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### Report of Telephone Conversation

**Date/Time of Call:** March 24, 2012 @ 2:41 PM EDT

**CBER Representative(s):** Richard Heath Coats, Biologist, OCBQ/DMPQ

**Organization Representative:** Kim Sullivan  
Vice President Research and Regulatory

**Organization:** SmartPractice

**Subject:** Request for SOPs regarding Purchasing Controls

**STN:** 125579

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#### **Background:**

DMPQ phoned Kim Sullivan to request recently revised and created SOPs called out in a Gap Analysis performed by the firm. These SOPs are:

- SOP #343 for Suppliers of Services
- SOP #199 for Purchasing of Raw Materials and Packaging Materials
- SOP #357 for Supplier Audits

Ms. Sullivan did not answer the phone and a voice message was left. Ms. Sullivan followed up with Elizabeth Valenti who instructed Ms. Sullivan to submit English translations of the procedures as an official amendment to BLA 125579/0.

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