

Reprocessing Statement

Aucta Pharmaceuticals, Inc. (Aucta), the ANDA applicant, is not proposing any reprocessing in the manufacture of Clobetasol Propionate Foam, 0.05%.

In case re-processing is required, certifies that it will comply with 21 CFR §211.115.

- (a) Written procedures should be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to ensure that the reprocessed batches will conform with all established standards, specifications, and characterization.
- (b) Reprocessing shall not be performed without the review and approval of the quality control unit.

Tina Lee
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by Tina Lee
Date: 2020.07.27
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Tina Lee
Executive Director, Regulatory Affairs
Aucta Pharmaceuticals, Inc.