KELLER AND HECKMAN LLP

SERVING BUSINESS THROUGH LAW AND SCIENCE®

1001 G STREET. N. W. SUITE 500 WEST WASHINGTON, D.C. 20001 TEL. 202.434.4100 FAX 202.434.4646 WWW.EHLAW.OM

WRITER'S DIRECT Access

Melvin S. Drozen
(202) 434-422

(202) 434-422 drozen@khlaw com

男 2

P5:20

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

Washington, D.C. 03P-0171 BRUSSELS

SAN FRANCISCO

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

cc: William J. Spain Timothy S. Ernst