



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

**DATE:** November 7, 2018

**TO:** File: STN BL 125563/30

**FROM:** Tod Merkel, PhD, CMC Reviewer, Chair  
Microbiologist  
LRSP/DBPAP/OVRR/CBER

**THROUGH:** Michael Schmitt, PhD, Lab Chief  
LRSP/DBPAP/OVRR/CBER

**PRODUCT:** Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine  
Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate  
[Meningococcal Protein Conjugate] and Hepatitis B [Recombinant]  
vaccine (DTaP-IPV-Hib-HepB/PR5I).

**SUBJECT:** CMC Review

**APPLICANT:** MCM Vaccine Company

**Background:**

MCM Vaccine Company filed this amendment to register the following modifications to the (b) (4) process for Pertactin (PRN) performed as part of the manufacturing of 5-Component Acellular Pertussis Adsorbed ((b) (4) ) to improve (b) (4)

[REDACTED]

[REDACTED]

[REDACTED]


PR5I is a hexavalent combination vaccine being co-developed by Sanofi Pasteur and Merck Sharp and Dohme Corp., a subsidiary of Merck & Co., Inc. [Merck]. MCM Vaccine Co., was created to manufacture and license this vaccine. PR5I is manufactured using modified and/or existing bulk intermediates from vaccines licensed in the US by Sanofi Pasteur and Merck. The pertussis antigens are provided by Sanofi-Pasteur. The seed culture, fermentation, purification, detoxification and storage of the pertussis adsorbed antigens used in the PR5I vaccine are the same as that for the already licensed Sanofi-Pasteur pertussis-component containing vaccines DAPTACEL®, Adacel®, and Pentacel® with the exception that (b) (4)

[REDACTED]

In the manufacture of pertussis-component containing combination vaccines, Sanofi-Pasteur (b) (4)

[REDACTED]

(b) (4)



**Review and Recommendation:**

On 20 February 2013, Sanofi Pasteur Ltd. submitted a Trans-BLA CBE-30 supplement for STN BL:103666/5315 (DAPTACEL®), STN BL:125145/269 (Pentacel®) and STN BL:125111/497 (Adacel®) to register the two modifications to the (b) (4) process for Pertactin (PRN) antigen. This trans-BLA supplement was approved on 05 December 2014 and implemented for the US-licensed vaccines DAPTACEL®, Adacel®, and Pentacel®. Because these changes to the manufacturing process of adsorbed PRN bulk were reviewed and approved and demonstrated to have no impact on the quality of the adsorbed PRN bulk antigen, it is acceptable for use in the formulation of PR5I. I recommend approval of this supplement.