

**UNITED STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

August 15, 2012

Division of Dockets Management)
Food and Drug Administration) Docket No. _____
Department of Health and Human Services)
5630 Fishers Lane, rm. 1061)
Rockville, MD 20852)

Submitted by

CITIZENS FOR HEALTH

CITIZEN PETITION

Citizens for Health, a consumer voice of the natural health community, a nonprofit group founded in 1992 with over 130,000 supporters, submits this petition under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s), 342, 348, and 371) to request the Commissioner of Food and Drugs to (1) take action to protect the public from the illegal, mislabeled use of high fructose corn syrup (“HFCS”) that is above 55 percent fructose (which was specifically excluded by the FDA as a GRAS ingredient); and, in the interim, to provide consumers with very important labeling information on foods and beverages regarding the specific fructose amount in the blend of HFCS that was used, be it 42, 55, 65,¹ 70, 80, 90,² or some other percentage.

A. ACTION REQUESTED

1. CITIZENS FOR HEALTH REQUESTS AN ADDITION TO THE WORDING OF 21 C.F.R. 184.1866.

The current wording of 21 C.F.R. 184.1866 is:

“§21 C.F.R. 184.1866 High fructose corn syrup.

(a) High fructose corn syrup, a sweet, nutritive saccharide mixture containing either approximately 42 or 55 percent fructose, is prepared as a clear aqueous solution from high dextrose equivalent corn starch hydrolysate by partial enzymatic conversion of glucose (dextrose) to fructose using an insoluble glucose isomerase enzyme preparation described in § 184.1372. The product containing more than 50 percent fructose (dry weight) is prepared through concentration of the fructose portion of the mixture containing less than 50 percent fructose.

(b) The ingredient shall conform to the identity and specifications listed in the monograph entitled “High-Fructose Corn Syrup” in the Food Chemicals Codex, 4th ed. (1996), pp. 191–192, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the

¹ A recently published, peer-reviewed study that measured the composition of the sweeteners used in popular caloric beverages, showed that the fructose content of some sweetened with HFCS was 30% higher than it would be if the drinks had been made with sucrose, and thus accounted for as much as 65% of the sugars content. See E.E. Ventura, J.N. Davis, M.I. Goran. “Sugar content of popular sweetened beverages based on objective laboratory analysis: focus on fructose content,” *Obesity* (Silver Spring), Apr. 2010;19(4):868-74 [Appendix pp. 3-11].

² “Mention of HFCS with higher fructose content (ie, HFCS-80 or HFCS-90) is occasionally seen in the literature” White JS, “Straight Talk About High-Fructose Corn Syrup: What It Is And What It Ain’t,” *American Journal of Clinical Nutrition*, 2008; 1716S-21S, at 1717S [App. p. 18].

Center for Food Safety and Applied Nutrition’s Library, 200 C St. SW.,
rm. 3321, Washington, DC, or at the Office of the Federal Register, 800
North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no
limitation other than current good manufacturing practice.

The requested addition to 21 C.F.R. 184.1866 is:

“§21 C.F.R. 184.1866 High fructose corn syrup.

...

(d) When labeling high fructose corn syrup on food products, the
concentration of fructose shall be incorporated into the ingredient name
and clearly identified; e.g. high fructose corn syrup with 42% fructose
would be labeled, ‘high fructose corn syrup 42.’

(e) If a food manufacturer manipulates the amount of fructose in its high
fructose corn syrup to a different concentration than a standardized blend
of 42 or 55, the manufacturer is required to accurately test the amount of
fructose present and incorporate that concentration into the ingredient
name; e.g. high fructose corn syrup with 90% fructose would be labeled,
‘high fructose corn syrup 90.’”

**2. CITIZENS FOR HEALTH REQUESTS THAT THE FDA INITIATE
APPROPRIATE ANALYSIS AND ENFORCEMENT ACTIONS
AGAINST FOOD PRODUCERS AND RETAILERS FOR THE USE
OF NON-APPROVED FOOD ADDITIVES**

Food producers are using high fructose corn syrups with fructose concentrations
outside the range approved by the FDA. Citizens for Health asks the FDA to (1) conduct
its own analysis, (2) require that food producers using HFCS in any fructose amount
other than approximately 42 or 55 percent have those HFCS formulations go through the
pre-market approval process, and (3) initiate enforcement actions against food producers
who continue to use HFCS containing amounts of fructose other than approximately 42
or 55 percent.

B. STATEMENT OF GROUNDS

HFCS is used by the food industry in several formulations containing differing
concentrations of fructose. Consumers have been led to believe that the only
concentrations used –and labeled as HFCS—are 42 and 55 percent fructose. Moreover,
the FDA has only thus far designated concentrations of approximately 42 and 55 percent
as Generally Recognized As Safe (GRAS). Consumers have been and are presently being

confused and misled to believe that HFCS is carefully regulated to contain a fructose content of either approximately 42 or 55 percent.

The proposed additions in section A1 would promote honesty and more complete disclosure of the fructose content of this ingredient in the interest of accuracy and consumers' right to know the actual contents of the foods they consume.

The proposed actions in section A2 would restrain further violations of the law regarding food additives and violations of consumers' trust.

1. HIGH FRUCTOSE CORN SYRUP IS MANUFACTURED USING THREE DIFFERENT PERCENTAGES OF FRUCTOSE

High fructose corn syrup with 42 percent fructose (HFCS 42) was developed in 1967. In the 1970s, high fructose corn syrup with 90 percent fructose (HFCS 90) was synthesized.³ It is common knowledge in the food industry that high fructose corn syrup is officially manufactured with three amounts of fructose: 42, 55, and 90. HFCS 90 is approximately 25 percent sweeter than sucrose.⁴

2. DIFFICULTIES WITH THE CURRENT FDA DEFINITION OF “HIGH FRUCTOSE CORN SYRUP”

The current FDA definition of “high fructose corn syrup” includes the concentration of fructose, specifically 42 or 55 percent. This creates a difficulty and possibly a loophole – is a high fructose corn syrup with a fructose concentration of 65% still high fructose corn syrup? Or is it a different ingredient, a particularly high fructose syrup that is not remotely like the composition of natural sucrose?

Defining new food ingredients, new syrups, strictly because they are not 42 or 55% fructose would be confusing. Consumers are already acquainted with HFCS, there is no reason to create entirely new names such as fructose / glucose syrups when HFCS is not only relevant, but perfectly able to communicate to consumers what the ingredient is. By adding the concentration of fructose to the end of HFCS, consumers should have little to no difficulty in understanding (1) that there are more than two concentrations of fructose in HFCS products and (2) which concentration is in the food they are viewing.

For this petition, if the ingredient is substantially similar to HFCS 42 and 55 other than its concentration of fructose, it is called HFCS.

3. FOOD PRODUCTS MADE WITH HIGH FRUCTOSE CORN SYRUP CONTAIN VARYING AMOUNTS OF FRUCTOSE

Despite the information given to consumers, in large part through a multimillion dollar campaign by the Corn Refiners Association, high fructose corn syrup (HFCS) is not limited in its food use to HFCS 42 and 55.

³ Suzen M. Moeller, et. al, “The effects of high fructose syrup,” *Journal of the American College of Nutrition*, Vol. 28, No. 6, 619-626 (2009) [App. pp. 155-163].

⁴ J.U. McGregor et al, “Effect of Sweeteners on the Quality and Acceptability of Yogurt,” *Journal of Dairy Science*, Vol. 69, No. 3, 698-703 at 699 (1986) [App. p. 25].

(a) Conducting a simple Google search will turn up numerous articles and reports disclosing the uses of HFCS 90. It is reported in the literature that HFCS 90 is used in soft drinks (including reduced-calorie ones), salad dressings, jams, jellies, table syrups, wines, low-calorie frozen yogurts, desserts, and “light” foods.^{5,6}

(b) Archer Daniels Midland (ADM), one of the leading manufactures of HFCS, makes HFCS 42, 55 and 90 under the brand name “Cornsweet.” The ADM product “Cornsweet 90” is described on the official ADM corporate website as follows: *Cornsweet® 90, containing about 90% fructose, is ADM's sweetest high fructose corn syrup. Its high sweetness makes it the ideal choice for reduced calorie foods such as beverages, jellies and dressings.*⁷

(c) There are numerous patents that have been applied for and granted describing various methods of using HFCS 90 in a variety of foods and beverages. An example being a patent published March 31, 2005 by Lee, et al. which is an invention that combines a low-calorie natural sweetener with HFCS 90 to produce a reduced-calorie beverage. This patent was assigned to PepsiCo, Inc.⁸

4. THE FRUCTOSE CONTENT OF BEVERAGES HAS BEEN FOUND TO BE HIGHER THAN 55 PERCENT

Researchers from the University of Southern California Childhood Obesity Research Center found in 2010 that the fructose content of some HFCS-sweetened beverages came in as high as 65 percent fructose, almost 20 percent higher than if they had actually been sweetened using HFCS 55, and 30 percent higher than if they had been sweetened with natural sucrose. As the study’s senior author Dr. Michael I. Goran noted, “The elevated fructose levels in the sodas most Americans drink are of particular concern because of the negative effects fructose has on the body.”⁹ Indeed, it is well recognized that fructose in particular has been epidemiologically and clinically linked with obesity and metabolic syndrome.¹⁰

⁵ Ibid at 1 [App. p. 24].

⁶ G.E. Inglett, “Sweeteners – a review,” *Food Technology*, March 1981, pp, 37, 38, 40, 41 [App. pp. 11-15].

⁷ Archer Daniels Midland webpage on CORNSWEET® 90: http://origin.adm.com/en-us/Products/_layouts/ProductDetails.aspx?productid=11 (last accessed 8/9/2012) [App. pp. 1-2].

⁸ Naturally-sweetened reduced-calorie beverages, U.S. Patent No. 20050069616 (available at <http://www.google.vu/patents/US20050069616?printsec=description#v=onepage&q&f=false>) [App. pp. 80-84].

⁹ *Study Pops the Cap on Soda Contents* (Childhood Obesity Research Center), Oct. 28, 2010 (available at <http://www.foodpolitics.com/wp-content/uploads/HFCSpress.pdf>) [App. pp. 152-154].

¹⁰ See, e.g., P.J. Havel (2005) “Dietary fructose: Implications for dysregulation of energy homeostasis and lipid/carbohydrate metabolism,” *Nutrition Reviews* 63:133–157 [App. pp. 85-111]; Luc Tappy and Kim-Anne Lê (2010) “Metabolic effects of fructose and the worldwide increase in obesity,” *Physiological Reviews* 90:23–46 [App. pp. 55-79]; R.J. Johnson, et al. (2007) “Potential role of sugar (fructose) in the epidemic of hypertension, obesity and the metabolic syndrome, diabetes, kidney disease, and cardiovascular disease,” *American Journal of Clinical Nutrition* 86:899–906 [App. pp. 134-142]; R.J. Johnson, et al. (2009) “Hypothesis: Could excessive fructose intake and uric acid cause

5. FOOD PRODUCTS WITH FRUCTOSE AMOUNTS OF MORE THAN 55 PERCENT ARE BEING LABELED AS “HIGH FRUCTOSE CORN SYRUP”

Despite 21 C.F.R. 184.1866, the GRAS affirmation regulation for high fructose corn syrup, which describes the ingredient as being either 42 or 55 percent fructose, searches of articles, websites, studies and literature, as well as information we have received, all indicate that food products with fructose amounts higher than 55 percent, are being labeled as “high fructose corn syrup.” This not only is misleading to consumers, who have been told that HFCS only contains 42 or 55 percent fructose, but would make such products misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. In addition, Citizens for Health member Linda Bonvie received an email from an Archer Daniels Midland contractor knowledgeable about HFCS 90, who stated that the ADM product Cornsweet 90 (HFCS 90) “...can be labeled HFCS since that is not misleading...”

6. HIGH FRUCTOSE CORN SYRUPS CONTAINING MORE THAN 55 PERCENT FRUCTOSE DO NOT HAVE GRAS DESIGNATION OR PREMARKET APPROVAL

Citizens for Health is not aware of any GRAS designated or premarket approved high fructose corn syrup with a concentration of fructose above 55%. In the FDA’s 1996 GRAS (re)approval of HFCS 42 and 55, “...FDA did not include HFCS-90 in the agency’s exposure estimate for HFCS, even though the agency was aware of minor uses of HFCS-90 as an ingredient in low-calorie foods.”¹¹ Before making a ruling on HFCS-90, FDA would need “...additional data on the effects of fructose consumption that is not balanced with glucose consumption... to ensure that this product is safe.”¹²

7. NO UNFAVORABLE INFORMATION

The petitioner is unaware of any information directly unfavorable to its petition or the evidence the petition relies upon. The FDA may find relevant information to this petition in the recent Corn Refiners Association petition, Docket No. FDA-2010-P-0491, which the FDA denied in its May 30, 2012 letter to the President of the Corn Refiners Association (Document ID: FDA-2010-P-0491-2181).

type 2 diabetes?” *Endocrine Reviews* 30:96–116 [App. pp. 112-133]; K.L. Stanhope, et al. (2009) “Consuming fructose-sweetened, not glucose-sweetened, beverages increases visceral adiposity and lipids and decreases insulin sensitivity in overweight/obese humans,” *The Journal of Clinical Investigation* 119:1322–1334 [App. pp. 30-43]; S.E. Perez-Pozo, et al. (2010) “Excessive fructose intake induces the features of metabolic syndrome in healthy adult men: Role of uric acid in the hypertensive response,” *International Journal of Obesity* (London) 34:454–461 [App. pp. 143-151]; K.L. Stanhope, et al. (2011) “Consumption of fructose and high fructose corn syrup increase; postprandial triglycerides, LDL-cholesterol, and apolipoprotein-B in young men and women,” *Journal of Clinical Endocrinology and Metabolism* 96:E1596–E1605 [App. pp. 44-54].

¹¹ Direct Food Substances Affirmed as Generally Recognized as Safe; High Fructose Corn Syrup, 61 Fed. Reg. 43447, 43450 (Aug. 23, 1996) (to be codified at 21 C.F.R. pts. 182 and 184).

¹² *Id.*

C. ENVIRONMENTAL IMPACT

21 C.F.R. 25.30(a), (b), (h), & (k) categorically excludes the need of an environmental impact statement or analysis for this petition. The 21 C.F.R. 25.30(a) exclusion includes inspections, such as our request for an agency analysis of HFCS used in foods today. The 21 C.F.R. 25.30(b) exclusion includes requesting FDA to take enforcement actions. The 21 C.F.R. 25.30(h) exclusion includes amending regulations. The 21 C.F.R. 25.30(k) exclusion includes establishing food labeling requirements.

D. ECONOMIC IMPACT

No request for this information has been made 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.

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