Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

February 13, 2001

RE: Docket No. 00D-1598

Dear FDA:

I'm writing regarding your "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have Been Developed Using Bioengineering." I am deeply disappointed that the FDA continues to ignore the will of the public and refuses to make labeling of genetically engineered foods mandatory.

Your agency admits to receiving more than 50,000 comments last year regarding GE foods. You concede: "Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was bioengineered or was produced from bioengineered food." Yet you ignore the will of the public saying the comments "did not provide data or other information regarding consequences to consumers from eating the food." The truth is *there has not been ample evidence submitted* to the FDA for you to conclude that these foods are "substantially equivalent" to non-GE foods. Yet your agency continues to ignore the independent research that has been conducted.

Studies have shown that biotech soybeans contain altered levels of nutrients such as isoflavones. They have been shown to have higher levels of Kunitz trypsin inhibitor, a known antinutrient and allergen. GE foods contain antibiotic marker genes and may contain built-in pesticides. These are not found in non-GE foods. I do not want to eat these biotech foods, but without mandatory labeling, my choice has been denied me.

Last year, Monsanto admitted to finding "unexpected gene fragments" in their genetically engineered soybeans. What other "unexpected gene fragments" are contained in other GE foods? No one knows, particularly not the FDA, because these experimental foods have not been adequately tested. New proteins never before consumed by humans are being created and brought to market without any extensive tests being done to show that they are not causing allergies, cancer, or other diseases.

In the case of GE foods, the FDA has done a poor job of protecting the safety of consumers. Please remember that the potential allergies created by the ingestion of StarLink corn completely escaped the FDA regulatory guidelines. It was the EPA that discovered the digestive problems associated with StarLink corn.

The FDA has been accused of being a pawn of the biotech industry. Documents such as your "Draft Guidance for Industry..." lead many to feel this belief holds some truth. In your Draft Guidance you question whether manufacturers who choose not to use GE ingredients should be able to label their products as GMO free. It is bad enough that the FDA does not require the mandatory labeling of GE foods. Now your agency even seems to be exploring the idea of restricting the ability of a manufacturer to let consumers know his products are NOT genetically engineered. Such regulatory restrictions would be an outrageous act of censorship by the FDA.

Genetically engineered foods are required to be labeled in the European Union nations, in Japan, Australia, New Zealand and other countries. Recently, both the EU-US Biotechnology Consultative Forum and the Consumer Federation of America recommended mandatory labeling of GE foods. The FDA should stop working on behalf of the manufacturers of genetically engineered foods and begin to work for the safety and rights of the American public (which, I believe, is your reason for being). I insist that GE foods be labeled!

Sincerely,

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