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July 17, 2003

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

Dear Sir or Madam:

**Re: Docket No. 02N-0434, Withdrawal of Certain Proposed Rules and Other Proposed Actions; Notice of Intent**

**Specifically** in reference to the proposed withdrawal of **Docket No. 90N-361M, Declaration of Ingredients – Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; “And/Or” Labeling for Soft Drinks; Proposed Rule; 58 Fed Reg 2950, January 6, 1993**

#### **Action Requested**

In the interest of providing consumers accurate food labeling information, the Sugar Association commends Food and Drug Administration (FDA) action to withdraw the proposed rule to allow “and/or” labeling of Soft Drinks.

The soft drink industry continues to use “and/or” labeling without a final rule or a temporary permit due to FDA’s decision not to initiate enforcement action against the industry. This decision was submitted to the National Soft Drink Association in a May 28, 1997 letter signed by F. Edward Scarbrough, PhD, Director, Office of Food Labeling. (Attachment 1)

To fully implement the FDA’s action to withdraw “and/or” labeling of soft drinks, the Association requests the FDA also rescind its decision “not to initiate enforcement action against soft drink manufactures that use “and/or” labeling in the listing of sweetener.”

#### **Background**

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.

Be sure it's Sugar: The Natural Sweetener. 15 Calories Per Teaspoon!

02N-0434

THE SUGAR ASSOCIATION, INC

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1101 15th Street, NW Suite 600 • Washington D.C. 20005



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Over the years, the Sugar Association has in both formal comments and in several meetings with agency representatives, urged FDA to actively bring an end to this improper use of “and/or” labeling that is being employed by the soft drink industry to deceive consumers about the quality of their product. The attached summary documents the history of this issue as it has evolved since 1983 when the soft drink industry began using high fructose corn syrup (HFCS) instead of sugar in most products (Attachment 2)

In the six years since FDA informed the industry that it would not take enforcement action against the soft drink industry, the United States soft drink and beverage industries have not used appreciable amounts of sugar, but have instead essentially replaced sugar with HFCS.

### **Review of Grounds for Denial of “and/or” Labeling in Soft Drinks “And/Or” Labeling Precedent**

Current regulations permit “and/or” ingredient labeling only for fats and oils (when they are not the predominant ingredient in the product) [21 CFR 101.4 (b) (14)], for leavening agents [21 CFR 101.4 (b) (16)] and for firming agents [21CFR 101.4 (b) (19)]. In each instance, a compelling case was made for the flexibility that “and/or” labeling provides. Moreover, the ingredients that can be substituted and represented on the label are not perceived by consumers as possessing added value when comparing one type of ingredient to another. We emphasize that in these three instances ingredients not present in a product may be listed only if they are sometimes used in the product. We believe FDA mandated this provision to insure that consumers would not be totally misled by the “and/or” designation. The current label would suggest that sugar is almost always present when in fact it never is in beverages that have the “high fructose corn syrup and/or sugar” label.

When sugar is used in the manufacture of soft drinks these products are labeled correctly as sweetened only with sugar (e.g.):

- During the eight-day period of Passover when a small number of bottlers use sugar because corn syrup is not considered Kosher. The ingredient statement lists sugar as the sole sweetener in these soft drinks, and for obvious reasons the “and/or” designation is absent.
- In 1996 a number of Louisiana bottlers started producing “Louisiana Pepsi” in recognition of the 200<sup>th</sup> anniversary of the Louisiana cane sugar industry. “Louisiana Pepsi” was a sugar-sweetened beverage that was labeled correctly as sweetened only with sugar.

### **Economic Rational**

FDA’s primary rationale for the “and/or” exemption was to allow manufacturers to take advantage of claimed periodic price changes and fluctuations of ingredients. However,

this argument is unwarranted when applied to sweeteners since HFCS is lower in price than sugar. Soft drink manufacturers have no economic incentive to switch from HFCS to sugar and there is absolutely no evidence that this situation will change in the foreseeable future.

### **Technological Problems Overstated**

In 1993, the soft drink industry cited “technological problems” and the need for “flexibility” as a rationale for allowing “and/or” labeling of soft drinks. The fact is that bottlers today manage larger and more varied inventories, requiring a number of differently labeled packages. Today’s realities demonstrate that the industry has the capability to manage the diversity of label formats required to comply with current ingredient labeling regulations. Hence, current bottling technology has resolved “technologic problems,” while maintaining production “flexibility” that enables the soft drink industry to comply with FDA’s ingredient labeling regulations, as evident in Passover soft drinks and Louisiana Pepsi. The soft drink and beverage industries are proving that the need for “and/or” labeling is unnecessary.

### **Contradicts Legal Precedents**

The FDA’s legal precedents support continuation of specific ingredient labeling (common or usual name) for nutritive sweeteners, including those used in soft drinks. The FDA has designated that “sugar, in the ingredient statement, should refer to sucrose from sugar cane or sugar beets.” In 1991 the FDA denied the National Soft Drink Association’s 1984 “and/or” labeling petition stating, “Labels on products that do not include the names of specific sweeteners used to fabricate the foods misbrands the products under section 403 (i) of the act.”

### **Accurate Consumer Information**

The real issue is consumer deception. Sweeteners are not interchangeable since they differ in the way they metabolize, function and taste. (Attachment 3, Consumer Email)

Gastrointestinal health is one example where consumers may need to know the exact content of their food product. The American Dietetic Association in its 1998 position statement made this distinction between sucrose and HFCS regarding gastrointestinal problem, “Fructose is better absorbed when consumed in sucrose, than in products where the amount of free fructose exceeds the amount of glucose (e.g., in honey, prunes, apples and juice, HFCS, or crystalline fructose). Fructose is primarily absorbed from the gut by facilitated diffusion. Persons vary in their abilities to absorb fructose-some experience symptoms of malabsorption with 20- to 50-g load. (A 12-oz sweetened soda or fruit drink has between 14 and 22 g fructose; 1 c apple juice has 14-g fructose.)” Consumers should be given accurate ingredient information to allow them to make informed decisions when choosing their food products. (1)

Docket Management Branch

July 17, 2003

Page 4 of 4

Allergens are another example of consumers need for accurate information. Consumer concerns about corn allergies are increasing. The number of consumer inquiries to the Association looking for alternative sources of powdered sugar without the traditional 3% cornstarch added to control caking has increased significantly over the past few years.

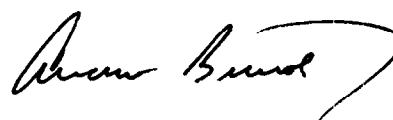
Although HFCS is made up of portions of glucose and portions of fructose, manufacturers also report variable amounts of "higher saccharides," which are essentially cornstarch residuals. In, Vol. 56 No. 120 *Fed Reg* 28604, FDA acknowledged consumer reports of allergic reaction to corn-derived sweeteners. Consumers are entitled to know the exact ingredient in their food product.

The Association believes the product label is the proper context for consumers to evaluate the nutritional quality and ingredients in food products. The use of "and/or" labeling by the soft drink and sweetened beverage industries continues to mislead consumers as to the actual sweetener in these products.

The Association respectfully requests the Food and Drug Administration formally withdraw all approval that permits "and/or" labeling for sweeteners in carbonated soft drinks and sweetened, still beverages. A twenty-year track record is proof of the soft drink industry's longstanding disregard of FDA's advice, requests and formal warnings. Furthermore, in the past twenty years the soft drink industry has shown by its sole use of HFCS in "and/or" products that the merits of their argument has been predicated on a false premise that has misled the American public and the FDA.

Please do not hesitate to let us know if we can answer any questions or provide further information pertaining to these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew Briscoe, III". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Andrew C. Briscoe, III  
President and CEO

(1) 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



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

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NO:36

Howard R. Roberts, Ph.D.  
Senior Vice President  
Scientific and Regulatory Affairs  
National Soft Drink Association  
1101 Sixteenth Street, N.W.  
Washington, D.C. 20036

Dear Dr. Roberts:

This responds to your letter of September 26, 1996, to David Kessler, M.D., former Commissioner of Food and Drugs, regarding "and/or" labeling for sweeteners in soft drinks. We regret the delay in responding to your inquiry, and hope that the following is helpful.

First, let me thank you for the additional information you submitted with your correspondence on relevant practices in the soft drink industry. Please be assured that this information has been noted and copies will be added to Docket No. 90N-361M.

As you are aware, the agency has decided to exercise its enforcement discretion and has not initiated enforcement actions against soft drink manufacturers that use "and/or" labeling in the listing of sweeteners. Because of limited agency resources and because this issue does not involve food safety, the agency will likely maintain this position until rulemaking on this issue is complete.

The agency hopes to be able to further address this issue in the near future. Please be assured that all comments will be considered before a final decision on this issue is reached.

Sincerely,

F. Edward Scarbrough, Ph.D.  
Director  
Office of Food Labeling  
Center for Food Safety  
and Applied Nutrition

90N-361M

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## ATTACHMENT 2

### “AND/OR” LABELING FOR SWEETENERS

#### SUMMARY OF REGULATORY ACTIVITY

- May 1983 The Sugar Association informs FDA of the emerging practice of the soft drink industry whereby manufacturers change the sweetener ingredient of their products from “sugar” to “high fructose corn syrup” but do not reflect this change on the label, thereby materially misrepresenting the nature and quality of the soft drink.
- Aug 1983 FDA notifies the National Soft Drink Association (NSDA) that “the ingredient declaration of ‘sugar’ on products containing non-sucrose sweeteners...is in violation of the (FD&C) act and the regulations.” The agency’s action goes unheeded by the soft drink industry and FDA fails to uphold its established policy through enforcement action.
- Jan 1984 NSDA petitions FDA for permission to use “and/or” ingredient labeling for sweeteners.
- Jan 1984 FDA meets with NSDA representatives. A Memorandum of Meeting (1/27/84) states that soft drink industry representatives were told: “If a combination of high fructose corn syrup and sugar are being used to sweeten beverages and the labels declare sugar and/or corn sweetener(s) the products are misbranded”
- Feb 1984 The Sugar Association petitions FDA to issue a regulation formalizing its policy that the term “sugar” in ingredient labeling designates sucrose from sugar cane or sugar beets. The petition was granted. 21 C.F.R. 184.1854; 21 C.F.R. 101.4(b)(22). This rulemaking was significant in establishing a clear and concise definition of “sugar” that comports with consumers’ expectations.
- Aug 1986 FDA Atlanta Field Office sends a Notice of Adverse Findings to the Coca Cola Company stating that labels for Coca Cola products “are not in compliance with federal regulations and are in violation of Federal Food, Drug, and Cosmetic Act.” Among the violations listed is” “The term “high fructose corn syrup and/or sucrose’ which appears in the ingredient statements is not the specific common or usual name of a sweetener. These ingredients may only be declared if actually present and, and if present, must be declared separately in the proper overall order of predominance in the food.”

- Sept 1986 FDA's New York District office sends a Notice of Adverse Findings to Pepsico Inc. Labeling for several of the company's products "are in violation of the Federal Food, Drug, and Cosmetic Act," the Notice stated. Among the violations listed is: "The term "high fructose corn syrup and/or sugar' is not a appropriate ingredient name. Each ingredients may only be declared if actually present and, if present, must be declared in the proper order of predominance..."
- June 1991 FDA denies the 1984 NSDA petition, stating: "Labeling on products that do not include the names of the specific sweeteners used to fabricate the foods misbrand the products under section 403(i) of the act. Firms should take prompt steps to correct such misbranding." 56 *Fed Reg* 28607, June 21, 1991. Nevertheless, the soft drink industry chooses to ignore the enforcement actions undertaken by FDA and its rejection of the NSDA petition.
- Jan 1993 In response to NSDA's request, FDA reopens the issue by proposing a special labeling exemption to allow "and/or" declarations of sweeteners only in beverages 58 *Fed Reg* 2950, January 6, 1993. In seeking comments on this and other ingredient labeling issues FDA does not indicate any change in its existing "and/or" rule or in its enforcement practices.
- March 1993 The Sugar Association comments oppose FDA's proposal, stating: "At this point the Association confesses to utter frustration with the breakdown of regulatory process with regard to ingredient labeling in soft drinks. We do not understand FDA's apparent intention to condone the soft drink industry's longstanding disregard of agency advice, requests and formal warnings, by granting a special privilege based on a petition of questionable merit."
- July 1993 NSDA supplements it comments on the proposal by submitting a survey of soft drink bottlers purporting to show the need for "and/or" labeling of sweeteners in soft drinks. With "and/or" labeling, NSDA states, "consumers would always know what sweeteners may be in soft drinks."
- July 1993 The Sugar Association's response to NSDA's submission maintains the NSDA's data show that the proposed exemption would benefit very few companies at the expense of misleading and misinforming millions of consumers. "The NSDA 'solution'...is no help to consumers at all. This pseudo-solution means that consumers will never know what sweeteners are in soft drinks.
- Sept 1996 NSDA writes a letter to FDA Commissioner David M. Kessler, reiterating the soft drink industries position on "and/or" labeling and concludes in its final paragraph "Until FDA has made a decision in this area, it would be

pointless to undertake enforcement actions against an industry that is responding to what the agency has acknowledged are the necessities of the marketplace.”

May 1997      FDA sends a letter to the NSDA informing them of their decision to exercise its enforcement discretion and not initiate enforcement actions against soft drink manufactures.



## Cheryl Digges

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**From:** [REDACTED]  
**Sent:** Friday, June 13, 2003 8:45 AM  
**To:** digges@sugar.org  
**Subject:** Sugar.org Feedback form

### FORM INFORMATION:

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Sent: 6/13/2003 - 09:45:11 AM EST  
Browser: Mozilla/4.0 (compatible; MSIE 6.0; Windows NT 5.0)  
IP: 170.222.100.82

### FORM VALUES:

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comments: Hi, I have two milk companies that what to supply milk to the children in our school district. One flavored milk is sweetened with sugar, the othe one is sweetened high-fructose corn syrup. I have been reading that HFCS maybe not a wise choice. What are our opinions? Thanks Bonnie  
heard\_about: Found it on the internet  
interest: Nutriton information for our students and family  
related\_info:  
more\_useful:  
name: [REDACTED]  
orgname: Essex Town School District  
address1: [REDACTED]  
address2:  
city: Essex Junction  
state: VT  
zip: 05452  
country:  
phone: [REDACTED]  
ext: [REDACTED]  
email: [REDACTED]

## Cheryl Digges

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**From:** [REDACTED]  
**Sent:** Monday, June 23, 2003 2:11 PM  
**To:** digges@sugar.org  
**Subject:** Sugar.org Feedback form

### FORM INFORMATION:

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Sent: 6/23/2003 - 03:10:49 PM EST  
Browser: Mozilla/4.0 (compatible; MSIE 6.0; Windows NT 5.0; .NET CLR 1.1.4322)  
IP: 129.33.49.251

### FORM VALUES:

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comments: I'm very upset with the foods having so much corn sweeteners in them. I find it better for me to have sugar and not corn sweeteners. How did this happen in all our foods?  
heard\_about: google web  
interest: raw sugar and it's true name.  
related\_info:  
more\_useful: It had just what I needed.  
Turbinado Sugar:  
This sugar is a raw sugar which has been partially processed, removing some of the surface molasses. It is a blond color with a mild brown sugar flavor and is often used in tea.  
name: [REDACTED]  
orgname: MySelf  
address1: [REDACTED]  
address2:  
city: Ormond Beach  
state: Fl  
zip: 32174  
country: USA  
phone: [REDACTED]  
ext:  
email: [REDACTED]

## Cheryl Digges

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**From:** Cheryl Digges [mailto:cheryl.digges@sugar.org]  
**Sent:** Monday, June 23, 2003 8:34 PM  
**To:** digges@sugar.org  
**Subject:** Sugar.org Feedback form

### FORM INFORMATION:

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Sent: 6/23/2003 - 09:33:52 PM EST  
Browser: Mozilla/4.0 (compatible; MSIE 5.5; Windows 98; Win 9x 4.90)  
IP: 67.73.204.81

### FORM VALUES:

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comments: Dear Sirs, I was surprised to read an article Sunday, June 22, in the Cleveland Plain Dealer about sugar, "Debate over sugar's effects turns bitter," by Lance Gay and Lee Bowman. It seems terribly inaccurate. I'm also surprised that the Sugar Association hasn't flooded news services with factual information and news releases regarding the awful references to "sugar." The biggest complaint I have is that the term sugar seems to replace the term sweetener in their article. They state that many food items are packed with sugar. I don't believe any of the food items they mentioned have any sugar; certainly no sugar to the levels they claim. Those food items I believe contain high fructose corn syrup and/or corn syrup instead of sugar. For example, they claim Coca-Cola has 10 teaspoons of sugar in a 12 ounce can. Does Coke contain ANY sugar? They claim half of each teaspoon of ketchup is sugar. The ketchup in my fridge has no sugar listed in the ingredients! , but lists 4 grams of Sugars per teaspoon. The ingredients do contain high fructose corn syrup and corn syrup.

I do not know your organization's position on HFCS (high fructose corn syrup) but I have none of the concerns about true sugar that I have about HFCS. Sugar gives sweet products (the ones that are supposed to have sugar) an honest taste. HFCS gives those products a cheap sweet taste. I lived in Mexico for 2 years, and am disheartened that many local products (from companies owned by US firms) are switching to HFCS. Please keep fighting to keep the honest taste of sugar in the right foods. And, disclose the absurdities of the Scripps Howard article on sweeteners.

heard\_about: google  
interest: nutritious, healthy food, free of high fructose corn syrup  
related\_info: more about the differences between cane sugar and corn syrup and high fructose corn syrup  
more\_useful:  
name: [REDACTED]  
orgname: none  
address1: [REDACTED]  
address2:  
city: Willowick  
state: OH  
zip: 44095  
country:  
phone: [REDACTED]  
ext:  
email: [REDACTED]