

SEP 17 2002

Mr. Vircher B. Floyd
1019 Meadowbend Drive
Leesburg, Florida 34748

Dear Mr. Floyd:

This responds to your letter of April 25, 2002, to the Food and Drug Administration (FDA), regarding the labeling of bioengineered foods. Your letter was forwarded to our office for reply. In your letter you requested that FDA develop regulations requiring labeling of all genetically modified plants and animals used for human consumption. You stated that you suffer from skin blotches that you believe are related to eating genetically modified corn on the cob. We understand your concern regarding your skin blotches. We regret the delay in responding to your inquiry and hope the following information is helpful.

FDA has no scientific 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 has no basis to 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 Federal Food, Drug, and Cosmetic 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. 4) If a new 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 a Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering (a copy is enclosed). FDA published this 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

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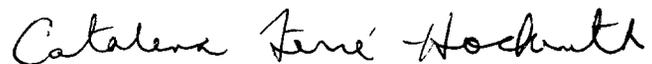
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voluntarily provide information on a food label about bioengineering. This guidance aids manufacturers in ensuring that their labeling is truthful and informative. FDA has received many public comments on the draft guidance. Please be assured that we will consider all comments before making a final decision on this issue.

FDA handles adverse reactions and other problems associated with products that we regulate. Currently, FDA's Office of Scientific Analysis and Support (OSAS) has in place an adverse event reporting system, which includes reports regarding conventional foods and dietary supplements. FDA conducts an initial clinical review of all adverse event reports received. Because of resource constraints, FDA is able to perform risk assessments of only the most significant public health issues associated with the use of the products. Information about reporting adverse reactions or other problems associated with a food or dietary supplement as well as how FDA handles these reports is available to consumers at: <http://www.fda.gov/opacom/backgrounders/problem.html>. This system of tracking and following-up on adverse events is used to monitor the safety of all FDA-regulated food products. We have forwarded your letter to OSAS to be reviewed. If you have any further questions on this issue, do not hesitate to contact us.

Sincerely yours,



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

Enclosure