



January 22, 2001

7686 '01 JAN 26 10:08

FDA Commissioner Jane Henney  
Dockets Management Branch (HFA 305)  
Food and Drug Administration  
5630 Fisher's Lane, Rm. 1061  
Rockville, MD 20852

**RE: Docket No. 00N-1396, and 00D-1598**

Dear Ms. Henney,

Harrington Investments, Inc., is a registered investment advisor managing over \$150 million in assets for individuals and institutions concerned with social as well as financial return. As a fiduciary we are concerned with potential legal and financial liability of companies that manufacture, distribute or use genetically engineered organisms.

I am outraged by your proposed federal regulations on genetically engineered (GE) foods. Despite overwhelming consumer demand and receiving more than 50,000 written comments, your agency still failed to require safety testing and mandatory labeling for GE foods. Your "notification" policy is an insult to consumers, and irresponsibly ignores strong scientific evidence of numerous potential health and environmental risks to GE foods. These foods could be toxic, could cause allergic responses, could change the nutritional value, could compromise immune responses in consumers, could cause irreparable damage to the environment and could pose as tremendous legal and financial liability for companies manufacturing, distributing, selling or using GE ingredients. Why do you think the entire European Economic Community has banned GE foods? Why do you think the British Medical Society has called for a moratorium on the planting of GE crops?

I am sure you are aware that only months ago, Kraft, Mission Foods Co., Safeway and other leading food companies recalled taco shells containing GMO corn not approved for human consumption. Costing Kraft millions, the company recalled approximately 2.5 million boxes of shells, which were already on store shelves and even in the homes of consumers. In the October 17 edition of the *Wall Street Journal*, ConAgra Foods, Inc., one of the nation's largest packaged-foods companies, announced it has temporarily halted operations at one of its mills because it fears it may have been contaminated with bio-engineered corn unfit for human consumption. These incidences prove how difficult it is to contain genes once they are introduced to foreign environments. It also proves consumer fear and lack of confidence in companies regulating themselves to be justified. Corporate American should not be held responsible for ensuring the safety of GE ingredients. The FDA should take this initiative. In addition, over forty people have become sick consuming these products and major litigation has been filed.

00D-1598

C 61



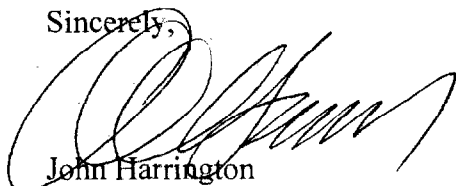
I am also strongly opposed to your new "voluntary labeling" policy, which denies consumers a basic right to know. Without mandatory labeling, neither consumers nor health professionals will know if an allergic or toxic reaction was the result of a genetically engineered food. Consumers will also be deprived of the critical knowledge they need to know which food products are hazardous. Further, the burden of proof that GE foods are safe beyond a reasonable doubt should be the responsibility of the federal government and the FDA. It should be the FDA's job to prove that food products released for public consumption meet maximum health and safety standards and be proven safe for consumption and the environment. Based on your proposed rules, the public must prove that a product endangers the public safety before the government will act to remove the product from our grocery store shelves. At that point it may be too late since the GM foods will be spread widely across America's table. How many consumers will have to become ill or die for the FDA to act? Shouldn't the FDA require a corporation to prove that a food product is safe before releasing it for human consumption?

Your requirement that a corporation inform you 120 days in advance of bringing a new bio-engineered food to market is ridiculous. Under these rules, the FDA totally relies on a food corporation's data. FDA is not even required to substantiate such data or provide an independent pre-release safety test. Why don't you just turn over the Administration of the FDA to Monsanto?

Your proposed "voluntary" labeling rule is even more of an insult to consumers and the American public by prohibiting language you believe to be "loaded," such as, "genetically modified" or "genetically engineered." Obviously, you have done everything in your power to support transnational food companies' profit maximization at the expense of the American consumer. Shame!

Your proposed rules ignore serious concerns, and appear to be a decision made to support corporate management at the expense of public health and safety and the environment. While I'm certain that such action will ensure your future employment and a substantial increase in salary in a large transnational food company, it will be to the detriment of public welfare. I have no faith in the FDA and am convinced that this letter will be ignored as was our testimony and the testimony of thousands of other consumers.

Sincerely,



John Harrington  
President

Encl.

## **TESTIMONY FOR THE FDA HEARINGS**

Oakland, California

December 13, 1999

My name is Alana Smith, and I am the Director of Research & Development for Harrington Investments, Inc., a registered investment advisor managing over \$130 million in assets for individuals and institutions. As a fiduciary we are concerned with potential legal and financial liability of companies that manufacture, distribute or use genetically engineered organisms.

Unfortunately, the FDA and other U.S. regulatory agencies have failed the American public by not requiring comprehensive pre-release safety testing, or at the very minimum, requiring companies to label GMO's. This leaves food, seed and agricultural chemical companies, grocery stores and the federal government legally and financially liable for health and environmental affects that may result from the premature release of GMO's. The burden of proof should be on the federal government to prove, beyond a reasonable doubt, that food products released for public consumption meet maximum health and safety standards and be proven safe for consumption and safe for the environment. Currently, the public must prove that a product endangers the public safety before the government acts to remove the product from our grocery store shelves. It may be too late since the GMO genie is already out of the bottle.

On October 27, 1999, Harrington Investments, Inc., filed shareholder resolutions with seven food companies: Coca-Cola, PepsiCo, General Mills, Quaker Oats, Sara Lee, Procter & Gamble, and McDonalds. These resolutions demand the removal of all genetically modified ingredients from foods sold or manufactured until long-term safety testing has shown such foods are safe for human and animal consumption and the environment. We also ask that in the interim companies voluntarily label and identify these products that may contain genetically modified ingredients.

Our clients are not alone, there are many other concerned shareholders, stakeholders, and environmental groups currently in dialogue with corporate management to protect the public from potentially dangerous foods that may cause irreversible damage to the environment and public health. But this alone is not enough. We call upon the FDA to act immediately to phase out the production, distribution and sale of GMO's, or at a minimum, require immediate GMO labeling on all foods sold to the public.



FDA Commissioner Jane Henney  
Dockets Management Branch (HFA 305)  
Food and Drug Administration  
5630 Fisher's Lane, Rm. 1061  
Rockville, MD 20852

