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Docket No. 00n-1396 Docket No. 00D-1959
FDA Commissioner, Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

1) I think it must be mandatory to have pre-market safety testing. Why do you state that genetically engineered (GE) food are assumed "genetically recognized as safe and they are not subject to mandatory pre-market review under the FDA and Cosmetic Act's Food additive petition process." What happens when genes from peanuts are added to food and a person is extremely allergic to peanuts?

2) Also the FDA also "maintains the companies may voluntarily consult with FDA concerning the safety of their foods." This seems to be a relaxing of the rule that consultations would be mandatory.

3) Genetically engineered food producers must send a letter of intent 120 days in advance of marketing a genetically engineered food. Information required:

a) description of the foods
b) methods of food development
c) substances introduced into the food, including allergenicity issues
d) information comparing it to comparable food.

It seems that getting this information would necessitate testing and therefore testing should be required. What real effect would a letter of intent have?

4) Further, the FDA has no ability to trace a GE food through the food supply should harm to public health become apparent. The pre-market letter should require methods of detecting food once in the marketplace.

5) There should be mandatory labeling of GE foods. Without labeling, health professionals would not know if an allergic or toxic reaction was the result of GE foods. Also, consumers would not have critical knowledge to hold producers liable if these novel foods prove hazardous.

6) The FDA says the new process will make safety and review information more transparent and accessible to the public.

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This is not likely because:

a) information about pre-market notification and voluntary consultation documentation would be subject to the Freedom of Information Act. However GE food producers may claim such information is a trade secret

b) the voluntary nature of submissions prevent public scrutiny of real safety issues.

c) the rules seem to convenience industry at the expense of public health, consumer information and the environment.

7) Environmental review - these crops could cause irreparable damage to the environment. Examples are the introduction of purple loosestrife which crowds out natural plants. This example is not quite comparable, but plants that are made resistant to diseases often crowd out those that do not have this quality and we lose some biodiversity.

8) While admitting that public comments overwhelmingly support labeling, the FDA reasserts that it will not require mandatory labeling of GE foods. In accordance with this, the FDA has released non-binding guidance on how labeling should take place for producers who want to voluntarily label their food.

9) The guidance documents suggests that the FDA will severely limit the type of voluntary labels that may be used.

Thank you for the opportunity to comment on regulations the FDA is proposing for GE foods. Please respond to these comments.

Sincerely yours,

Geraldine Schulte

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