



DONALD DANFORTH
PLANT SCIENCE CENTER

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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President
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Dear Sir or Madam:

I wish to make a comment regarding the draft of the document "Guidance for Industry: Drugs, Biologics, Medical Devices from Bioengineered Plants for Use in Humans and Animals", Docket No. 02D-0324. The Donald Danforth Plant Science Center supports the goals of the USDA and FDA to ensure the safe production of plant-made pharmaceuticals. I am also aware of the recent events that have brought greater recognition of the importance that strong and effective regulations will play as new advances in biotechnology are made.

Plants have the potential to play an important role in the production of pharmaceutical materials and compounds in the near future. However, they will not do so unless:

- (1) the regulatory process is fair and science based, and if risk assessment is based upon scientific knowledge;
- (2) the public perceives that the process of evaluation is transparent and is based upon science;
- (3) the production of crops that produce pharmaceutical proteins or other materials are shown to be safely grown (in genetic or physical containment) and that materials are kept apart from the food supply;
- (4) the process is cost effective for both the producer and manufacturer.

The scientific community, along with government input and oversight, must continue to work with industry, and to develop flexible science-based standards that guarantee safety of the food supply, while bringing benefits to the American agriculture community.

We support this technology, and some of the work at the Danforth Center may add substantially to its success. We applaud the FDA and USDA in their effort to develop effective regulations to this new industry in a manner that permits its advancement while guarding the safety of our foods.

Sincerely,

Roger N. Beachy

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