Jane L. Collins
Attorney at Law
13610 Kishwaukee Valley Road
Woodstock, Illinois 60098
(815) 338-8339 01 15 '01 MAR -9 P2:47

March 5, 2001

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

RE: DOCKET NO. 00N-1396
DOCKET NO. 00D-1598

To Whom it May Concern:

I. The proposed policy revisions do not meet the standard of proof required by your agency's mandate to protect public health.

If we take a basic approach to the health-based statutes under which your agency has been delegated the authority to protect human health, the FDC Act requires that your agency make a threshold finding that "there is substantial evidence that [the introduction of GE food] is safe and effective," and that "there is no imminent hazard to public health."

What you are suggesting is unacceptable, and would not provide the appropriate level of protection to public health. We would see products introduced into the market place, but have no notice or information about those products.

Worse, your agency would have no way of tracking or recalling those products that cause harm. (Witness the StarLink fiasco.)

II. To ensure public health is protected, you must require pre-market testing, mandatory labelling, and full public disclosure of all test results.

III. To ensure that these products do not cause harm to the environment, these rules must be subjected to a National Environmental Policy (NEPA) review.

Respectfully submitted,

Jane L. Collins

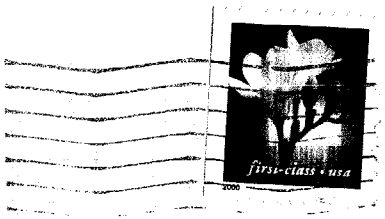
Jane L. Collins

00D-1598

C 2040

Jane L. Collins
Attorney at Law
13610 Kishwaukee Valley Road
Woodstock, Illinois 60098

PALATINE IL 600
PM
06 MAR
2001



FDA Commissioner
Dockets Mgmt Branch (HFA-305)
FDA
5630 Fishers Lane Room 1061
Rockville MD 20852

re Docket No 00N-1396
00D-1598

20857/0001