

From: Hoffman, Kelsy
Sent: Tuesday, December 18, 2018 2:30 PM
To: 'Kristen.Mayer@sanofi.com' <Kristen.Mayer@sanofi.com>
Cc: Chattopadhyay, Rana <Rana.Chattopadhyay@fda.hhs.gov>; Ramachandran, Girish <Girish.Ramachandran@fda.hhs.gov>
Subject: BLA 125563/0 PI

Dear Ms. Mayer,

We are reviewing your BLA for STN 125563/0 for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine for "Active immunization against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease due to Haemophilus influenzae type b (Hib) as a three dose series in children from 6 weeks through 4 years of age (up to the 5th birthday)." We have completed our review of the attached draft package insert submitted on December 18, 2018, and have no additional edits. We accept the package insert as final draft labeling for the BLA.

We request further discussions, post-approval of VAXELIS, regarding shortening the non-proprietary name for VAXELIS and aligning the non-proprietary names of the related licensed monovalent and multivalent (e.g., Pentacel) products through labeling supplements.

Thank you,

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