

Results Memo, April 25, 2012 - MenHibrix

To STN# 125363; MENHIBRIX File
From Dr. James L. Kenney, HFM-682
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Through: Dr. William McCormick, HFM-680
Director, Division of Biological Standards and Quality Control
CC: Joseph Temenak, HFM-481 Chair, BLA Review Committee
Subject: Endotoxin and Sterility Test results on Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine, Product Lot Numbers: -----
------(b)(4)-----.

GlaxoSmithKline Biologicals submitted three lots of Meningococcal Groups C and Y and Haemophilus b Tetanus Toxoid Conjugate Vaccine (MENHIBRIX). These lots were tested for sterility and endotoxin in the Division of Biological Standards and Quality Control's Laboratory of Microbiology, *In-vivo* Testing and Standards at CBER and the results are as follows:

Product	Lot Number	Endotoxin Test Results*	Sterility Test Results
MENHIBRIX	---(b)(4)--- ---	------(b)(4)----- ---	Passed
MENHIBRIX	---(b)(4)--- ---	------(b)(4)----- ---	Passed
MENHIBRIX	---(b)(4)--- ---	------(b)(4)----- ---	Passed

* Endotoxin Lot-release specifications are ---(b)(4)--- one dose is -(b)(4)-- mL after reconstitution.