Healthy Plants • Healthy World

January 27, 2003

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. The American Phytopathological Society generally supports the FDA and USDA's guidelines to ensure the safe production of pharmaceuticals produced by plants, including in crops that conventionally have been grown exclusively for food and feed. We appreciate this opportunity to provide input.

Bioengineered plant pharmaceuticals, or plant-made pharmaceuticals (PMPs), have enormous potential to produce products more economically, and in greater purity and volume. The agencies have produced a very thoughtful analysis and presentation, but a number of concerns remain to be addressed.

MAKE THE RECOMMENDATIONS FOR PLANT-MADE PHARMACEUTICALS MANDATORY. The public is often not aware of the use of such guidance documents. Hence, language should be inserted that the recommendations will be considered mandatory as appropriate for the specific plant and product.

PROVIDE FOR RECOGNITION OF PMPS. Companies could be encouraged to use a recognizable physical marker or label on their material to facilitate recognition of PMP presence.

ALLAY PUBLIC CONCERNS VIA TESTING. Tests in animals, simulating ingestion of the proposed PMP, should be considered and preferably published to address public fears of inadvertent consumption. This should include enzymes and industrial products, which are not addressed in the current document.

ADDRESS SEGREGATION OF MULTIPLE PMPs. An initial product could be harvested with dedicated machinery, but subsequent products likely would be produced in the same genetic background or 'platform'. Is it realistic to speak of dedicated machinery in these cases? Viable alternatives to sole reliance on sanitation for mechanical separations should be explored. Non-target effects of PMPs on microbes and arthopods may occur and should be assessed at least by comparative monitoring of non-modified (parent) plants and modified plants.

This area of biotechnology is in its infancy and has significant potential for benefit. The American Phytopathological Society is pleased to see a sound and transparent process being promoted to both encourage the advancement of PMPs and to 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,

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APS President

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