NDA 206333, Deoxycholic acid for the improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults

Erratum to the FDA Briefing Document
Dermatologic and Ophthalmic Drugs Advisory Committee Meeting
March 9, 2015

Erratum to the FDA Background Package

Efficacy Endpoints

1. **Last paragraph on page 7:** “The patient-reported scale was in parallel with the clinician-reported scale and also ranged from 0-4 (see Appendix C and PR-SMFRS table below). The patient-reported scale included line drawings as well as verbal descriptors (see Appendix D). Copies of these instruments are appended.”

   **Correction:** The patient-reported scale was in parallel with the clinician-reported scale and also ranged from 0-4 (see Appendix C and PR-SMFRS table below). The PR-SMFRS included verbal descriptors for each severity level (see Appendix C). The PR-SMFRS did not include line drawings. As a separate secondary assessment, not part of the PR-SMFRS, patients were asked to select from among 10 shuffled line drawings the one that best matched themselves in submental fullness (see Appendix D).

Summary of Efficacy

2. **Second paragraph on page 9:** “The primary efficacy endpoints were based on the CR-SMFRS and PR-SMFRS scales. Each grade of the CR-SMFRS was accompanied by representative photographs, while each grade of the PR-SMFRS was accompanied by representative line drawings.”

   **Correction:** “The primary efficacy endpoints were based on the CR-SMFRS and PR-SMFRS scales. Each grade of the CR-SMFRS was accompanied by representative photographs; in addition to the PR-SMFRS, as a separate secondary assessment, representative line drawings were given to patients.”