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U.S. Food + Drug Administration;

In human gene therapy, the biological properties of living cells are altered for therapeutic use. Xenotransplantation is the transfer of organs from an animal to a human.

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The public must know whats going on in the forefront of medicine.

This proposal only brings gene therapy and xenotransplantation in compliance with the same types of information already released to the public by other government agencies. Because of grave public health risks, disclosure should include additional information such as physicians, medical centers, and so on - make public all information except trade secrets and patient identification.

The FDA must assume the sole responsibility for summarizing and distributing information submitted by the research sponsor, rather than leave it to the sponsor's discretion.

Because of the public health risks, ethical issues, cost uncertainty and the inability to adequately assess other alternatives, all xenotransplantation clinical trials should stop. Docket # 00N-0989.

Elizabeth Gingery
1921 Ellison Dr.
Modesto, CA 95355

Elizabeth Gingery

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Elizabeth Gingery
1921 Ellison Dr.
Modesto, CA 95355

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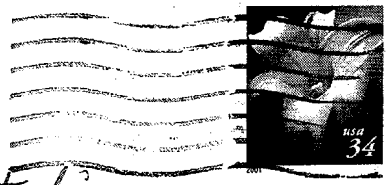

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HFA-305
Rockville
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