GREENPEACE
702 H Street, NW, Suite 300, Washington, DC 20001
Tel: 202-462-1177 • Fax: 202-462-4507
www.greenpeaceusa.org

4 January 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

Greenpeace comments submitted to Docket Number 02D-0324:
Draft "Guidance for Industry: Drugs, biologics, and medical devices derived from bioengineered plants for use in humans and animals"

Thank you for the opportunity to submit comments on the FDA draft guidance to industry on plants engineered to produce pharmaceuticals. We have four major concerns regarding the draft guidance; the following recommendations address these concerns.

1. The FDA should prohibit the use of food crops for the production of pharmaceuticals or industrial chemicals. The potential for contamination of food supply chains is too great. Seed stocks can be contaminated at the breeding stage; seeds can fall off trucks and out of sacks during transportation; contamination through pollination cannot be 100% prevented; and as the Prodigene scandal of this fall demonstrated, there are multiple points at which food stocks could be contaminated post-harvest. The only possible action the agency could take to protect the food supply from contamination is to ban completely the production of these novel chemicals in food crops.

2. Any regulation of plants engineered to produce pharmaceuticals must also include plants engineered to produce industrial chemicals. There is not necessarily a qualitative difference between proteins used for pharmaceuticals and proteins used as industrial enzymes. Both can have physiological effects in humans. There is no *a priori* reason, biological or otherwise, for regulating plants producing laccase differently from plants producing a TGEV protein. Currently plants producing industrial enzymes are slipping through a large regulatory hole, with not even permit-granting oversight being exercised by the USDA. This situation is unacceptable and should be addressed by both agencies immediately.

02D-0324 C 567

3. No outdoor cultivation of plants expressing pharmaceutical or industrial proteins should be allowed. The risks to be avoided include:

- cross-pollination with related species, introgression and geographic spread (a worst case, though unfortunately plausible, scenario would be contamination of the Central American center of maize diversity);
- negative impacts on wildlife, including insects;
- exudation of novel compounds into soils, with concomitant disruption of soil microfloral and microfaunal communities; and
- horizontal gene transfer of novel sequences to soil-dwelling bacteria and subsequent, sustained production of a novel protein toxic to soil ecosystems.

4. The USDA and the FDA must develop mandatory regulations for companies using plants to produce pharmaceutical and industrial proteins. It is extremely troubling, especially after the recent Prodigene scandal, to see such language in the document as "measures *should* be in place to ensure that there is no inadvertent mixing..." and "*we strongly recommend* that you have tests available that can detect the presence of the target gene..." (emphasis added). This technology holds numerous risks for the public and the environment, and must be strictly regulated. To allow the industry to design its own rules is to open the door to more StarLink and Prodigene scandals and a further erosion of faith in the ability of the regulatory agencies to protect the food supply and the environment from contamination.

We appreciate the opportunity to submit these comments and await the agency's response to our concerns.

Sincerely,

PhD

Doreen Stabinsky, PhD
Science advisor
Greenpeace