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Commissioner Jane Henney
FDA Dockets Management Branch
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

SUBJECT: Dockets No. 00P-1211/CP1 and No. 99N-4282

Dear Commissioner Henney:

I am writing to encourage FDA to adopt mandatory pre-marketing safety testing and labeling for genetically modified (GM) foods.

There are two main reasons why FDA should adopt these measures: possible health risks, and citizens' right to choose.

First, **POSSIBLE HEALTH RISKS**. As a Ph.D. biologist, I believe that most of the genes inserted to date in GM foods are safe. In other words, the chemicals that those genes produce (like biodegradable insecticides from bacteria or proteins that block premature tomato ripening) are probably safe for human consumption. So, where's the risk? The risks I worry about are the **indirect effects from inserting the genes** into a plant or animal. **First**, genes cannot yet be inserted in a precise location on the chromosome (the technology will get there someday, but it's not there yet). So, an inserted gene must "shoulder its way" into the existing genome of the plant or animal. In so doing, it pushes aside genes that were previously next to each other, or (most worrisome) **splits existing genes asunder**. What is the result? How do the newly-divided genes change the chemical composition of the plant or animal? The answer is, **NO ONE KNOWS**. And that's one reason we need pre-marketing safety testing. GM technology is not equivalent to the breeding that farmers have done for centuries (in which entire, intact chromosomes get swapped around). Farmers have almost never split up existing genes (yes, crossing-over between chromosomes does occur at very low rates during traditional breeding).

The **second** indirect but very-real risk is the markers that get inserted along with the desired genes. Markers allow breeders to confirm that the gene they were trying to insert actually made it into the genome. Unfortunately, the **markers are often genes that code for resistance to antibiotics**. Very simple and elegant for the breeders: expose the target cells to antibiotics and if they live, you can be confident that your gene made it. But, potentially dangerous for public health. To mention just one example: antibiotic-resistant tuberculosis currently is winning the race against doctors' best weapons. Using antibiotic-resistance as a marker is just short-sighted stupidity. Again, technology will solve this problem eventually, by developing better markers. But until it does, FDA should not breach the public's trust by allowing antibiotic-resistance genes into the food supply and the environment.

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To me, the indirect risks of inserting genes (splitting existing genes and fostering antibiotic resistance) are sufficient to justify pre-marketing safety testing. Nonetheless, there is an additional health risk: **the tradition of scientific arrogance**. Scientists are trained to believe that they know best. But in fact, like any group of professionals, they are fallible. The past 60 years have seen many failures of well-intentioned scientists to predict safety: the safety of pesticides, of hormone-mimicking chemicals, and (apparently) of global warming. **In nearly every case, scientists have been forced to admit that things were more risky (not less risky) than they previously thought.** They didn't know best; they only thought they did. Nonetheless, today we have many genetic engineers assuring us that they know best, and that there is no risk. FDA should not add GM food to the list of mistakes made by arrogant scientists. Instead, FDA should adopt the so-called "cautionary principle": when faced with unknown risk, assume it is real, and test it.

I hope that the health risks alone will compel FDA to implement both pre-market testing and labeling. But even if there were no health risks, labeling is justified simply by the **CITIZENS' RIGHT TO CHOOSE**. The United States is founded on the ideal of the right to choose. In today's language, it sounds frivolous when expressed as "the pursuit of happiness"; but it means that citizens should be able to live their lives as they see fit. As a federal agency, FDA should dedicate itself to helping all citizens realize their "pursuit of happiness". And for their pursuit, citizens require information. It is not for any of us -- not scientists, not FDA, certainly not food-industry lobbyists -- to decide whether citizens should avoid GM foods. It is up to each citizen. Therefore, **citizens must be provided with labeling information so that they can avoid GM foods if they choose.** Maybe such a choice seems foolish to FDA. By all means, permit the food industry to try to convince consumers that GM foods are their best buy. But don't permit industry to tell you that consumers don't even deserve to have a choice.

If FDA is committed to its mandate of protecting citizens' interests against health risks and against infringements on the right to choose, you should implement mandatory pre-marketing safety testing and labeling of GM foods.

Yours sincerely,



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