February 5, 2001

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

Dear FDA Commissioner:

Genetic engineering involves manipulations 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 genetically modified organisms 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 and totally unforeseen changes to the environment. Studies such as the ones conducted on the effects of genetically engineered crops on monarch butterflies are only one example of such unintended consequences manifesting themselves.

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. This is absurd and clearly shows FDA's motivation is to protect the interests of the multinational 'companies that produce GEF's, not the consumers of these products. FDA must require full disclosure.

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

Sincerely,

Jerry McGeorge
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