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WOMEN'S HEALTH RESEARCH

*Changing the Face of Medicine* 1039 16 01-2 2113

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January 6, 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 Society for Women's Health Research supports the issuance of FDA and USDA guidelines to ensure the safe production of plant-made pharmaceutical crops from commodity grains intended for food and feed. We agree that any company wishing to participate in producing bioengineered plants must adhere to strict, stewardship principles and procedures.

While plant-made pharmaceutical technology represents a great opportunity with tremendous potential, the Society for Women's Health Research also recognizes the potential risks to agriculture and the food industry. The success of this technology is predicated upon strong, transparent regulations coupled with an industry-wide commitment to stewardship. Government, the scientific community, and industry must continue to cooperate to develop feasible, science-based, performance standards in order to protect U.S. agriculture, to instill public confidence and to ultimately realize the potential benefits of this innovative technology. We applaud FDA and USDA's efforts to regulate this industry in a way that both allows for its advancement and protects the food supply.


The Society for Women's Health was created in 1990 to address the inequalities in medical research that were affecting the quality of health care for women. As the only national advocacy organization dedicated solely to improving the health of women through research, we advocate for the inclusion of women in clinical research trials and promote research

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in sex-based biology, which seeks to understand the biological reasons behind the health differences between women and men.

Sincerely,



Phyllis Greenberger, MSW  
President and CEO