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the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 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