

# Teleconference Memorandum - July 8, 2009

DEPARTMENT OF HEALTH & HUMAN SERVICES  
FDA/CBER/OVRR/DVRPA

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## Teleconference Memorandum

**DATE:** July 8, 2009  
**TIME:** 1:35 pm, eastern standard time  
**SUBJECT:** Hiberix BLA STN 125347—Request for clarification regarding Section 6.1 of Hiberix package insert sent by Email 7/8/09  
**PRODUCT:** Hiberix  
**SPONSOR:** GlaxoSmithKline (GSK)  
**CBER Participants:** Karen Farizo  
**GSK Participants:** Elisa Harkins

CBER initiated this call to request clarification regarding Lines 93 and 94 of the Hiberix draft annotated package insert sent by GSK via Email on 7/8/09, as follows: In the package insert, GSK indicated that the number of subjects in Hiberix booster immunization studies who were primed with ActHIB was 234 and the number of subjects who were primed with PedvaxHIB was 27. CBER acknowledges that these numbers are consistent with Table 11 in the Summary of Clinical Safety (m2.7.4). However, CBER noted that for Study DTPa-HBV-IPV-035, the data in Table 11 of the Summary of Clinical Safety appear to be inconsistent with the data in Supplement 5 of the Modified Interim Report for Study DTPa-HBV-IPV-035 and in Table 2 of Addendum 1 to the study report. In the latter two tables, it appears that 26 subjects were primed with PedvaxHIB and 40 subjects were primed with ActHIB + Infanrix + Orimune. The GSK representative indicated that she would direct this question to one of GSK's clinical representatives and would provide a response by Email tomorrow. Call concluded.