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February 5, 2001

Docket No. OON- 1396 & Docket No. OOD-I 598 FDA Commissioner, Dockets Management Branch (HFA-305) Food and Drug Administration 563 0 Fishers Lane, Room 106 1 Rockville, Maryland 20852

Dear Sir or Madam:

Genetic engineering involves manipulation of genes between different species and allows scientists to bypass the natural barriers which protect the genetic integrity of species. Foods containing or produced from genetic engineering can 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.

FDA's proposal for companies to merely voluntarily 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 ail 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 pre-market 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 disclosure. All GEFs should be taken off the supermarket shelves until these are established.

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