

September 10, 2004

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.

More specifically, in reference to a letter dated July 17, 2003 from Sugar Association President & CEO Andrew C. Briscoe, urging FDA to withdraw the proposed rule to allow "and/or" labeling of soft drinks.

Our firm, White Technical Research, is located in Argenta, IL. With 25 years of experience in nutritive sweetener chemistry, metabolism and nutrition, we provide technical research services to the food and beverage industry. Please accept this submission made on behalf of one of our clients, the Corn Refiners Association of Washington, DC, the trade association that represents the corn wet milling industry. We are writing to correct several misstatements of fact relating to sucrose and high fructose corn syrup (HFCS) in Mr. Briscoe's letter.

Intestinal Absorption

On page 3 of Mr. Briscoe's letter, the last paragraph addressing gastrointestinal health implies that the glucose and fructose in HFCS are absorbed from the small intestine substantially differently than the glucose and fructose in sucrose. Further, Mr. Briscoe implies that HFCS — at levels found in soft drinks — will cause some persons to experience symptoms of malabsorption. Both of these statements are factually untrue and require the following corrections:

- (1) Mr. Briscoe has incorrectly focused attention on the fructose component of HFCS, while ignoring the glucose component. In

fact, both sucrose and HFCS contain nearly equal amounts of glucose and fructose.

- (2) Mr. Briscoe has confused HFCS with pure fructose. These are two distinct products, used in very different food applications. To reiterate, HFCS contains nearly equal parts of both glucose and fructose. Pure fructose is not used in soft drinks carrying the "and/or" label.
- (3) Work by Riby *et al*¹ demonstrated that any malabsorption present when pure fructose alone is administered to test subjects is effectively alleviated when fructose and glucose are administered together in the proportions found in HFCS and sucrose. Thus, malabsorption is no more a consequence of consuming an HFCS-sweetened soft drink than it is a consequence of consuming a sucrose-sweetened one.
- (4) A recent report from the Center for Food Nutrition Policy (Virginia Tech) concluded that HFCS and sucrose are both readily absorbed from the small intestine. Once absorbed, the human body is not able to discern the ingredient source of the fructose and glucose, and they are processed via well-characterized metabolic pathways.²

Allergens

Mr. Briscoe suggests, on page 4 of his letter, that increasing consumer concerns about corn allergies are a cause for concern. His suggestion lacks merit when applied to HFCS, however, as demonstrated by the following facts:

- (1) HFCS undergoes numerous purification steps during manufacture. It should not contain allergens that pose a significant health risk either for the general population or for gluten- or sulfite-sensitive consumers.
- (2) The prevalence of corn allergy in the U.S. is exceedingly low — estimated to affect no more than 0.016% of the general population.³
- (3) The U.S. Food and Drug Administration has concluded that allergic reactions to corn-derived sweeteners do not represent a major health concern in the United States.⁴ A significant portion of the allergenic gluten (protein) component is removed from corn wet-milling-based starches and sweeteners. Therefore, it should not be a problem for gluten intolerant consumers.⁵

- (4) Corn and corn wet-milling-based ingredients are not on the Codex Alimentarius Commission's 1999 list of foods than can cause hypersensitivity.⁶
- (5) Corn is not one of the eight major food allergens listed in the Food Allergen Labeling and Consumer Protection Act (FALCPA), recently passed by Congress and signed by the President.⁷

Sucrose Inversion

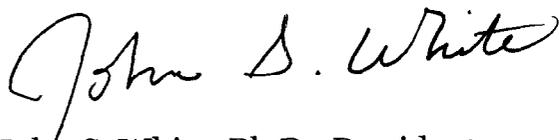
Left unstated in Mr. Briscoe's letter are the following facts well known to bottlers and sugar chemists about the behavior of sucrose in soft drinks:

- (1) Prior to HFCS introduction into soft drinks, it was common to use medium invert sugar (partially hydrolyzed sucrose), a syrup product containing sucrose, fructose and glucose.
- (2) Under the acidic conditions present in soft drinks, sucrose undergoes hydrolysis ("inversion") to glucose and fructose. Under conventional soft drink warehouse temperatures and inventory holding times, it is possible for 90% or more of the sucrose to invert.⁸
- (3) Soft drinks formulated with sucrose will approximate the glucose/fructose composition of soft drinks formulated with HFCS by the time they reach consumers.
- (4) Whether labeled as sucrose or whether labeled as HFCS, soft drinks will always contain predominantly glucose and fructose.
- (5) Consumers will not expect any fructose or glucose in a soft drink labeled "sucrose;" a sucrose-sweetened soft drink without "and/or" labeling will always be mislabeled.

Both consumers and analytical chemists alike will find it difficult to distinguish soft drinks formulated with HFCS "and/or" sucrose.

We appreciate your consideration of these corrections as you deliberate the proposed withdrawal of "and/or" labeling of soft drinks.

Respectfully yours,



John S. White, Ph.D., President
White Technical Research

¹ Riby, J.E., T. Fujisawa & N. Kretchmer, Fructose absorption, *Am J Clin Nutr*, 58(suppl):748S, 1993.

² Hein, G.L., M.L. Storey & D.R. Lineback. Ceres Workshop on the *Highs and lows of high fructose corn syrup*, Center for Food and Nutrition Policy, Virginia Tech, 10 May 2004.

³ Taylor, S.L., Allergenicity of corn and corn products. Food Allergy Research & Resource Program, University of Nebraska, Lincoln, 7 February 2000.

⁴ Nomenclature for Sweeteners, *Federal Register*, 58(3):2865, 6 January 1993.

⁵ For specific foods — gluten labeling, *Federal Register*, 58(3):2864, 6 January 1993.

⁶ Codex Alimentarius Commission, Draft recommendations for the labeling of foods that can cause hypersensitivity (draft amendment to the general standard for the labeling of prepackaged foods), Alinorm 99/22, Appendix III, Section 4.2.1.4, 1999.

⁷ H.R. 3684.

⁸ Marov, G.J. & J.F. Dowling, Sugar in beverages, in *Sugar – A User's Guide to Sucrose*, N.L. Pennington & C.W. Baker, eds., Van Nostrand Reinhold, New York.