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

Dear Sir or Madam:

These comments are in response to the recent draft document entitled: Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals, Docket No. 02D-0324. I generally support the FDA and USDA's guidelines to ensure the safe production of pharmaceuticals produced by plants, including in crops that are conventionally grown for food and feed.

Bioengineered plant pharmaceuticals represent enormous opportunities to produce materials that are otherwise in short supply or very costly at potentially reduced cost and equal or higher degree of purity, but there currently are a number of concerns not addressed.

The agencies are to be commended for a very thoughtful analysis and presentation without being overly prescriptive. Unfortunately, the public does not recognize the use of such guidance documents. Perhaps language can be inserted to indicate that, dependent on the plant and product, most recommendations will be considered mandatory.

Language could also be added to encourage companies to have an easily distinguishable physical marker on their material to enable easy detection of adventitious presence. Some tests in animals simulating ingestion of 'contaminated' food or feed should be considered and ideally published to allay fears of inadvertent consumption.

It is not clear why enzymes and industrial products are not mentioned, since this is a joint document between two agencies. Procedures would presumably be similar, if not identical.

Segregation of multiple products is not addressed. The first product could be harvested with dedicated machinery; the second and subsequent products likely would be produced in the same genetic background or 'platform'. Is it realistic to speak of dedicated machinery in these cases? Nothing is said about the possibility for using disposable parts, rather than relying solely on sanitation for mechanical separations. A high value drug might warrant such attention.

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Non-target effects on microbes and arthropods may occur and should be assessed at least by some monitoring of parent plants (non-modified) in comparison with modified plants.

This area of biotechnology is in its infancy and has significant potential. It is no mean task to both encourage its advancement and protect the nation's food and feed supply and the environments in which such plants are grown.

I hope these comments are of assistance.

Sincerely,

Anne K. Vidaver
Professor & Head