Questions for Panel Discussion

The panel is being asked to address the following four topic areas related to pre-market evaluation of energy delivery devices for dermatology and aesthetic indications.

1. What would be acceptable clinical study endpoints for devices that are not intended to be therapeutic, that is, for devices intended to have indications for use such as
    a) a change in the appearance of cellulite;
    b) a temporary change in the appearance of cellulite;
    c) for body contouring;
    d) for body contouring through fat reduction.

2. For dermatologic energy delivering devices intended for aesthetic/cosmetic/non-therapeutic improvement that are low risk, is patient satisfaction alone sufficient to support marketing or should scientifically validated evaluation scales be developed possibly including masked evaluations? Should the treatment also have a clinical efficacy? For example should body contouring/reduction in abdominal fat also show an improved health outcome? If clinical outcome is necessary, what specific measures of clinical improvement would be appropriate and how large of an improvement is necessary?

3. For devices that are intended for aesthetic (temporary change in appearance) should the treatment be so well understood that the user can pre-set the amount of change that will occur? For example, if the device is intended for eye brow lift, should the amount of lift to be achieved be controlled and predictable before initiation of treatment?

4. What recommendations would you make regarding the Agency's review of those aesthetic devices that present minimal risk and appear to have little or minimal tissue effect for indications such as body contouring or reduction in fat thickness or improvement in skin appearance?