

www.agingresearch.org

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January 23, 2003

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

Dear Sir or Madam:

In response to the recent draft entitled, "Guidance for Industry: Drugs, Biologics, and Medical Devices Derived From Bioengineered Plants for Use in Humans and Animals," Docket No. 02D-0324, the Alliance for Aging Research, an independent, not-for-profit organization, promoting research in diseases that afflict older Americans, supports the FDA and USDA's guidelines to ensure the safe production of plant-made pharmaceutical crops from commodity grains intended for food and feed. The Alliance concurs that any company wishing to participate in producing bioengineered plants must adhere to strict, self-imposed, stewardship principles and procedures.

The Alliance For Aging Research represents the needs of Americans as they age. We understand that the primary benefit of plant-made pharmaceuticals may be the opportunity plants offer to produce a greater variety of pioneering life-saving drugs at more economical costs. Plant-made pharmaceuticals appear to offer great possibilities for the economical and efficient production of novel proteins to diagnose, treat or prevent a wide variety of human diseases. The Alliance believes that it is important to pursue all new feasible opportunities for advancements and breakthroughs in medicine, especially those with the potential to develop cost-effective treatments and therapies that can reach patients swiftly.

We encourage innovative research that can provide life-saving treatments and cures for the devastating effects of age-related diseases such as Alzheimer's, Parkinson's and diabetes. As along as this source of technology is governed by strong regulation, plant-made pharmaceuticals are a promising source of innovation and possess significant potential to unleash new discoveries, which would benefit millions of aging Americans that suffer from these diseases.

The Alliance for Aging Research supports this technology, and applauds the FDA and USDA's efforts to regulate this industry in a way that allows for both the advancement and protection of agriculture, while moving forward with promising research that may help Americans defeat the diseases and conditions of aging.

Sincerely,

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