

From: Krissy.Carrington@sanofi.com <Krissy.Carrington@sanofi.com>
Sent: Tuesday, July 17, 2018 9:48 AM
To: Hoffman, Kelsy <Kelsy.Hoffman@fda.hhs.gov>
Subject: RE: STN 125563/0.36 Information Request

Dear Kelsy,
Thank you for highlighting this point. I will keep you updated on the submission. Kind regards,
Krissy

From: Hoffman, Kelsy [<mailto:Kelsy.Hoffman@fda.hhs.gov>]
Sent: Tuesday, July 17, 2018 9:37 AM
To: Carrington, Krissy /CA
Subject: [EXTERNAL] RE: STN 125563/0.36 Information Request

Dear Ms. Carrington,

Also, please note that copies of all cartons and containers for the vaccine (with currently proposed proprietary name) will need to be submitted to the BLA for review as well.

Sincerely,
Kelsy

Kelsy F. Hoffman, Ph.D.
LCDR, USPHS
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
Kelsy.Hoffman@fda.hhs.gov



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From: Hoffman, Kelsy
Sent: Monday, July 16, 2018 6:21 PM
To: 'Krissy.Carrington@sanofi.com' <Krissy.Carrington@sanofi.com>
Subject: STN 125563/0.36 Information Request

Dear Ms. Carrington,

We have received your June 29, 2018, submission to BLA 125563/0 “Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine” which contained your response to our complete response letter dated November 2, 2015. We have the following comments:

1. As indicated in the letter dated July 2, 2018, under IND 14496, please submit a Proprietary Name Review (PNR) request to the BLA 125563/0 in order to change the proprietary name from (b) (4) to Vaxelis.
2. Please submit an updated Package Insert (PI) to include the newly proposed proprietary name, Vaxelis, in the place of the previously proposed proprietary name, (b) (4)
3. Please revise Section 8, Special Populations, as prescribed by Pregnancy, Lactation, and Reproductive Potential: Labeling for Human Prescription Drug and Biological Product — Content and Format Guidance for Industry [<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425398.pdf>] and Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling- Final rule [<https://www.federalregister.gov/documents/2014/12/04/2014-28241/content-and-format-of-labeling-for-human-prescription-drug-and-biological-products-requirements-for>] to include all required elements and language.

Please let me know if you have any questions.

Sincerely,
Kelsy

Kelsy F. Hoffman, Ph.D.
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Office of Vaccines Research and Review
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