



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

February 2, 2000  
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Ms. Ellen Heck, M.T., M.A.  
Director, Transplant Services Center  
University of Texas  
Southwestern Medical Center  
5323 Harry Hines Blvd.  
Dallas, Texas 75390-9074

Dear Ms. Heck:

I have received your January 12, 2000, letter to Commissioner Jane Henney, M.D., and to me regarding proposed Food and Drug Administration (FDA) regulations for human cellular and tissue-based products. As you may know, on September 30, 1999, FDA published a proposed rule entitled "Suitability Determination for Donors of Human Cellular and Tissue-based Products." This proposed rule addresses the screening and testing of donors of these products, including corneas.

I am forwarding your letter to Docket 97N-484S that has been established for comments to this proposed rule. We will be carefully evaluating all comments received prior to finalizing these regulations.

Thank you for your interest in this important public health issue.

Sincerely,

*Ruth Solomon, M.D.*

Ruth Solomon, M.D.  
Director, Human Tissue Program  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research

cc: Dockets Management Branch, (HFA-305)  
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HTP file

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