

FDA'S QUESTION:

8. Please clarify why you have omitted or modified the following inclusion criteria (Section 3.2.4.1):
- a. BCVA should be 20/40 or better in both eyes.
 - b. Contact lens wearers should:
 - i. Remove soft or gas permeable contact lenses two weeks prior to baseline measurements
 - ii. Remove hard contact lenses three weeks prior to baseline measurements, and have two central keratometry readings and two manifest refractions taken at least one week apart that do not differ by more than 0.50 diopters in either meridian; axes should be regular.
 - c. The spherical or cylindrical portion of manifest refractions should progress 0.50 diopter or less during the year prior to the baseline exam.
 - d. Subjects should be willing and capable of returning for follow-up examinations for the duration of the study.
 - e. Videokeratography should be normal.

DR. NEVVAS' RESPONSE:

- 8.a Having a BCVA of 20/40 or better in both eyes is consistent with the screening criteria we currently use for evaluating LASIK candidates. This inclusion criterion has been added to Protocol NEV-97-031.
- 8.b Contact lens criteria are provided in the protocol in Section VII.C, entitled "Contact Lens Wearers." The protocol specifies that soft lenses be discontinued for at least 1 day prior to examination and surgery. Gas permeable lenses and hard contact lenses should be discontinued at least 2 weeks prior to examination and surgery and remain out until the investigator has determined refractive stability.

Our usual standard is to leave soft contact lenses out for three days prior to the screening examination and prior to the surgical procedure; thus, we have revised the requirement for

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