



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

## Telecon

**Date:** April 1, 2019

**Sponsor:** Sanofi Pasteur

**File:** STN 125682

**Sponsor Participants:** Patrick O'Neil, Michael Stirr

**CBER Participants:** Kirk Prutzman, Marion Gruber

### SUMMARY OF DISCUSSION:

Sanofi Pasteur (SP) requested a teleconference to discuss their decision regarding a licensure pathway for Dengvaxia. SP indicated that they understood and agreed with the concern identified by the Vaccines and Related Biological Products Advisory Committee (VRBPAC) at the March 7, 2019, meeting that the data in individuals 17 to 45 years of age living in Puerto Rico were limited. SP informed CBER that for this BLA they have decided to seek an age indication for Dengvaxia for subjects 9 through 16 years of age, and that they will not seek licensure for individuals 17 through 45 years of age at this time. CBER accepted SP's decision.

Call ended.