Executive Summary:
Legal Petition to FDA to Require Labeling of Genetically Engineered Foods

Submitted by Center for Food Safety, September 29, 2011

**ACTIONS REQUESTED:**

- Issue new regulations requiring labeling of all foods produced using genetic engineering; and
- Issue a new policy redefining a “material” fact as a change in food at the atomic, molecular, or genetic level that a significant share of consumers would find relevant to their purchasing decisions

**STATEMENT OF GROUNDS:**

1. Unlabeled GE Foods Are Misleading, and Therefore Prohibited

The Federal Food, Drug, and Cosmetic Act (“FFDCA”) prohibits the marketing or sale of foods if the label is misleading “in any particular.” Unlabeled genetically engineered (“GE”) foods are misleading because they carry unknown risks: there have been very few independent, peer-reviewed, comprehensive studies of their long-term human health and environmental impacts, and the few that exist give cause for concern. Further, overwhelming public demand for GE labeling—consistently near 95%—demonstrates that consumers do not expect unlabeled food to be genetically engineered. FDA’s continued failure to mandate labeling is an abdication of its statutory mandate to prohibit misleading food labels.

2. A Broader Interpretation of “Material” Facts Is Both Permissible And Necessary

FDA currently limits mandatory labeling to “material” facts, defined to include solely “organoleptic” characteristics (those which can be detected by the senses) or altered “performance characteristics.” FDA can and should adopt a broader understanding of “material” facts based on the following grounds: First, FDA’s labeling policy is outdated, using 19th century ideas to regulate 21st century foods. Second, novel technologies make silent changes to our food, placing the reality of food production further and further beyond the public’s expectations—and senses. Finally, without labeling, consumers reasonably assume that food is not genetically engineered. By allowing GE foods to go unlabeled, FDA’s current definition of “material” actively facilitates the deception that FDA is supposed to prevent.

3. Consumers Have a Judicially Recognized Right to Know

U.S. courts have recognized a fundamental “right-to-know” rooted in the U.S. Constitution and in common law. Whether FDA believes that GE foods are “of the same or equal quality” as their conventional counterparts is irrelevant to the question of whether unlabeled GE foods are misleading. The proper focus is consumers’ expectations and whether they are being deceived. Because consumers do not expect foods to be genetically engineered absent special labeling, their right to know what is in their food is being abridged by FDA’s GE labeling policy.

4. The Patentability of GE Foods Demonstrates They Are Materially Different
To be patentable, an invention must be “novel”—i.e., substantially different. That companies have patented so many GE crops demonstrates that they are significantly, “materially” different from traditionally produced foods.

5. Internationally, Mandatory Labeling for GE Foods is Widespread

At least 22 countries, as well as all of the EU member states, have mandatory labeling laws for GE foods, rendering U.S. policy an outdated and mistaken outlier. The longer the U.S. clings to its antiquated policy on GE food labeling, the more its standing as a leader in scientific integrity will be compromised.