



Food and Drug Administration
College Park, MD

Mr. Kenneth Cromer
631 Hayes Street
Rockdale, Illinois 60436-2433

JUN 14 2002

1754 02

HFA-305
Dockets
ETS# 77199

Dear Mr. Cromer:

This responds to your letter of August 3, 2001, to the Food and Drug Administration (FDA), regarding the labeling of bioengineered foods. Your letter was forwarded to our office for reply. We regret the delay in responding to your inquiry, and hope that the following is helpful.

In your letter you asked why genetically engineered foods are not labeled. To answer your question we should explain that The Federal Food, Drug, and Cosmetic Act (the act) is the law that governs our actions. The act gives FDA the authority to regulate foods and drugs, among other products. Specifically, section 403 of the act governs the labeling of foods. Under section 403(a)(1), a food is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the act states that labeling is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food to which labeling relates under conditions of use prescribed in labeling, or under such conditions of use as are customary or usual. In the past FDA has required special labeling on the basis of it being "material" information in cases where the absence of such information may: 1) pose special health or environmental risks (e.g., warning statement on protein products used in very low calorie diets); 2) mislead the consumer in light of other statements made on the label (e.g., requirement for quantitative nutrient information when certain nutrient content claims are made about a product); or 3) in cases where a consumer may assume that a food, because of its similarity to another food, has nutritional, organoleptic, or functional characteristics of the food it resembles when in fact it does not (e.g., reduced fat margarine not suitable for frying).

FDA believes that it has no basis for concluding that bioengineered foods differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by genetic engineering techniques present any different or greater safety concern than foods developed by traditional plant breeding. Therefore, FDA does not require that foods be labeled to indicate the fact that a food is produced through bioengineering. FDA's requirements that apply to foods in general also apply to foods produced using genetic engineering. Section 403(i) of the act requires that each food bear a common or usual name or, in the absence of such a name, an appropriately descriptive term. In addition, under section 201(n), the label of the food must reveal all material facts about the food. Thus: 1) If a genetically engineered food is significantly different from its traditional counterpart such that the common or usual name no longer adequately describes the new food, the name must be changed to describe the difference; 2) If an issue exists for the food or a constituent of the food regarding how the food is used or consequences of its use, a statement must be made on the label to describe the issue; 3) If a bioengineered food has a significantly different nutritional property, its label must reflect the difference; and 4) If a new

OOD-1598

LET 2

Page 2 – Mr. Kenneth Cromer

food includes an allergen that consumers would not expect to be present based on the name of the food, the presence of that allergen must be disclosed on the label.

On January 18, 2001, FDA published draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (a copy is enclosed). FDA published this draft Guidance to assist manufacturers who wish to voluntarily label their foods being made with or without the use of bioengineered ingredients. We took this action in response to requests from food manufacturers regarding appropriate ways that industry could voluntarily provide information on a food label about bioengineering.

FDA has received many public comments on the draft guidance. We are currently reviewing these comments. Please be assured that we will consider all comments before making a final decision on this issue. If you have any further questions on this issue, do not hesitate to contact us.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Catalina Ferre-Hockensmith". The signature is fluid and cursive, written in a professional style.

Catalina Ferre-Hockensmith
Division of Standards
and Labeling Regulations
Office of Nutritional Products, Labeling
and Dietary Supplements

Enclosure