the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (30 ) 443-6597.

We have enclosed the guidance document entitled "Sponsor's Responsibilities for a Significant Risk Device Investigation" to help you understand the functions and duties of a sponsor. Also enclosed is the guidance document "Investigators' Responsibilities for a Significant Risk Device Investigation" which you should provide to participating investigators.

If you have any questions, please contact Everette T. Beers, Ph.D. at (301) 594-2018.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures
(1) Procedures to Request Re-Evaluation of HCFA Reimbursement Categorization Determination
(2) Sponsor's Responsibilities for a Significant Risk Device Investigation
(3) Investigators' Responsibilities for a Significant Risk Device Investigation