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Docket No. 00N-1396 & Docket No. 00D-1598
FDA Commissioner, Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

"Genetic engineering" involves transfer of genes between different species. Gene splicing technologies not only insert genes which produce the protein(s) desired in the recipient species, but also splice genes from viruses and bacteria which are used to transport the desired genetic material and to detect whether the gene splice was successful; antibiotic-resistance genes are widely used for the latter purpose. Because of the presence of proteins produced by these genes not found in nature in the genetically-manipulated species, foods containing or produced from genetic engineering may cause allergic responses, be toxic, have lowered nutritional value and/or compromise immune responses in consumers. Likewise, genetically engineered crops can have unpredictable, irreversible changes to the environment caused by genetic drift from the genetically engineered crop through pollen, insect vectors, and transfer of genetic material among bacteria. At least one such instance each of the above listed problems has been documented to date.

FDA's proposal for companies to merely voluntary consult with FDA concerning the safety of their foods is totally inadequate. FDA must require MANDATORY pre-market safety testing.

FDA's proposed rule that environmental review procedures be exempt under the National Environmental Policy Act does not protect the environment. FDA must require MANDATORY pre-market environmental review.

FDA's proposed rule makes all labeling of genetically engineered foods (GEFs) only voluntary. This does not protect my right-to-know or allow me consumer choice to protect my family and the environment. Voluntary labeling unfairly reverses the financial burden onto producers who do not use GEFs. Mandatory labeling is essential for the traceability of GEF products throughout the food supply for health professionals. Mandatory labeling also protects overseas markets for farmers. FDA must require MANDATORY labeling of GEFs.

FDA's proposed rule is unlikely to provide the public with adequate information on GEFs for independent review. The FDA notes that producers of GEFs may claim that any such information, including the premarket notification, is trade secret or confidential business information subject to exemption from public disclosure requirements. FDA must require full disclosure.

I will settle for nothing less than mandatory safety testing, labeling, pre-market environmental review, and full diclosure. All GEFs should be taken off supermarket shelves until these are established.

Sincerely yours,

LaRue Christie

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