



**BLA EXCLUSIVITY
INFORMATION REQUEST**

Our STN: BL **125563/0**

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

Dear Ms. Carrington:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (PHS Act) for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine.

We also refer to your August 12, 2014, request regarding exclusivity. In order to assist FDA in evaluating the date of first licensure as described in section 351(k)(7)(C) of the PHS Act for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine, FDA suggests that you provide the following information:

1. A list of all licensed biological products that are structurally related to the biological product that is the subject of the 351(a) application being considered. This list should include products that share some of the same principal molecular structural features of the biological product being considered, but generally can be limited to products that affect the same molecular target. Products that target different epitopes of the same molecular target should be included. Where specific molecular targets have not been defined, this list should include products that share the narrowest target that can be characterized. This may be a pathway, cell type, tissue, or organ system. If your assessment results in the conclusion that no products that have the same molecular target or share some of the same principal molecular structural features have been licensed, please provide an adequate justification to support the assertion that there are no previously licensed products that are relevant for purposes of determining the date of first licensure.
2. Of those licensed biological products identified in item 1 above, please identify the products for which you or one of your affiliates, including any licensors, predecessors in interest, successors in interest, or related entities are the current or previous license holder.

3. Description of the structural differences between the biological product being considered and any products identified in item 2 above. For protein products, this should include, but is not limited to, changes in amino acid sequence, differences due to post-translational events, infidelity of translation or transcription, differences in glycosylation patterns or tertiary structure, and differences in biological activities.
4. Evidence of the change in safety, purity, and/or potency between the biological product being considered and any products identified in item 2 above. This should include, but is not limited to, a description of how the structural differences identified in item 3 above relate to changes in safety, purity, and/or potency.

Any other information and data that would assist FDA in making a determination regarding the date of first licensure for Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, Inactivated Poliovirus, Haemophilus b Conjugate [Meningococcal Protein Conjugate] and Hepatitis B [Recombinant] Vaccine should also be included.

We request a prompt written response to the items enumerated above.

If you have any questions, please contact the Regulatory Project Manager, Katie Rivers, MS, 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