Approval Date: December 19, 2019

Product: PENTACEL

Proper Name: Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine

Manufacturer: Sanofi Pasteur Limited

Indication: Active immunization against diphtheria, tetanus, pertussis, poliomyelitis and invasive disease due to Haemophilus influenzae type b.

Description: Pentacel consists of a Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus (DTaP-IPV) component and an ActHIB® component combined through reconstitution for intramuscular injection

BLA: 125145

Regulatory Milestone:

On September 21, 2010, Sanofi submitted an Investigational New Drug Application (IND), 14496, for conducting Phase 3 development of the PR5I vaccine in the U.S. On August 13, 2014, MCM submitted a Biologics License Application (BLA) for PR5I to CBER, FDA which was assigned the STN 125563. The proprietary name of the vaccine at the time of the BLA submission was proposed as On February 14, 2018 Sanofi submitted a request to IND 14496 for withdrawing that proprietary name of the vaccine and on February 16, 2018, submitted a Proprietary Name Review (PNR) request to the same IND for changing the name of the product from to VAXELIS.

CBER provisionally accepted VAXELIS as the proprietary name of the vaccine on June 19, 2018. MCM submitted a PNR request to the BLA on August 27, 2018.

CBER issued a two-item CR letter on November 01, 2015, which contained comments on (1) OOS pertactin (PRN) potency assay data for multiple manufactured lots of VAXELIS and (2) proposed use of expired lot of PRP-OMPC as a reference standard. MCM submitted a response to the CR letter on June 29, 2018 addressing both of the issues cited in the CR Letter. This submission initiated a new 6-month review clock with a Resubmission Action Due date of December 29, 2018.

PDUFA Goal Date: July 30, 2012

Package Insert: Package Insert - Pentacel

Summary Basis for Regulatory Approval: July 19, 2012 Summary Basis for Regulatory Action - PENTACEL

European Public Assessment Report: No data

Advisory Committee:

There were no issues in this supplement that required input from an Advisory Committee.

Safety: Not applicable.

NCT Numbers:

- NCT00772928
- NCT01659996
- NCT01129362
- NCT00804284
- NCT00802867
- NCT00258895
- NCT01000974
- NCT00772369
- NCT00390130
- NCT00255047
- NCT00662870
- NCT00855855
- NCT01049035
- NCT02096263
- NCT03893448
- NCT01340937

- NCT00551915
- NCT00475033
- NCT00310856
- NCT00729001
- NCT01346293
- NCT03620162
- NCT01000311
- NCT01337167
- NCT00467519
- NCT00362427

EudraCT Numbers:

- 2013-004304-19
- 2015-003500-23
- 2015-005589-43
- 2008-004765-26
- 2014-005061-72
- 2011-004095-10
- 2013-004194-27
- 2011-004108-39

Publications:

- Dhillon, S., & Keam, S. J. (2008). DTaP-IPV/Hib vaccine (Pentacel). *Paediatric drugs*, *10*(6), 405–416. https://doi.org/10.2165/0148581-200810060-00008
- Guerra, F. A., Blatter, M. M., Greenberg, D. P., Pichichero, M., Noriega, F. R., & Pentacel Study Group (2009). Safety and immunogenicity of a pentavalent vaccine compared with separate administration of licensed equivalent vaccines in US infants and toddlers and persistence of antibodies before a preschool booster dose: a randomized, clinical trial. *Pediatrics*, *123*(1), 301–312. https://doi.org/10.1542/peds.2007-3317
- Johns, T. L., & Hutter, G. E. (2010). New combination vaccines: DTaP-IPV (Kinrix) and DTaP-IPV/Hib (Pentacel). *The Annals of pharmacotherapy*, *44*(3), 515–523. https://doi.org/10.1345/aph.1M468
- Behzad, B., Jacobson, S. H., Jokela, J. A., & Sewell, E. C. (2014). The relationship between pediatric combination vaccines and market effects. *American journal of public health*, *104*(6), 998–1004. https://doi.org/10.2105/AJPH.2013.301780
- Gold, R., Barreto, L., Ferro, S., Thippawong, J., Guasparini, R., Meekison, W., Russell, M., Mills, E., Harrison, D., & Lavigne, P. (2007). Safety and immunogenicity of a fully liquid vaccine containing five-component pertussis-diphtheria-tetanus-inactivated poliomyelitis-Haemophilus influenzae type b conjugate vaccines administered at two, four, six and 18 months of age. *The Canadian journal of infectious diseases & medical microbiology = Journal canadien des maladies infectieuses et de la microbiologie medicale*, *18*(4), 241–248. https://doi.org/10.1155/2007/289842
- Pollard A. J. (2007). New combination vaccines still need a boost. *Archives of disease in childhood*, *92*(1), 1–2. https://doi.org/10.1136/adc.2006.106724