DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

NOV 3 0 2000

To sponsors, prospective sponsors, and researchers who may be using fetal cellular or tissue products in human clinical studies:

The purpose of this letter is to advise you that the Food and Drug Administration (FDA) has jurisdiction over fetal cells and tissues intended for use in humans, and to inform you of the FDA regulatory process governing such products. There has been confusion in the press and research community about federal oversight of these products. Because this is an evolving field with a number of issues to resolve, we request that you contact FDA to determine whether any clinical investigations you are conducting, planning or sponsoring would require submission of an Investigational New Drug (IND) application. We would be pleased to provide you with information and guidance regarding filing such an application.

Examples of fetal cell and tissue products include, but are not limited to, human fetal neuronal cells to treat Parkinson's disease; fetal retinal tissue to prevent blindness; and fetal spinal cord to treat syringomyelia. Clinical trials involving the use of the tissues described in these examples are subject to FDA's regulations on investigational new drugs, including those for the submission and review of an IND set forth in Title 21 of the Code of Federal Regulations (CFR), Part 312. The agency has provided notice of the applicability of these requirements to cellular and tissue-based products in many public forums and in various published documents including the following:

- A Federal Register (FR) notice describing FDA's authority over cell and gene therapy products ("Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products," October 14, 1993, 58 FR 53248).

- A comprehensive regulatory program for the regulation of human tissue and cell based products, based on a tiered, risk-based assessment ("A Proposed Approach to the Regulation of Cellular and Tissue-Based Products," March 4, 1997, 62 FR 9721).

In addition, FDA has published two proposed rules on cellular and tissue based products: "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, Proposed Rule", May 14, 1998 (63 FR 26744); "Suitability Determination for Donors of Human Cellular and Tissue-Based Products; Proposed Rule", September 30, 1999 (64 FR 52696).

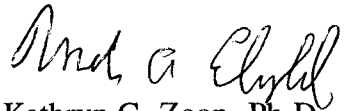
Information is enclosed on submitting an IND to the FDA, along with copies of the relevant sections of Title 21 of the Code of Federal Regulations (21 CFR), namely parts 312 (investigational new drug applications), 50 (protection of human subjects) and 56 (institutional review boards). The Center for Biologics Evaluation and Research (CBER) has a detailed

Internet page with IND forms, regulations and advisory sheets (www.fda.gov/cber/ind/ind.htm). INDs are to be submitted in triplicate to the following address:

Center for Biologics Evaluation and Research
Attn: Office of Therapeutics Research and Review
HFM-99, Room 200N
1401 Rockville Pike
Rockville, MD 20852-1448

The specific information required in an IND will depend upon the experimental system and the phase of study. For assistance in determining whether you need to file an IND submission and in preparation of a submission, please contact Dr. Joyce Frey-Vasconcells at 301-827-5102.

Sincerely,



for Kathryn C. Zoon, Ph.D.
Director
Center for Biologics Evaluation and Research
Food and Drug Administration

cc: Lana Skirboll, Ph.D.
Associate Director, Office of Science Policy,
National Institutes of Health