5311 Tuscarawas Road-8 19 42 Bethesda, MD 20816-3123 February 5, 2001

FDA Commissioner, Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. CON-1396 Docket No. OOD-1598

Dear Sir or Madam:

I am writing to ask for substantive changes in the proposed rules for genetically engineered food.

- 1. The proposed rule does not require pre-market safety testing. A rule which "allows" voluntary testing in no way changes the present situation: nothing now prevents companies from testing for safety should they choose to do so. Only a rule requiring pre-market testing would in any way change the status quo, and only required pre-market testing would give any measure of protection to the public.
- 2. Exemption of genetically engineered foods from environmental review procedures mandated by the National Environmental Policy Act is not acceptable. It is precisely the environmental dangers of GEFs--both known and as yet unknown--that most alarm large segments of the scientific community. Genetically engineered foods must be subject to mandatory pre-market environmental review. There is absolutely no scientific or legal justification for exempting GEFs from NEPA.
- 3. Voluntary labeling, like voluntary testing, represents non-action by the FDA: no manufacturer is restrained by law from labeling a product as containing or not containing GEFs; and, in fact, many now do. Both the public at large and scientific investigators are deprived of their right to know and choose by any rule short of mandatory public disclosure.

Respectfully

Marcia Rucker

OON-1396