



**U.S. FOOD & DRUG**  
ADMINISTRATION

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## Telecon

**Date:** March 27, 2019

**Sponsor:** Sanofi Pasteur

**File:** Original BLA STN 125682/0

**Sponsor Participant:** Patrick O'Neil

**CBER Participant:** Kirk Prutzman

### **SUMMARY OF DISCUSSION:**

Dr. Kirk Prutzman called Mr. Patrick O'Neil to discuss the revised "Request for Deferral of Pediatric Studies" that was submitted in Amendment 34 on March 25, 2019. Dr. Prutzman noted that Sanofi had included a date for submission of the final report for each of the deferred studies that was in the past. Dr. Prutzman asked Sanofi to submit a revised "Request for Deferral of Pediatric Studies" to include a date in the future for the submission of the final report for each deferred study. Mr. O'Neil agreed to submit a revised "Request for Deferral of Pediatric Studies" in an amendment to STN 125682 by March 29, 2019.