UNIVERSITY OF ILLINOIS
AT URBANA-CHAMPAIGN

Office of Research

College of Agricultural, Consumer
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Illinois Agricultural Experiment Station
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Urbana, IL 61801

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

RE: Docket No. 02D-0324

Dear Sir or Madam:

I am writing to comment on the recent draft, "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals," Docket No. 02D-0324. I, Bruce M. Chassy, Associate Director of the Biotechnology Center at the University of Illinois, applaud the effort to ensure the safe production of plant-made pharmaceutical crops from commodity grains intended for food and feed. I strongly support the draft guidelines that you have published.

There can be no doubt that production *in planta* offers great promise to increase the supply of critically needed pharmaceuticals at lower cost and greater safety for consumers. I, Bruce M. Chassy, also recognize, however, that no new technology is without risks. Plant-made pharmaceutical processes present new risks to the food and agricultural systems.

I strongly support this technology and the significant potential it possesses, and I concur with FDA and USDA's efforts to regulate this industry in a way that both allows for its advancement and protects the food supply.

Sincerely,

Bruce M. Chassy

Bruce M. Chassy, Ph. D.
Executive Associate Director
Biotechnology Center

02D-0324

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