

The lots below are associated with this Supplement.

| STN Number | Supplement Number | License Number | Product   | Lot Type | Lot Number | Sample Received Date |
|------------|-------------------|----------------|---|----------|------------|----------------------|
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | B        |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |
| 125363     | 0                 | 1617           | Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine | FC       |            |                      |

The requested sample testing is not complete at this time for lot numbers ---b(4)-----

Protocols for these lots have not yet been submitted to the PRB.

If you need more information please contact me.

**Since lots are associated with this supplement please be sure to provide a copy of the signed approval to the Product Release Branch by fax to 301.594.6924 or e-mail the letter to CBER Lot Clearance.**

Jacqueline Glen  
Consumer Safety Officer  
PRB/DMPQ/OCBQ/CBER/FDA  
301 827 0848  
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**From:** Staten, David  
**Sent:** Wednesday, May 09, 2012 2:23 PM  
**To:** CBER Lot Clearance  
**Cc:** Temenak, Joseph; Prutzman, Kirk C  
**Subject:** OVRP Lot Clearance request STN 125363/0

Two lots were submitted on December 21, 2011 (---b(4)-----). At the time of approval there will not be any launch lots. The sponsor estimates that the launch lots and reagents will available toward the end of July.

Please confirm that there are no lots associated with this Supplement.

**STN:** 125363/0

**Lic. #:** 1617

**Company/Address:**

GlaxoSmithKline Biologicals, S. A. d/b/a GlaxoSmithKline  
Rue de l'Institut 89  
B-1330 Rixensart  
BELGIUM

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**Product:** meningococcal and Hib TT conjugate vaccine

**Subm Type:** BLA

**First Action Due Date:** June 1, 2012

**Short Summary:**

active immunization of infants and toddlers 6 weeks through 15 months of age for the prevention of invasive diseases caused by Haemophilus influenzae type b and Neisseria meningitidis serogroups C and Y

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