DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

January 6, 2014

The Honorable Yvonne Gonzalez Rogers
United States District Court
Northern District of California
1301 Clay St., Suite 400S
Oakland, CA 94612-5212

The Honorable Jeffrey S. White
United States District Court
Northern District of California
450 Golden Gate Avenue, Box 36060
San Francisco, CA 94102-3489

The Honorable Kevin McNulty
United States District Court
District of New Jersey
Frank R. Lautenberg U.S. Post Office and Courthouse
2 Federal Square
Newark, NJ 07101-0999

Re: Referrals to the United States Food and Drug Administration in *Cox v. Gruma Corp.*, No. 4:12-cv-6502-YGR (N.D. Cal.), *Barnes v. Campbell Soup Co.*, No. 3:12-cv-05185-JSW (N.D. Cal.), and *In Re General Mills, Inc. Kix Cereal Litigation*, No. 2:12-cv-00249-KM-MCA (D.N.J.)

Dear Judges Gonzalez Rogers, White, and McNulty:

This letter responds to your Orders issued on July 11, July 25, and November 1, 2013, respectively, in the above-referenced cases, which referred the question of whether food products containing ingredients produced using bioengineered ingredients may be labeled "Natural" or "All Natural" or "100% Natural" to the Food and Drug Administration ("FDA" or "agency") for an administrative determination under 21 C.F.R. § 10.25(c). In those cases, the plaintiffs allege that the "Natural," "All Natural," and/or "100% Natural" labeling on the Defendants' products are misleading because the products contain corn grown from bioengineered, genetically modified seeds. The *Cox* and *Barnes* cases were stayed for six months with the potential for a further extension; the *Kix Cereal Litigation* was administratively terminated pending FDA's response to the referrals.

FDA has not promulgated a formal definition of the term "natural" with respect to foods. The agency has, however, stated that its policy regarding the use of the term "natural" on food labeling means that "nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." *See* 58 Fed. Reg. 2302, 2407 (1993).

If FDA were inclined to revoke, amend, or add to this policy, we would likely embark on a public process, such as issuing a regulation or formal guidance, in order to determine whether to make such a change; we would not do so in the context of litigation between private parties. Issuance of a regulation or guidance document allows an agency to obtain data, information, and views from all stakeholders wishing to engage on an issue. Here, given the complexities of the current request, including the competing concerns among and between stakeholders (e.g., various consumer organizations, diverse industry segments), it would be prudent and consistent with FDA's commitment to the principles of openness and transparency to engage the public on this issue.

We note that defining the term "natural" on food labeling necessarily involves interests of Federal agencies other than FDA, including the United States Department of Agriculture ("USDA"), as well as competing views on the part of stakeholders. FDA has discussed the complexities of such a definition with USDA and both agencies have been considering the issue. Any definition of "natural" on food labeling has implications well beyond the narrow scope of genetically engineered food ingredients about which the Court's referral pertains. For example, if the agencies were to define the term, they would likely need to consider among other things: relevant science; consumer preferences, perceptions, and beliefs; the vast array of modern food production technologies in addition to genetic engineering (e.g., use of different types of fertilizer, growth promotion drugs, animal husbandry methods); the myriad food processing methods (e.g., nanotechnology, thermal technologies, pasteurization, irradiation); and any strictures flowing from the First Amendment. Thus, even if we were to embark on a public process to define "natural" in the context of food labeling, there is no assurance that we would revoke, amend, or add to the current policy, or develop any definition at all. [1]

At present, priority food public health and safety matters are largely occupying the limited resources that FDA has to address foods matters. These matters include developing food safety regulations that implement the FDA Food Safety Modernization Act of 2011, many of which have statutory and/or court-ordered deadlines; issuing nutrition labeling regulations, including regulations that implement the Patient Protection and Affordable Care Act of 2010; other actions with direct public health impact (such as addressing the legal status of partially hydrogenated oils); and numerous other matters, such as responding to outbreaks of food-borne illness and overseeing the safety of imported foods. Because, especially in the foods arena, FDA operates in a world of limited resources, we necessarily must prioritize which issues to address.

[1] FDA was notified by letter dated December 5, 2013, that the Grocery Manufacturers Association ("GMA") intends to file a citizen petition early in 2014 asking FDA to "issue a regulation authorizing foods containing ingredients derived from biotechnology to be labeled 'natural.'" For all of the reasons set forth previously, we believe that, if the agency were to decide to examine this policy question, the public would be better served if the agency used its administrative processes, rather than providing a response in the context of private litigation on the issue.

Based on the foregoing considerations, we respectfully decline to make a determination at this time regarding whether and under what circumstances food products containing ingredients produced using genetically engineered ingredients may or may not be labeled "natural."

Sincerely,

Leslie Kux
Assistant Commissioner for Policy

cc: The Honorable Madeline Cox Arleo
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