

PANEL QUESTIONS FOR P020012
ARTECOLL PMMA/COLLAGEN IMPLANT

1. The degree of nasolabial fold wrinkle severity 6 months after treatment was statistically significantly ($p < 0.001$) better for Artecoll than Control patients with a difference of 0.77 points on the FFA scale, (unadjusted results). Please discuss the effectiveness of Artecoll treatment for wrinkles in the nasolabial fold area of the face.
2. The differences in wrinkle severity at 6 months after Artecoll and Control treatments for glabellar folds (0.02 FFA points), upper lip lines (-0.14 FFA points) and mouth corners (0.17 FFA points) were not statistically significant, (unadjusted data). Please comment on the effectiveness of Artecoll concerning:
 - a. whether the proposed product indication for use (i.e., “Artecoll implant is indicated for the correction of contour deficiencies of soft tissue”) is appropriate; and
 - b. whether product approval could be considered for treatment of wrinkles solely in the nasolabial fold area of the face.
3. Comparing the types and duration of adverse events for Artecoll treated patients who were followed for 12 months to the Control group that was followed for only 6 months presents a challenge. However, considering that Artecoll benefit is related to an improvement in a patient's aesthetic appearance and that the majority of adverse events impacted the aesthetic appearance of a patient, please discuss whether the safety profile of Artecoll demonstrates an absence of unreasonable risk.
4. Do the data in P020012 demonstrate that there is reasonable assurance that in a significant portion of the target population, Artecoll for its intended uses and conditions of use will provide clinically significant results, when accompanied by adequate directions for use and warnings against unsafe use?
5. If the Panel recommends approval of the Artecoll PMMA / collagen implant, please discuss whether the conditions of approval should include a post-approval study to collect additional long term safety information. If you believe such a study is appropriate, please provide recommendations on study duration and the number of patients that should be followed.