3. You have not provided in your protocol the methodology for performing any of the clinical evaluations. For each clinical evaluation, please specify the testing procedures and instruments that will be used, including the lighting conditions and charts you will use to measure distance vision and near vision, etc.

4. You have indicated that pupil size measurements will be performed in dim lighting conditions, ~2 lux. However, this is closer to photopic than mesopic conditions (~0.1 lux) that are required for appropriate inclusion of subjects in the study. Please specify in your protocol how the pupil size measurement will be obtained, as requested above, and revise the lighting conditions under which this measurement will be obtained to assure that the measurement will be performed under mesopic conditions. We recommend dark adaptation for 10 minutes prior to the measurement and the use of an infrared pupillometer for consistency of the measurement.

5. Section 8.7 of each protocol states that the manufacturer's recommended settings are provided in Attachment D, and that the optical zone size (transition zone = 7.5 mm or 9.0 mm) will be selected by the investigator in accordance with the manufacturer's recommendations. Attachment D was not provided, however, and the previous statement implies that the optical zone size may be varied within each protocol. Please provide the optical zone and corresponding transition zone sizes for each of the indications - spherical myopia, myopic astigmatism, spherical hyperopia, and hyperopic astigmatism. Please note that we do not recommend varying the optical zone and transition zone according to an algorithm. However, if you choose to utilize varying optical zones, please provide adequate justification and the algorithm for determining zone size. In this case, you are reminded that outcomes must be stratified by optical zone and, possibly, transition zone.

6. The refractive inclusion criteria for Protocol NEV-01-002 (Myopia/Myopic Astigmatism) indicate that the uncorrected refractive error must consist of spherical myopia (-0.5 D to -16.0 D) or myopic astigmatism (-0.50 D to -16.0 D MRSE; cylinder -0.5 D to -6.0 D) for inclusion in the study. You also noted that the minimum allowable cylinder treatment is -0.5 D and that eyes with cylinder between 0.0 D and < 0.5 D may be enrolled in the study, but the cylinder cannot be treated. The refractive inclusion criteria for Protocol NEV-97-003 (Hyperopia/Hyperopic Astigmatism) indicate that the uncorrected refractive error consists of spherical hyperopia (+0.50 to +6.00D) or hyperopic astigmatism (+0.50 to +6.00 D MRSE; cylinder +0.50 to +4.00 D) for inclusion in the study. You also noted that the minimum allowable cylinder treatment is 0.5 D and that eyes with cylinder between 0.0 D and < 0.5 D may be enrolled in the study, but the cylinder cannot be treated. It has been FDA's experience that there is more variability in refractive outcomes with lower corrections. Therefore, please justify the lower limits of your refractive inclusion criteria by providing a scientific argument for why you think you will be able to accurately treat and measure the outcomes at the lower limits of the refractive ranges you have chosen. Otherwise, please use 0.75 D as your lower unit for sphere and cylinder.