DEPARTMENT OF HEALTH & HUMAN SERVICES

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

September 8, 2000

Dear Colleague:

The purpose of this letter is to inform or remind you of how the Food and Drug Administration (FDA) regulates allogeneic pancreatic islets for transplantation. These cellular therapies are regulated as biological products subject to licensing under Section 351 of the Public Health Service Act (PHS Act). 42 USC 262. They also meet the definition of "drug" in the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 USC 321(g), and are thus subject to certain requirements of the FD&C Act. An Investigational New Drug (IND) application should be submitted for review by FDA and be in effect prior to the initiation of clinical studies in humans of allogeneic pancreatic islets for transplantation. 21 CFR Part 312.

The Agency has published documents and held meetings concerning the regulation of cellular/tissue based products intended for transplantation and somatic cell therapies, including allogeneic pancreatic islets. Relevant documents and meetings include the following:

- On February 28, 1997, FDA's Center for Biologics Evaluation and Research (CBER) published an approach to the regulation of human cellular and tissue-based products*.
- On March 30, 1998, CBER published "Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy †."
- On March 20-21, 2000 issues specifically related to allogeneic pancreatic transplantation were discussed at a meeting of the FDA Biologic Response Modifier Advisory Committee‡.

Despite these efforts to inform the transplant community, FDA recognizes that some transplant centers or surgeons remain unaware that investigational study of allogeneic pancreatic islets for transplantation requires the submission of an IND. Therefore, FDA now reiterates that all institutions, transplant centers or surgeons with active programs of allogeneic pancreatic islet cells for transplantation, that are not currently under IND, should refrain from performing any allogeneic islet cell transplants until an IND has been submitted and is in effect. INDs are to be submitted in triplicate as follows:

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* A Proposed Approach to the Regulation of Cellular and Tissue-based Products, February 28, 1997 (62 FR 9721) available at: http://www.fda.gov/cber/gdlns/CELLTISSUE.pdf

† Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy, (63 FR 36413) http://www.fda.gov/cber/gdlns/somgene.pdf

‡ Transcript of discussion of allogeneic pancreatic islets by FDA Biologic Response Modifier Advisory Committee on March 20-21, 2000, available at: http://www.fda.gov/ohrms/dockets/ac/cber00.htm

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

Information on IND regulations, required forms and how to submit an IND to CBER can be obtained from the FDA website at: http://www.fda.gov/cber/ind/ind.htm or by calling the Office of Communication, Training and Manufacturers Assistance at 301-827-2000.

If you have any questions, please contact the Regulatory Project Manager, Jeanne Delasko, at (301) 827-5101.

Sincerely,

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