

Panel Questions

1. Based on the data in the PMA, please discuss the potential of Restylane to induce hypersensitivity reactions.
2. 21 CFR 860.7(d)(1) states that there is a reasonable assurance that the device is safe when it can be determined that the probable benefits to health from use of the device for its intended uses, when accompanied by adequate instructions for use and warnings against unsafe use, outweigh any probable risks. Considering the data in the PMA, please comment on whether there is a reasonable assurance that the device is safe.
3. 21 CFR 860.7(e)(1) states that there is a reasonable assurance that a device is effective when it can be determined, based on valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will produce clinically significant results. Considering the data in the PMA, is there reasonable assurance that the device is effective? If you believe that there is a reasonable assurance of effectiveness, please comment on whether the data demonstrate that Restylane is superior to the control device (Zyplast) for the proposed intended use.
4. Only two African-American patients were enrolled in the Restylane clinical study (i.e., patient #s 410 and 618). Ten patients listed as “other” were enrolled and the remaining patients were Caucasian. If the device is approved, should the sponsor be required to conduct a post-approval study to collect safety data on specific minorities? Is specific labeling needed to address potential use in minorities that may be at a higher risk for adverse clinical outcome, e.g., African Americans?
5. Investigators treated 138 nasolabial folds in the study. The sponsor proposes the following indications for use “Restylane is intended for temporary correction of moderate to severe facial wrinkles and folds, such as nasolabial folds.” Please discuss the adequacy of these indications based on the fact that only nasolabial folds were treated in the PMA.