

Panel Questions  
General and Plastic Surgery Devices Panel  
November 21, 2003

1. 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.
2. 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?
3. Only three African-American patients were enrolled in the Hylaform clinical study. There were 16 Hispanic, 5 Asian and 5 "Others". 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?
4. The sponsor proposes the following indications for use "Hylaform is intended for the correction of soft tissue contour deficiencies, such as wrinkles and acne scars." Please discuss the adequacy of these indications based on the fact that only nasolabial folds were treated in the PMA.
5. As shown by Genzyme, the duration of effect of this device is short, and multiple maintenance doses will be needed to maintain the desired cosmetic effects. To assess safety of these repeated doses the sponsor has provided serum hylan B IgG levels for the repeat study population. Clinically, no significant changes in adverse events were noted in this group. Does this data support the safety of the device for repeated use, or do you believe that a post-approval study is needed to address this issue?