

October 6, 2003

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

Re: Docket No. 03P-0171

To Whom It May Concern:

The Sugar Association, Inc. (Association) represents the United States sugar cane growers and refiners and sugar beet growers and processors. Association members account for over 90% of this country's sugar production. As the public information arm of the sugar industry, the Association disseminates scientifically substantiated information concerning sugar through public education and communication programs.

In response to the Federal Register Notice on April 24, 2003, the Sugar Association, Inc. hereby submits comments on the Del Monte Corporation petition to Amend the Standard of Identity for Canned Tomatoes at 21 C.F.R. 155.190. The Association is pleased to respond to the Food and Drug Administration (FDA) request for comments on the issues raised in the Del Monte petition.

We are addressing the specific issues that Del Monte cites as justifications for changing the Standard of Identity for Canned Tomatoes. **First and foremost, we contend that the two principle justifications, economic and ergonomics, provided by Del Monte in support of their petition are flawed in that these issues are not consistent with FDA's criteria for the granting of a Temporary Marketing Permit (TMP) or amending standards of identity.**

Economic Considerations

In its petition, Del Monte states it anticipates the use of liquid sweeteners will result in significant cost savings compared to dry nutritive sweeteners. Del Monte also maintains that cost savings from using cheaper sweeteners in the manufacture of canned tomatoes may result in economic benefit to consumers.

Del Monte provides no supporting documentation to validate its contention that savings on product ingredients are passed on to consumers. Therefore, Del Monte is offering to FDA a theoretical benefit as a justification for granting this petition.

03P-0171 Be Sure It's Sugar: The Natural Sweetener... 15 Calories Per Teaspoon!™

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The food industry seldom, if ever, passes on savings from less expensive ingredients to the consumer. The Association is providing an analysis of U.S. Department of Agriculture data that, in fact shows the opposite is true. (Attachment 1-7)

Ergonomic Consideration

In its petition, Del Monte states, "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." Although we would concede that lifting is the number one cause of back injuries, the petition states specifically "Lifting 50-pound bags of dry sucrose is a potential source of back injuries." Back injuries can result from many sources including lifting cases of the final product.

Furthermore, sugar processors provide sucrose in a variety of packaging options including delivery by semi-truck and railroad car for direct pneumatic unloading to holding facilities at processing plants, as well as in 25-pound bags to resolve the issue of lifting 50-pound bags.

Also, mechanized ingredient handling equipment is widely available to help employers to meet OSHA requirements and to ensure the safest possible work environment for employees. In fact, OSHA statistics show that number of sprain and strains, most often involving the back, declined by 34.5 percent from 1992 to 2001, undoubtedly due to the availability of better mechanized ingredient handling equipment (1).

Del Monte has not supplied supporting documentation that shows a specific or inordinate injury problem from handling dry sucrose in its manufacturing processes. We submit that this is an OSHA issue, not an FDA issue.

Consumer Health Considerations

We would also like to address Del Monte's assertion that changes in the standard would come at no health or nutritional cost to consumers. The FDA rule regarding temporary marketing permits (21 C.F.R. 130.7) indicates that TMPs are issued to determine whether there are "advantages to and acceptance by consumers" to amend a standard of identity, specifically to obtain data necessary to demonstrate, among other things, that the "interests of the consumer are adequately safeguarded." Given the issues raised over the past year by the scientific community regarding possible health implications of fructose and the increased consumption of free fructose particularly via HFCS, we believe that further consideration should be given this issue before granting this petition. Scientific references (2,3,4) where free fructose and health concerns are cited are listed below.

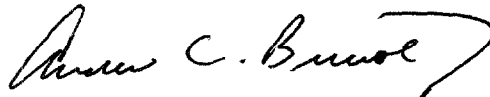
Finally, the Association contends that due to consumer confusion about the "Sugars designation" on the Nutrition Fact Panel, many consumers are not aware of the specific sugar or sweetener in a food product, even though listed in the ingredient statement. Consumers interpret the "Sugars" designation to mean sugar (sucrose). This may be the principal reason for lack of consumer response to Del Monte's temporary marketing test.

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Consumer ignorance to what ingredient changes have been made in a food product does not automatically equate to consumer acceptance.

In conclusion, the Association respectfully requests that FDA maintain the Standard of Identity in 21 C.F.R. 155.190. Please do not hesitate to let us know if we can answer any questions or provide further information pertaining to these comments.

Sincerely,



Andrew C. Briscoe III
President

- (1) Bureau of Labor Statistics, *Lost-Worktime Injuries and Illnesses: Characteristics and Resulting Days Away From Work, 2001*, <http://www.bls.gov/iif/home.htm>
- (2) National Academy of Sciences, Institute of Medicine, Food and Nutrition Board. *Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids*. National Academy Press, 2002. Page 6-23.
- (3) American Dietetic Association. Use of nutritive and nonnutritive sweeteners – Position of ADA. *Journal of the American Dietetic Association* **98(5)**: 580-587, 1998. Available at <http://www.eatright.com/adap0598.html>. Reaffirmed 2002.
- (4) American Diabetes Association. Evidence-Based Nutrition Principles and Recommendations for the Treatment and Prevention of Diabetes and Related Complications. *Diabetes Care* **25(Supplement 1)**: S50-S-60, 2002.