DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel
Food and Drug Administration
5600 Fishers Lane, GCF-1
Rockville, MD 20857

MEMORANDUM

Date: December 1, 1999

To: Associate Commissioner for Public Affairs
Director, Center for Biologics Evaluation and Research

From: Commissioner of Food and Drugs

Subject: Disclosure of Information -- OTC Gene Therapy

Due to the public health significance of, and the public interest in, experimental gene therapies, including public interest in the death of a participant in one study, I have determined under 21 C.F.R. section 601.51(d)(1) that FDA may disclose summary safety and effectiveness data in its possession relating to a clinical study of gene therapy in participants with ornithine transcarbamylase (OTC) deficiency carried out by Dr. James Wilson at the University of Pennsylvania's Institute for Human Gene Therapy. Disclosure of these data is appropriate for public consideration and an accurate public understanding of this gene therapy.

The summary information that will be disclosed will be appropriate for public consideration of the issues raised regarding the safety of OTC gene therapy. Summary information does not include the full reports of investigations required to be submitted for approval, and will not reveal the full administrative record of an IND. In determining the specificity of the summaries to be disclosed under this determination, I will use established precedent.

Jane E. Henney, M.D.