

February 16, 2009

Food and Drug Administration
Center for Devices and Radiological Health
9200 Corporate Blvd.
HFZ-460
Rockville, MD 20850
Attn: Don Calogero

Dear Mr. Calogero and Mr. Swink,

Enclosed please find 23 copies of an executive summary and supporting documents on the VisionCare Implantable Miniature Telescope (IMT™ by Dr. Isaac Lipshitz) for the March 27 FDA Ophthalmic Devices Advisory Panel meeting. One copy is designated for the industry representative and this copy is clearly labeled.

The panel package is organized as follows:

- Volume I executive summary, data tables and additional supporting documents
- Volume II pivotal study protocol (IMT-002) and long-term safety monitoring protocol (IMT-002-LTM); proposed extension to IMT-002-LTM (Protocol LTM-002-LTME), SSED, patient information, professional use information and physician training; bibliography and electronic copies of the Original PMA and Amendments A001-A019, as well as citations.
- Volume III reserved for FDA's information to the Advisory Panel.

Please note that since the set of data tables provided in Appendix 2 has been revised from the original draft copies of this Panel package, we are providing 22 new copies, and the 3 copies previously provided should be discarded.

If you need any additional information or copies, please contact me at (949) 715-0609 or via email at judy@clinregconsulting.com.

Sincerely,

Judy F. Gordon, D.V.M.
Regulatory Consultant to VisionCare Ophthalmic Technologies, Inc.