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From: Tarosky, Matthew [mailto:MJT@CDRH.FDA.GOV]
Sent: Thursday, August 05, 2004 10:55 AM
To: 'Jo Wills'
Subject: RE: FDA Letter

Hello Ms. Wills,

Thank you for your message. The office in which I work, the Division of Bioresearch Monitoring, treats information like that provided by you as serious and conducts an evaluation of all reports of research misconduct. The information that you provided to me was assigned to an office colleague. I believe she may have sent you a response. The investigation of Dr. Nevyas included two inspections over the past several years. If you would like a copy of those inspection reports and related correspondence, please contact FDA's Freedom of Information Office. You can also obtain information through the web at: http://www.fda.gov/opacom/backgrounders/foiahand.html The investigation of Dr. Nevyas is closed at this time.

It is my understanding that your adverse event report was reviewed from a public safety perspective along with all of the other adverse event reports received for the same medical device which ultimately resulted in the study being stopped. Thank you very much for the information that you provided. It was very helpful in FDA's evaluation of the risks and complications associated with the use of this medical device. Unfortunately, I can not give you any further details about the study. I do know, though, that FDA did introduce on their web-site awhile back a substantial amount of information about risks and complications regarding the use of lasers for corrective eye surgery. Hopefully, further complications will be minimalized.

Sincerely,

Matthew Tarosky, Pharm.D.
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