

EXHIBIT 4



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
College Park, MD 20740

SEP 16 2010

The Honorable Jerome B. Simandle
U.S. District Judge
United States Courthouse
One John F. Gerry Plaza
P.O. Box 888
Camden, New Jersey 08101

Re: Coyle v. Hornell Brewing Co., Inc., et al.
Civil Number 08-2797 (JBS-JS)

Dear Judge Simandle:

This is in response to your letter dated June 25, 2010, referring to the Food and Drug Administration ("FDA") for an administrative determination under 21 C.F.R. 10.25(c) the question of whether high fructose corn syrup ("HFCS") qualifies as a "natural" ingredient. For the reasons explained below, we respectfully decline to provide such a determination.

First, for the FDA to resolve whether HFCS qualifies as a "natural" ingredient in defendants' beverages, in the absence of a pre-existing regulatory definition, the agency would expect to act in a transparent manner by engaging in a public proceeding to establish the meaning of this term. Given the issues involved, making such a determination without adequate public participation would raise questions about the fairness of FDA's action. FDA's experience with such proceedings suggests that it would take two to three years to complete. We recognize that such a timeframe would likely not be useful to the Court in resolving the current case.

Second, priority food safety and applied nutrition matters are currently fully occupying the resources that FDA has available for public proceedings on foods matters. For example, the agency is involved in taking actions designed to improve (1) the safety of the food supply and (2) the dietary practices of Americans, because many of the underlying causes of chronic disease – high blood pressure, elevated cholesterol, obesity and diabetes – are the result of lifestyle factors, including unhealthy eating, and are largely preventable. Proceedings to define "natural" do not fit within these current priorities. See 21 C.F.R. § 10.25(c).


Consumers currently receive some protection in the absence of a definition of "natural" because the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations require that all ingredients used in a food be declared on the food's label. Thus, the label provides consumers with information to decide whether to purchase the food. So, for the food product at issue in the above-captioned case, the consumer would know from the label whether the product contained HFCS.

Page 2 – The Honorable Jerome B. Simandle

The most relevant statement of the agency's views is provided by the preamble language cited by the Court on page 6 of its June 15, 2010 opinion. The FDA there reiterated its interpretation that "natural" means nothing artificial or synthetic. This interpretation was not established by regulation but it is the most definitive statement of the agency's view. By contrast, Geraldine June's letter, which the Court cited on page 7 of its June 15, 2010 opinion, is an informal communication and does not provide a binding agency interpretation for the Court to follow. The opinions of individual employees do not bind the agency, and FDA has made clear that only the Commissioner can speak definitively for the agency. *See* 21 C.F.R. § 10.85(k); *see also Western Ill. Home Health Care v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998) (agency action not final if only the ruling of subordinate official); *Regenerative Sciences v. FDA*, No. 09-cv-00411, 2010 WL 1258010, at *7 (D. Colo. March 26, 2010) (finding that statements of lower level FDA officials do not rise to level of agency action even when contained in regulatory correspondence); *Genendo Pharmaceutical v. Thompson*, 308 F. Supp.2d 881, 885 (N.D. Ill. 2003) (statements of FDA officials in warning letter do not constitute final agency action).

We hope that this information is helpful to you.

Respectfully,



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cc:

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