CropLife AMERICA

Jay J. Vroom
President

February 7, 2003

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

Re: Guidance for Industry: Drugs, Biologics, Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals; Proposed Federal Actions; Docket Number 02D-0324

Dear Sir/Madam:

CropLife America is pleased to have this opportunity to respond to the U.S. Food and Drug Administration (FDA) above-captioned notice appearing in the Federal Register on September 12, 2002. 67 FR 57828. The FDA has requested comments in response to their combined efforts with the U.S. Department of Agriculture (USDA) to provide guidance with regard to the use of plant material to produce biological products (including intermediates, protein drugs, medical devices and new animal drugs) via modern biotechnology methods.

Organized in 1933, CropLife America is the not-for-profit trade organization representing global leaders in the development of existing and emerging agricultural technologies for the enhancement of crop production. Since CropLife America members are heavily involved in the development and application of modern biotechnology methods in agriculture, they are committed to the progress and commercialization of plant science technologies that comply with applicable federal laws and regulations.

CropLife America appreciates FDA's objectives and approach that have resulted in publication of this notice. Additionally, we agree with the FDA regarding their focus on the unique issues related to the use of biotechnology-derived plant material as a source of pharmaceutical products, including those plants infected with engineered vectors containing genetic material for the expression of FDA and/or USDA regulated products.

For the purpose of this response, we are forwarding the following comments for consideration in development of science - based policy that characterizes risks and benefits within the relevant context and the evolving nature of this technology:

- The vast majority of the draft guidance addresses issues relating to the safety, purity and efficacy of vaccines and drugs; therefore, the environmental and confinement section is not comprehensive and needs to be addressed in a separate regulatory forum. A separate regulatory statement from the USDA (developed in appropriate consultation with other agencies) would provide clarity not only for plant - made pharmaceutical (PMP) containment, confinement and production, but for other crops produced through biotechnology, intended for uses other than food or feed.

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- Crops that are developed through biotechnology for industrial use cover a broad spectrum of products; some of which may be intended for food or feed use, others that are clearly not intended for these uses. For the purpose of these comments, the term plant-made industrial products (PMIPs) refers only to those products not intended for food or feed. It is our position that PMIPs, like pharmaceuticals, be cultivated only under permit, both during the field testing timeframe, and maintained following commercialization.

- Performance verified and rapid testing methodologies must be provided to the appropriate regulatory agency by the PMP and PMIP permit applicants to confirm both the qualitative presence of the target gene and the protein in the raw agricultural commodity at the field - testing stage and at commercialization.

- Permit conditions should be sufficiently comprehensive to address and mitigate the health, safety, environmental and regulatory risks associated with the use of food crops to produce non-food PMPs or PMIPs. This would include comprehensive descriptions of how key production aspects would be performed, including dedicated land and equipment use, grower certification, and the entire crop production spectrum, from planting to waste crop disposal. The USDA's Animal and Plant Health Inspection Service (APHIS) should include mandatory audits and inspections as key permit elements.

CropLife America appreciates ongoing efforts in this area and offers our assistance as a key plant biotechnology industry stakeholder. Please contact Dr. Isi Siddiqui or Dr. Leah Porter of my staff at 202/296-1585 for further information and assistance.

Sincerely,

Jay J. Vroom
President, CropLife America