

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		

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
301 594 6924 fax
Jacqueline.Glen@fda.hhs.gov

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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 be 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

----b(4)-----

--b(4)-----

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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