

EXHIBIT 2



August 20, 2010

VIA Courier

Ralph S. Tyler
Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, Maryland 20857

Re: Coyle v. Hornell Brewing Co.
Civil No. 08-2797 (JBS-JS)

Dear Mr. Tyler:

On behalf of the Corn Refiners Association (CRA), I write to urge you to accept the referral for an administrative determination from Judge Simandle of the United States District Court for the District of New Jersey. The CRA is the national trade association representing the corn refining (wet milling) industry of the United States.

As you know, Judge Simandle recently referred to FDA, for an administrative determination, the issue of whether high fructose corn syrup (HFCS) qualifies as a “natural” food ingredient. FDA is well-suited to make this determination. The question lies within FDA’s field of expertise regarding food chemistry and the labeling of beverage products. Moreover, given FDA’s familiarity with this specific issue, the agency should not have to expend significant resources to provide the determination requested by Judge Simandle. This determination would have broad implications for pending suits filed in federal courts challenging the use of the term “natural” on beverage products containing HFCS as well as for the thousands of marketed food products that contain HFCS.

I. FDA is well-suited to determine whether HFCS qualifies as a “natural” food ingredient.

FDA, not the courts, is best equipped to resolve the issue of whether products containing HFCS may be labeled “natural.” Application of FDA rules to the manufacture of HFCS is a technical matter on which FDA possesses unparalleled expertise. This is exactly the type of issue highlighted by the agency as an appropriate basis for judicial referral.¹ As noted by Judge

¹ “The Commissioner encourages the judiciary to utilize the provisions of this new section. Referral of complex and technical issues falling within the jurisdiction of the Food and Drug Administration to the agency for an initial administrative determination will promote consistent (continued...) ”

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Simandle, “a federal judge normally would be unfamiliar with how a particular enzyme or fixing agent affects a substance’s qualification as ‘natural.’”²

FDA, on the other hand, possesses the institutional knowledge, capacity, authority, and experience to review this manufacturing process and determine whether it falls within FDA’s longstanding policy for “natural” claims. FDA employs food technicians, chemists, nutritionists, and numerous other specialists with particular expertise regarding food chemistry and the labeling of food and beverage products. More specifically, FDA’s Food Labeling and Standards staff has already studied the specific issue of the “natural” status of HFCS, reviewed relevant information, and provided a written opinion on the subject.³ The question referred by the Court is thus one with which FDA is familiar and one which FDA possesses the expertise to answer.

II. Making this determination should not consume significant agency resources.

The Court’s referral is hardly the first time FDA has considered “natural” claims in general or the natural status of HFCS more specifically. Over the past two decades, FDA has clearly articulated and consistently applied a specific policy for “natural” claims. Under the FDA policy, “natural” means that nothing artificial or synthetic has been included in, or added to, a food that would not normally be expected to be in the food. The FDA natural policy does not include a “minimally processed” requirement.

Moreover, as mentioned above, FDA is already familiar with the specific issues presented in the Court’s referral. Indeed, in 2008, the Food Labeling and Standards staff addressed the very question of the natural status of HFCS and provided a written opinion on the subject. The agency may certainly apply this institutional expertise to its analysis of the Court’s referral. This existing expertise should reduce the amount of agency resources that would need to be spent to determine the natural status of HFCS.

In addition, FDA is not required to use notice and comment rulemaking to make the administrative determination requested by the Court. Instead, the agency may use a variety of procedures, some of which are less burdensome on the agency. Under 21 C.F.R. § 10.60(c),

and fair interpretation and application of the law.” 40 Fed. Reg. 22950, 22960 (May 27, 1975) (citations omitted).

² Court’s Opinion at 10-11, *Coyle v. Hornell Brewing Co., et al.*, No. 08-2797 (D.N.J. June 15, 2010).

³ Letter from Geraldine A. June, Supervisor, Product Evaluation and Labeling Team, Food Labeling and Standards Staff, Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, to Audrae Erickson, President, Corn Refiners Association (July 3, 2008).

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FDA may, in its discretion, use any of the public procedures established in its regulations. Included in these procedures are guidance documents and advisory opinions.

Advisory opinions are statements of agency policy or interpretation that have broad applicability.⁴ Use of an advisory opinion to make the administrative determination requested by the Court is an appropriate procedure. The natural status of HFCS is a policy issue of broad applicability that transcends any particular product or label. HFCS is used in many different products including canned fruits, condiments, soft drinks, ice cream, frozen desserts, and other processed foods. In addition, the Court's referral implicates the agency's policy on "natural" food ingredients generally.

III. This determination would have sufficiently broad applicability to warrant issuance of an advisory opinion.

FDA's administrative determination in this situation would have broad applicability in at least two important respects. First, an agency advisory opinion would have important implications for numerous pending suits filed in federal courts challenging the use of the term "natural" on beverage products containing HFCS. In addition to the case pending before Judge Simandle, there are at least four other federal actions challenging the use of the term "natural" on products containing HFCS.⁵ In some of these cases the courts have explicitly recognized FDA's primary role in determining the natural status of HFCS. In one case, the Court stayed the action for six months and directed counsel to submit a proposal referring to FDA the question of the natural status of HFCS.⁶ In another case, the Court stayed the action for six months and referred to FDA the issue of whether HFCS qualifies as a natural ingredient.⁷

Second, the question of the natural status of HFCS has significant consequences for the food and beverage industry nationwide. HFCS is used in thousands of marketed products, including baked goods; yogurt; spaghetti sauces, ketchup, and condiments; beverages; granola and breakfast and energy bars; canned and frozen fruits; and frozen beverage concentrates. It is possible or even likely that, absent an authoritative opinion of FDA, different jurisdictions will reach different conclusions on the natural status of HFCS. As noted by Judge Simandle, this

⁴ See 21 C.F.R. § 10.85.

⁵ *Von Koenig v. Snapple Beverage Corp.*, No. 09-00606 (E.D. Cal. filed Mar. 4, 2009); *Weiner v. Snapple Beverage Corp.*, No. 07-8742 (S.D.N.Y. filed Oct. 10, 2007); *Holk v. Snapple Beverage Corp.*, No. 07-03018 (D.N.J. filed June 29, 2007), *rev'd*, 575 F.3d 329 (3d Cir. 2009); *Ries v. Hornell Brewing Co., et al.*, No. 10-01139 (N.D. Cal. filed Mar. 17, 2010). The Court in *Weiner* recently denied the plaintiffs' motion for class certification. Court's Order, *Weiner v. Snapple Beverage Corp.*, No. 07-8742 (S.D.N.Y. Aug. 3, 2010).

⁶ Court's Order at 9, *Ries v. Hornell Brewing Co., et al.*, No. 10-01139 (N.D. Cal. July 23, 2010).

⁷ Court's Order, *Holk v. Snapple Beverage Corp.*, No. 07-03018 (D.N.J. Aug. 10, 2010).

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would result “in inconsistent outcomes for essentially identical claims and [would affect] food and beverage purveyors with nationwide businesses.”⁸ An authoritative determination by FDA regarding the natural status of HFCS would alleviate this burden to industry and would promote a consistent interpretation and application of the law.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "A. Erickson". The signature is fluid and cursive, with a large initial "A" and a stylized "E".

Audrae Erickson
President

⁸ Court's Opinion at 12-13, *Coyle v. Hornell Brewing Co., et al.*, No. 08-2797 (D.N.J. June 15, 2010).