34. Please be advised that for possible future pre-market approval, although 300 eyes total are needed to support overall safety, data from approximately 125 eyes are needed to support each indication for which approval is being sought. Therefore, if you intend to seek approval for each indication you have proposed in the submission, you will need data from ~125 eyes in each of the following groups - the low spherical myopia only group, the high spherical myopia only group, the low myopia with astigmatism group, the high myopia with astigmatism group, the spherical hyperopia only group, and the hyperopia with astigmatism group.

35. Please be aware that if a subject moves and is, therefore, no longer followed in the study, the subject is considered lost-to-follow-up for purposes of reporting accountability.

If you have any questions, please contact Alfred Montgomery DVM at (301) 594-2080.

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
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Radiological Health

Enclosure
(1) Procedures to Request a Regulatory Hearing