General and Plastic Surgery Devices Panel Meeting
August 24-25, 2006

PANEL QUESTIONS
P050052
BioForm Medical – RADIESSE for Nasolabial Folds

1. Only three African-American patients were enrolled in the Radiesse clinical study. There were 16 Hispanic, 5 Asian and 5 "Others". The sponsor has not indicated in the device labeling that there are any ethnic considerations for treatment. Do you feel that the sponsor has adequately addressed this issue by providing data on "persons of color" in the facial lipoatrophy study, along with clinical evaluations such as CD4 counts, etc.?

2. Radiesse is composed of CaHA which is visible radiographically. The sponsor was asked to provide a better understanding of how this device will look in the skin of the face and to assess the pattern of migration of any particles of Radiesse. Provided for your review were radiographs taken at several time points to assess the possibility of this device mimicking a tumor or hiding a soft tissue tumor, as well as device migration. Please comment on the adequacy of the information to assess the risks associated with this device mimicking a tumor or hiding a soft tissue tumor after injection.

3. As noted in the panel memo the mean change from baseline of the LRS for Radiesse was greater than one-point, at both 3 and 6 months, thereby meeting that requirement for superiority (mean improvement of 1.50 and 1.23 points on the LRS). The Control had no improvement at 3 and 6 months (-0.09 and -0.05, respectively). In essence, the device was superior to a control that did not show any effectiveness. Please comment on the validity of the sponsor's superiority claim for the device based on these statistical outcomes.

4. 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.

5. 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?

6. The sponsor has provided 12 month data to support the safety and effectiveness of their device. Adverse events were few and generally minor. The device itself, CaHA, is intended as a long term implant. Based on the data provided, and the length of follow-up in the clinical trial, please discuss whether a post-approval study is indicated to assess further long term safety or effectiveness issues.