

- 18. More specific information regarding global satisfaction is necessary. In your March 5, 2004 email, you provided basic reasons for the patients who responded “no” to the global satisfaction data. Please provide more detailed reasons why patients responded “no” to the global satisfaction question, including a description of their clinical course. This is needed to provide adequate information for women who may be considering breast implants.**

18 Response:

The clinical course on the 20 patients who responded “no” to the global satisfaction questions is provided in Attachment D of this Report. Because there are no discernable trends in reasons for patient dissatisfaction, no conclusions can be drawn from these data. However, the large majority of the Core Gel patients (97%) stated that they would have the implant surgery again.