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March 24, 2001

US Food & Drug Administration
Dockets Management Branch
5630 Fishers Lane, Room 1061
HFA-305
Rockville, MD. 20852

Re: Docket # 00N-0989

The following are comments by the undersigned on FDA's proposed rule to provide public access to most of the study design and safety information on new or ongoing trials involving gene therapy or xenotransplantation.

This proposal brings gene therapy and xenotransplantation into compliance with information already made public by other government agencies. Disclosure should include additional information, such as physicians, medical centers, etc., all information except trade secrets and patient information.

It should be the FDA's sole responsibility to summarize and distribute information submitted by the research sponsor. The distribution of said information must not be left solely to the sponsor's discretion.

Because of the plethora of public health risks, ethical issues, cost uncertainties, coupled with the present inability to adequately assess possible alternatives, clinical xenotransplantation trials should stop until all of the above issues can be thoroughly investigated.

Yours truly,



Ursula Palenik

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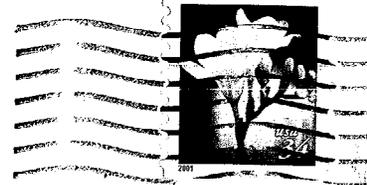
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Proud Supporter of Wildlife Land Trust

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