatoes.

In addition, pursuant to 21 C.F.R. §§ 130.17(f) and (i), we inform the Agency of Del Monte's intent to market additional varieties of canned tomatoes pursuant to the original TMP. These varieties will be marketed under the brand names of Del Monte (one new product), Contadina, and S&W. See enclosed proposed draft labels. We also request that these additional varieties be included in the TMP renewal requested above for the product varieties initially approved under the original TMP. We note that submitting one request to cover this entire matter is consistent with our discussions with Dr. Ritu Nalubola, who we understand discussed the situation with you.

As set forth below, Del Monte is requesting that the Agency permit the temporary use of the liquid carbohydrate sweeteners corn syrup or high fructose corn syrup (collectively, "liquid sweeteners") in its canned tomato products in lieu of the dry nutritive carbohydrate sweeteners ("dry sweeteners") now required by the standard of identity for canned tomatoes (21 C.F.R. § 155.190(a)(2)(iii)). In addition, the Petitioner requests that the Agency allow for the use of "chunky" as a style of canned tomatoes.

As required by 21 C.F.R. § 130.17(c), we submit the following information in support of this request in the order identified in the regulation.

1. 21 C.F.R. § 130.17(c)(1).

Del Monte Corporation One Market @ The Landmark P.O. Box 193575 San Francisco, CA 94119-3575

2. 21 C.F.R. § 130.17(c)(2).

Del Monte is regularly engaged in producing canned tomato products.

3. 21 C.F.R. § 130.17(c)(3).

Canned tomatoes -- 21 C.F.R. § 155.190(a)(2)(iii) (permits the use of dry nutritive sweeteners to offset the tartness of organic acids added to canned tomato products).

4. 21 C.F.R. § 130.17(c)(4).

Del Monte requests permission to use liquid sweeteners as an alternative to the dry sweeteners now permitted by 21 C.F.R. 155.190(a)(2)(iii). The specific level of liquid sweeteners used in the canned tomato products will be limited to the amount necessary to offset the tartness of added organic acids in the products, which is identical to the §155.190(a)(2)(iii) requirement for the addition of dry sweeteners to such products.

5. 21 C.F.R. § 130.17(c)(5).

The use of liquid sweeteners as substitutes for dry sweeteners is widely practiced in the food products industry and accepted by consumers. These liquid sweeteners are generally recognized as safe for addition to food (21 C.F.R. §§ 184.1865 and 184.1866).

6. 21 C.F.R. § 130.17(c)(6).

The specific level of liquid sweeteners used in the canned tomato products will be limited to the amount necessary to offset the tartness of the products' added organic acids, and is identical to the §155.190(a)(2)(iii) requirement for the addition of dry sweeteners to such products. In all other respects, the test products will comply with the standard of identity for canned tomato products. In addition, per the Federal Register notice announcing the issuance of Del Monte's TMP, the Company will ensure that the use of liquid sweetener does not 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 C.F.R. § 155.3(e). See 67 Fed. Reg. 43325 (June 27, 2002).

7. 21 C.F.R. § 130.17(c)(7).

Del Monte anticipates that the use of liquid sweeteners will result in significant cost savings and measurable health and safety gains for the employees involved in the production process. These benefits will take two forms:

- (1) Liquid sweeteners are typically available at significantly lower costs compared to dry nutritive sweeteners. Del Monte estimates that it will experience substantial cost savings if it can substitute liquid sweeteners for dry sweeteners as an optional ingredient in the manufacture of canned tomato products. These savings in this typically low margin industry would come at no health or nutritional cost to consumers. Cost savings in the manufacture of the product may result in economic benefit to consumers.
- The use of liquid sweeteners will also result in safer working conditions as part of the manufacturing process. Dry sweeteners typically are available in 50-pound bags, which must be manually handled as part of the manufacturing process. Back injuries are the most common form of injury among workers involved in manufacturing operations, and the number one cause of back injuries is lifting heavy objects. Lifting 50-pound bags of dry sucrose is a potential source of back injuries. Liquid sweeteners can be pumped into the manufacturing process through fixed piping systems, thus eliminating the need for heavy lifting.

8. 21 C.F.R. § 130.17(c)(8).

The use of liquid sweeteners may also benefit consumers by lowering their costs for canned tomato products. Moreover, the reduction in the cost of one ingredient (sweeteners) may allow the introduction of new products with more costly optional ingredients (e.g., peppers, seasonings or flavors) at the same price point. Thus, the modified products may lead to a larger variety of canned tomato products available to consumers.

9. 21 C.F.R. 130.17(c)(9).

Consumers will be able to distinguish the products being marketed under the TMP from other canned tomato products because "corn syrup" or "high fructose corn syrup" will be identified on the test products' ingredient lists instead of sugar. The products will be distributed under the Del Monte, Contadina, and S&W Brand labels. See attached sample labels.

10. 21 C.F.R. § 130.17(c)(10).

Pursuant to 21 C.F.R. § 130.17(i), Del Monte has submitted a Citizen Petition requesting that the Standard of Identity for canned tomatoes (21 C.F.R. § 155.190) be amended to permit

the use of liquid sweeteners and "chunky" as a style. Pursuant to the TMP granted in June 2002, approximately 5.6 million cases of canned tomatoes with liquid sweetener have been marketed. Del Monte has received no complaints or other information from consumers suggesting anything other than full consumer acceptance of the use of liquid sweeteners in canned tomatoes. Accordingly, for this reason and because the Company is submitting a Citizen Petition to amend 21 C.F.R. § 155.190, Del Monte requests a permit to market all referenced Del Monte, Contadina, and S&W products until such time as the Agency issues a regulation amending 21 C.F.R. § 155.190 as requested. Del Monte would like the revised and extended permit to be issued in time for its year-2003 pack season, which begins approximately July 1, 2003.

11. 21 C.F.R. § 130.17(c)(11).

Because Del Monte is requesting an unlimited TMP, it cannot accurately anticipate the number of cases to be distributed, although it would expect to distribute approximately 10.3 million cases annually. The tomato products that would be covered by the TMP are packed on a seasonal basis over an approximately eight-week time period.

12. 21 C.F.R. § 130.17(c)(12).

Because consumer taste preference may vary from state to state, Del Monte believes it is necessary to distribute the test product throughout the United States to determine the commercial viability of the test products.

13. 21 C.F.R. § 130.17(13).

The modified products will be manufactured by Del Monte Corporation at the following address:

Del Monte Corporation 10652 Jackson Avenue Hanford, CA 93230

14. 21 C.F.R. § 130.17(c)(14).

For the reasons set forth in paragraph 10 above, the test products will be distributed throughout the United States.

15. 21 C.F.R. § 130.17(c)(15).

N/A

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WRITER'S DIRECT ACCESS

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

April 23, 2003

Hand Delivery

Dockets Management Branch Food and Drug Administration 5630 Fishers Lane, Room 1061 (HFA-305) Rockville, MD 20852

Re: Citizen Petition to Amend the Standard of Identity for Canned Tomatoes at 21 C.F.R. § 155.190

To Whom It May Concern:

On behalf of the Del Monte Corporation ("Del Monte"), we respectfully submit this citizen petition pursuant to sections 401 and 701 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 341, 371) to request the Commissioner of the Food and Drug Administration to initiate rulemaking to amend the Standard of Identity for stewed tomatoes (21 C.F.R. § 155.190) for the purpose of promoting honesty and fair dealing in the interest of consumers.

A. Action Requested

The Petitioner requests that the Agency amend 21 C.F.R. § 155.190(a)(2)(iii) for canned tomatoes as follows to include liquid carbohydrate sweeteners (added language in bold type):

"(iii) liquid carbohydrate sweeteners or dry nutritive carbohydrate sweeteners whenever any organic acid provided for in paragraph (a)(2)(ii) of this section is used, in a quantity reasonably necessary to compensate for the tartness resulting from such added acid."

In addition, the Petitioner requests that the Agency amend 21 C.F.R. § 155.190(a)(4) be amended as follows to include "chunky" as an approved style of canned tomatoes (added language in bold type):

- "(4) Styles (i) Whole.
- (ii) Diced.

Washington, D.C.

- (iii) Sliced.
- (iv) Wedges.
- (v) Chunky."

We also note that as a condition of its current TMP and request for extension, Del Monte is ensuring that the use of liquid sweetener does not 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 C.F.R. § 155.3(e). See 67 Fed. Reg. 43325 (June 27, 2002). The Company would not object if FDA makes this condition a requirement in the amended Standard of Identity for canned tomatoes.

B. Statement of Grounds

Petitioner requests permission to use liquid sweeteners as an alternative to the dry sweeteners now permitted by 21 C.F.R. 155.190(a)(2)(iii). The specific level of liquid sweeteners used in the canned tomato products will be limited to the amount necessary to offset the tartness of added organic acids in the products, which would be identical to the §155.190(a)(2)(iii) requirement for the addition of dry sweeteners to such products. The use of liquid sweeteners as substitutes for dry sweeteners is widely practiced in the food products industry and accepted by consumers. Furthermore, liquid sweeteners have been used successfully in canned tomatoes currently being marketed under a temporary marketing permit previously requested by the petitioner. See 67 Fed. Reg. 43325 (June 27, 2002). Del Monte has received no complaints or other information from consumers suggesting anything other than full consumer acceptance of the use of liquid sweeteners in canned tomatoes.

Del Monte anticipates that the use of liquid sweeteners will result in significant cost savings and measurable health and safety gains for the employees involved in the production process. These benefits will take two forms:

- (1) Liquid sweeteners are typically available at significantly lower costs compared to dry nutritive sweeteners. Del Monte estimates that it will experience substantial cost savings if it can substitute liquid sweeteners for dry sweeteners as an optional ingredient in the manufacture of canned tomato products. These savings in this typically low margin industry would come at no health or nutritional cost to consumers. Cost savings in the manufacture of the product may result in economic benefit to consumers.
- (2) The use of liquid sweeteners will also result in safer working conditions as part of the manufacturing process. Dry sweeteners typically are available in 50-pound bags, which must be manually handled as part of the manufacturing process. Back injuries are the most common form of injury among workers involved in manufacturing operations, and the number one cause of back injuries is lifting heavy objects. Lifting 50-pound bags of dry sucrose is a potential source of back injuries. Liquid sweeteners can be pumped into the manufacturing process through fixed piping systems, thus eliminating the need for heavy lifting.

The use of liquid sweeteners may also benefit consumers by lowering their costs for canned tomato products. Moreover, the reduction in the cost of one ingredient (sweeteners) may allow the introduction of new products with more costly optional ingredients (e.g., peppers, seasonings or flavors) at the same price point. Thus, the amendment of the Standard of Identity would result in a larger variety of canned tomato products available to consumers.

C. Environmental Impact

This petition is subject to a categorical exclusion under 21 C.F.R. 25.32(a) (issuance, amendment, or repeal of a food standard).

D. Economic Impact

Information will be provided to the extent requested by the Commissioner.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Melvin S. Drozen

ce: William J. Spain Timothy S. Ernst

June, Geraldine A

From:

Nalubola, Ritu

Sent:

Thursday, June 26, 2003 12:04 PM

To:

June, Geraldine A

Subject:

FW: email to Dr. Nalubola

Geraldine,

Here is Mel Drozen's note. I took out the label attachments.

----Original Message----

From: Melvin Drozen [mailto:drozen@khlaw.com]

Sent: Wednesday, June 25, 2003 4:50 PM

To: Nalubola, Ritu

Cc: Tim.Ernst@delmonte.com; Sarah Key
Subject: Re: email to Dr. Nalubola

Dr. Nalubola,

In response to your voice mail message, please find attached the revised labels. As you can see, in response to your comments, Del Monte has made the following changes:

Contadina labels

"diced tomatoes in rich, thick juice" - the juice is now identified as "tomato juice" in all of the Contadina diced tomato varieties (see attached labels for diced tomatoes with roasted red pepper, with italian herbs, with roasted garlic, diced tomatoes primavera, and diced tomatoes marinara)

S&W label

"stewed tomatoes sliced with pear tomatoes, oregano & basil" - the label now reads "sliced pear tomatoes with oregano & basil"

Remaining label issues

- 1. Del Monte has discontinued the diced tomatoes in tomato juice with caramelized onions.
- 2. Contadina diced tomatoes roasted red pepper: (the ingredient statement identifies the pepper as "bell pepper" whereas the "red pepper" listed in the product descriptor could refer to another type of pepper) We confirmed with Del Monte that the bell pepper is a red bell pepper. We believe that there would not be any consumer confusion since we think it will be clear to consumers that product contains red bell peppers. Also, at this point, Del Monte would not be able to revise this label without incurring significant cost. Thus, at this point, the Company would prefer not to revise the labels. If you believe it is necessary, and it is acceptable to you, we would propose making revisions to this label when the labels are printed for the second time.

Please let us know if you need any additional information regarding the labels in order to move forward with the TMP extension. We will be sending you hard copies of the revised labels as soon as they are available. All of the revised labels below and the other draft labels that we initially submitted to you may be considered "final" for purposes of the TMP extension request.

As we have discussed, since Del Monte would like to begin packing the S&W and Contadina products very soon with shipment occurring by mid-summer, anything you can now do to expedite this TMP would be greatly appreciated.

Thank you for your continued assistance.

Regards,

Mel Drozen and Sarah Key

KELLER AND HECKMAN LLP

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WRITER'S DIRECT ACCESS

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

June 30, 2003

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: Revised Labels for Del Monte Temporary Marketing Permit Extension

Dear Ms. June:

At the request of Dr. Ritu Nalubola, please find enclosed revised labels for the following S&W and Contadina brand products in connection with Del Monte's request for an extension of its Temporary Marketing Permit:

- S&W Italian Recipe Stewed Tomatoes
- Contadina Diced Tomatoes Italian Herbs
- Contadina Diced Tomatoes Primavera
- Contadina Diced Tomatoes Roasted Garlic
- Contadina Diced Tomatoes Roasted Red Pepper
- Contadina Diced Tomatoes Marinara

Cordially yours,

Melvin S. Drozen

Mil Ingen

Enclosures

June, Geraldine A

From:

Nalubola, Ritu

Sent:

Tuesday, July 15, 2003 4:47 PM

To: Subject: June, Geraldine A FW: weight information

----Original Message----

From: Sarah Key [mailto:key@khlaw.com] Sent: Friday, June 27, 2003 2:41 PM To: Nalubola, Ritu

Cc: Melvin Drozen

Subject: weight information

Dr. Nalubola,

The weight of the 10.3 million cases Del Monte expects to distribute annually pursuant to the extended TMP is 226.6 million pounds. We will forward the revised labels to you as soon as possible.

Thank you for your assistance.

Regards,

Sarah A. Key, Esq. Keller and Heckman LLP 1001 G Street, NW Suite 500 West Washington, DC 20001 (202) 434-4236 (202)434-4646 fax





LABEL LENGTH 9 1/2"

COLOR COVERAGE 9 1/2"

WEEL 8 3/35.

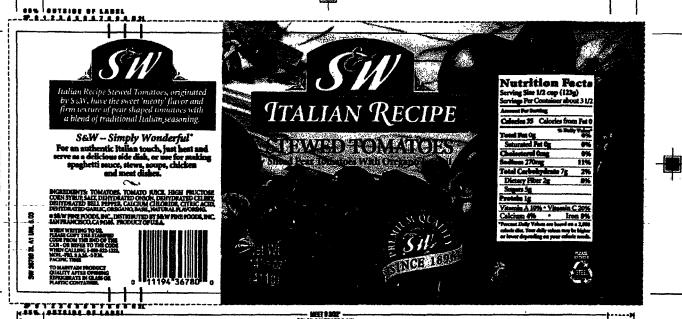
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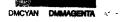








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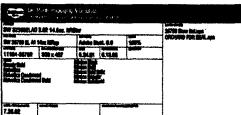


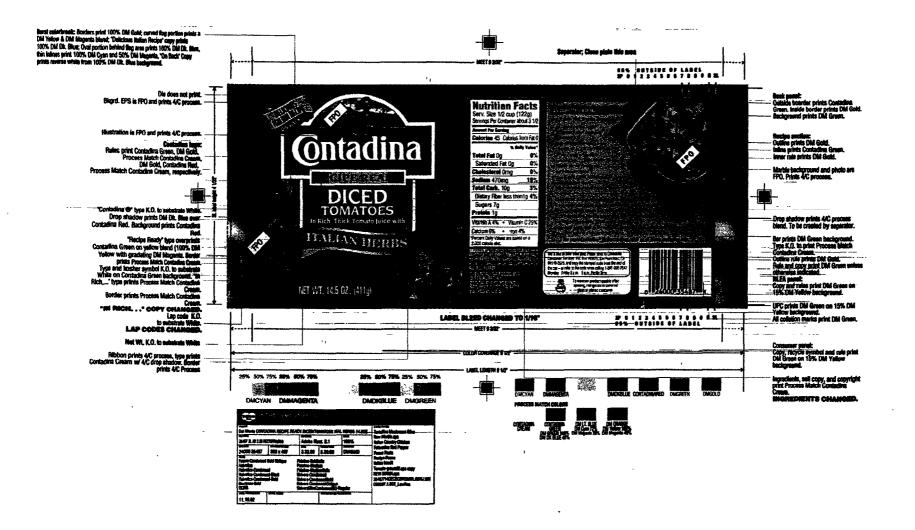




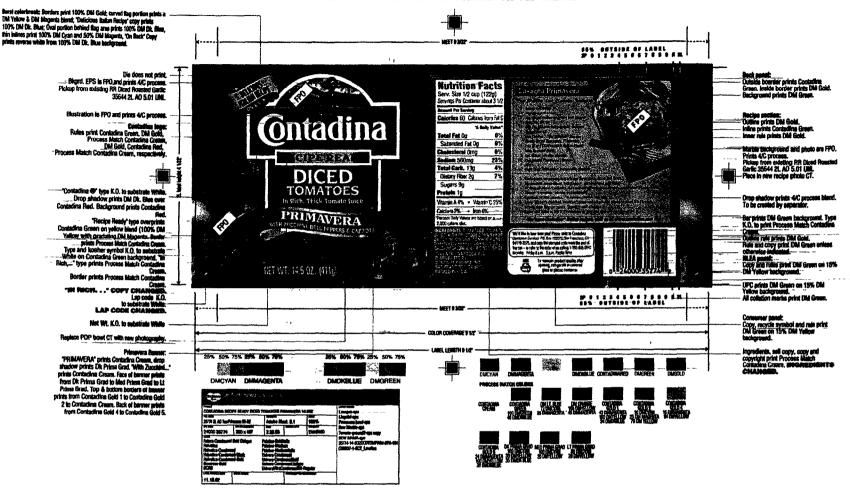








NOTE: USE BASE 35775 21, AN 3.02 UNL R1 & REMOVE "NEW" VIOLATOR.

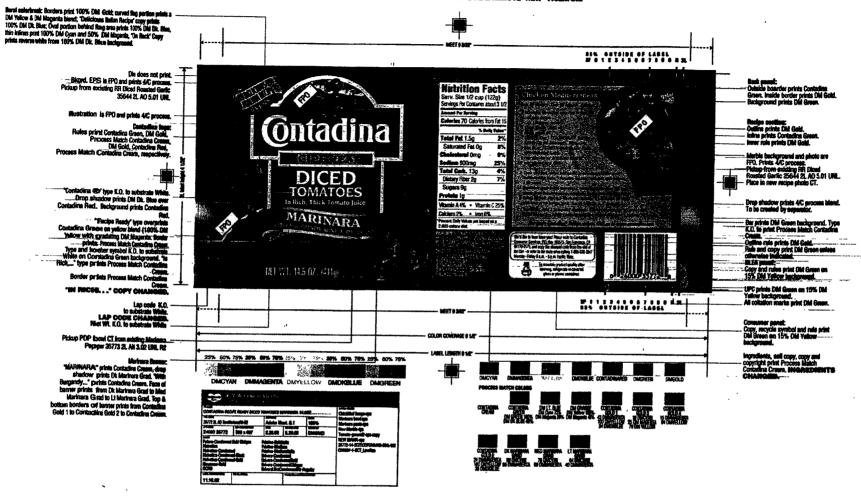


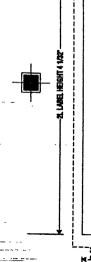


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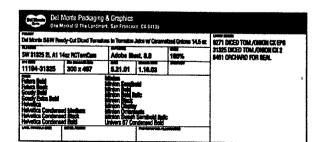
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S&W 14-1/2 OZ. READY-CUT DICEDTOMATOES WITH ROASTED GARLIC 4-1/32 X 9-3/32 X 9-1/2 JOB# 4280-37121 (01/16/02)



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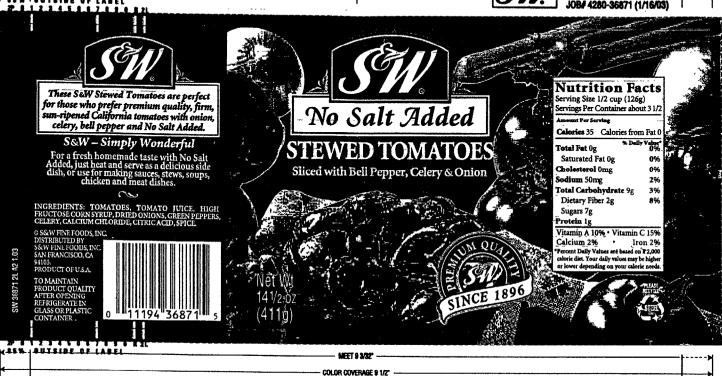
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S&W 14-1/2 OZ. NO SALT ADDED STEWED TOMATOES 4-1/32 X 9-3/32 X 9-1/2 JOB# 4280-36871 (1/16/03)



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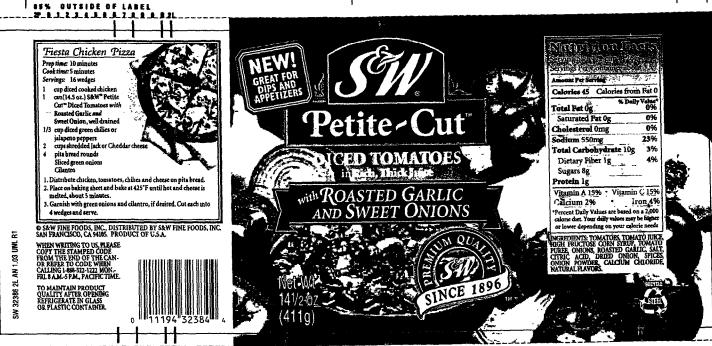




Del Monte Packaging & Graphics
One Market @ The Landmark, San Francisco, CA 94105



S&W 14-1/2 OZ. PETITE-CUT DICED TOMATOES GARLIC & ONIOMS 4-1/32 X 9-3/32 X 9-1/2 JOB# 3394-32384 (06/19/03)



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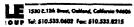
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DMCYA

DMMAGENT

DMDKBLUE

Del Monte Packaging & Graphics
One Monte! & The Landmark, San Francisco, CA 96105







S&W 28 OZ. ITALIAN STYLE STEWED TOMATOES 4 5/16 X 12 3/8 X 13 JOB# 4280-36783 (1/16/03)



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LABEL LENGTH 13"

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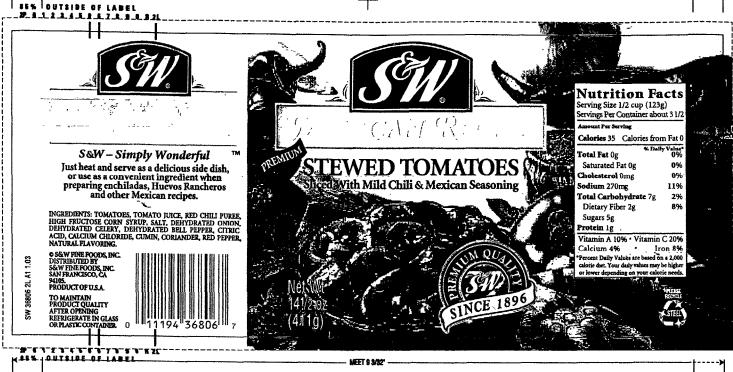
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14-1/2 OZ. MEXICAN RECIPE STEWED TOMATOES 4-1/32 X 9-3/32 X 9-1/2 JOB# 4280-36806 (1/16/03)



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DMCYAN DMMAGENTA

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MEET 9 3/32"

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TEST OUTSIDE OF LABEL





14-1/2 OZ. ITALIAN RECIPE STEWED TOMATOES 4-1/32 X 9-3/32 X 9-1/2 JOB# 4280-36780 (1/16/03)



LABEL LENGTH 9 1/2"

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Del Monte Packaging & Graphics