



Our STN: BL 125563/0

MAJOR AMENDMENT ACKNOWLEDGEMENT

MCM Vaccine Company
Attention: Krissy Carrington
Sanofi Pasteur, Inc.
Discovery drive
Swiftwater, PA 18370-0187

Dear Ms. Carrington:

We received your June 25, 2015, amendment to your biologics license application (BLA) submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine on June 25, 2015.

We consider your submission a major amendment under the reauthorization of the prescription drug user fee program in the *Food and Drug Administration Safety and Innovation Act* of 2012 and will add an additional three months to the time by which we should complete our review. Therefore, the action due date is November 11, 2015.

We will contact you regarding your proposed labeling no later than October 12, 2015. If post marketing study commitments (506B) are required, we will contact you no later than October 12, 2015.

If you have any questions regarding the above, please contact the Regulatory Project Managers, Kelsy Hoffman, Ph.D. or Katie Rivers, M.S., at 301-796-2640.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research