in their refractions of 1.125 to 1.625 diopters between the 3 and 6 month visits. We expect these eyes to reach refractive stability at the next scheduled visit. We would also expect the percentage of eyes that reach stability to increase at 6 months when more patients who were stable at 3 months reach their 6 month postoperative visit.

Key safety and efficacy variables for the 230 eyes that have undergone a single treatment (no retreatments) are summarized in Attachment 1.1.E-1. The "N" that is used for calculating percentages is the actual number of patients completing each visit because the study is not complete and data are being added to the database on an ongoing basis. By 3 months postop, 94.5% of the total eyes analyzed had reached refractive stability. The tables are stratified by preoperative MRSE at 3 months postoperatively (the point of stability for the overall group) to provide the most information about the safety and efficacy of Nevyas Excimer Laser for the treatment of myopia/myopic astigmatism. The summaries for uncorrected visual acuity are presented both with and without the monovision patients included in the analysis.

A comparison of the 3 month postoperative data for the Nevyas Excimer Laser with the FDA's LASIK guidance recommended criteria for low myopia (< 7 diopters) and proposed criteria for high myopia (≥ 7 diopters) that were issued for discussion on October 21, 1997 is summarized in Table 1.1.E-4 below and includes parameters for safety as well as efficacy.