Application Type	Clinical Efficacy Supplement
STN	125549/17
CBER Received Date	27 March 2015
PDUFA Goal Date	25 April 2016
Division / Office	Division of Vaccines and Related Product Applications (DVRPA) Office of Vaccines Research and Review (OVRR)
Committee Chair	Michael Smith, Ph.D.
Clinical Reviewer(s)	Lucia Lee, MD
Project Manager	Theodore Garnett, Ph.D., Ramachandra Naik, Ph.D. Tina S. Roecklein
Priority Review	N/A
Reviewer Name	Lihan Yan, Ph.D.
Supervisory Concurrence	Dale Horne, Dr. P.H., Branch Chief, VEB
Applicant	Wyeth Pharmaceutical Inc.
Established Name	Trumenba®
(Proposed) Trade Name	*Neisseria meningitidis* Serogroup B bivalent rLP2086 vaccine
Pharmacologic Class	Meningococcal serogroup B Vaccine
Formulation(s), including Adjuvants, etc	Sterile liquid suspension of 60 µg of subfamily A and 60 µg of subfamily B rLP2086 (120 µg total protein) per 0.5 mL dose
Dosage Form(s) and Route(s) of Administration	0.5 mL single-dose pre-filled syringes with 60 µg of subfamily A and 60 µg of subfamily B rLP2086 (120 µg total protein) per 0.5 mL dose, to be injected intramuscularly
Dosing Regimen	✓ 3-dose schedule (0, 1-2, and 6 months): 2 doses administered at least 1 month apart followed by a third dose given at least 4 months after the second dose. ✓ 2-dose schedule (0 and 6 months)
Indication(s) and Intended Population(s)	For active immunization to prevent invasive meningococcal disease caused by N. *meningitidis* serogroup B in individuals aged 10 through 25 years.

Addendum Summary

This is an addendum to the statistical review of STN 125549/17 by Dr. Barbara Krasnicka dated November 20, 2015. Dr. Krasnicka retired in November 2015 and is not able to revise her review. Therefore, this addendum is to address a change in terminology for two Trumenba® dosing schedules referred to in Dr. Krasnicka's review as originally proposed by the applicant.

The following revisions of the terminology for the dosing regimens were decided and finalized since Dr. Krasnicka's review:

- 3-dose schedule (0, 1-2, and 6 months): referred to as the "accelerated" dosing schedule in the sBLA and Dr. Krasnicka's review

- 2-dose schedule (0 and 6 months): referred to as the "standard" dosing schedule in the sBLA and Dr. Krasnicka's review.

These revisions were made upon consideration that both schedules reflect 6-month intervals and therefore were not appropriately referred to as "accelerated" or "standard." Thus, in order to be consistent with the current characterization of the schedules, all references to "accelerated" and "standard" schedules in Dr. Krasnicka's review should be replaced with "3-dose" and "2-dose" schedules, respectively.