Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, rm 1061 Rockville, MD 20852 February 13, 2001

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RE: Docket No. 00D-1598

Dear FDA.

I am writing about your "Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." I am deeply concerned that the FDA continues to ignore the will of the public and refuses to make labeling of genetically altered foods mandatory.

Your agency admits to receiving more than 50,000 comments last year regarding genetically altered foods. You concede: "Most of the comments that addressed labeling requested mandatory disclosure of the fact that the food or its ingredients was genetically altered or was produced from genetically altered food." Yet you continue to 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 that there has been ample evidence submitted to the FDA revealing that these foods are NOT "substantially equivalent" to nongenetically altered foods. Yet your agency continues to ignore this evidence.

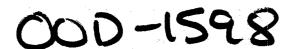
Studies have shown that biotech soybeans contain altered levels of such nutrients as isflavones. They have been shown to have higher levels of Kunitz trypsin inhibitor, a known antinutrient and allergen. Genetically altered foods contain antibiotic resistance marker genes and many contain built-in pesticides. Nobody knows what these built-in pesticides do to the adult human body, let alone to the immature developing body. These are not found in non-genetically altered foods. I do not want to eat these biotech foods, but without mandatory labeling I have no choice.

Last year, Monsanto admitted to finding "unexpected gene fragments" in their genetically altered soybeans. What other "unexpected gene fragments" are contained in other genetically altered foods? The truth is that the FDA does not know, 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, yet we are forced to eat them because they are unlabeled and we have no choice.

In the case of genetically altered foods, the FDA has done a poor job of protecting the safety of the 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.

Because of the revolving door between the biotech industry, the FDA has been accused of being a pawn of the biotech industry. Indeed, the joke is that the FDA is the Washington branch of Monsanto. It is such documents as your Draft Guidance for Industry that leads many to feel this belief is true. In your Draft Guidance you question whether manufacturers who chose not to use genetically altered ingredients should be able to label their products as GMO Free. It is unconscionable that the FDA does not require the mandatory labeling of genetically altered foods. Now your agency even seems to be exploring the idea of restricting the ability of a manufacturer to let consumers know the products are not genetically altered. Such regulatory restrictions are an outrageous act of censorship.

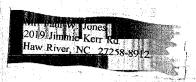
Genetically altered foods are required to be labeled in the European Union nations, Japan, Australia, New Zealand, and other countries. Recently, both the E.U.-Biotechnology Consultative Forum and the Consumer Federation of America recommended mandatory labeling of genetically altered foods. The FDA has been reckless and irresponsible by working on behalf of the manufacturers of genetically altered foods. The FDA needs to work for the safety and rights of the American public. If you and your family choose to





eat these Frankenfoods, so be it, but I don't want to, yet I have no choice because they remain unlabeled. I insist that genetically altered foods be labeled!

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