

Microbiological Review Memo, December 19, 2013-Q-Pan

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Division of Biological Standards & Quality Control, Office of Compliance & Biologics
Quality,
Center for Biologics Evaluation & Research, Food & Drug Administration, 1401
Rockville Pike, Rockville, MD 20852

19 December 2013

To Administrative File for STN 125419

From Dr. James L. Kenney,
Laboratory of Microbiology, *In-Vivo* Testing and Standards
DBSQC/OCBQ/CBER/FDA

Through Dr. William M. McCormick,
Director, Division of Biological Standards and Quality Control (DBSQC)
OCBQ/CBER/FDA

Subject Original Biological License Application (BLA): Influenza A (H5N1) Virus
Monovalent Vaccine (Q-Pan H5N1): Review of Microbiological Test Methods.

Conclusion

Based on the review of the information submitted in support of this Biological License Application (BLA) for GlaxoSmithKline Biologicals' (GSK's) microbiological testing methods, to include amendments 125419.9, 125419.12 and 125419.14, I recommend approval of GSK's:

- -----(b)(4)----- bacterial endotoxin test method performed on their H5N1 Antigen final container (FC) product;
- -----(b)(4)----- bacterial endotoxin test method performed on their AS03 Adjuvant FC product;
- ----(b)(4)----- method performed as an in-process monitoring test on their AS03 Adjuvant;
- sterility by ----(b)(4)----- test method performed on both their H5N1 Antigen and AS03 Adjuvant FC products; and

(b)(4)

Bioburden Assay

GSK performed a (b)(4) bioburden assay to quantify enumeration of mesophilic bacteria and fungi, which may grow under aerobic conditions in their (b)(4). To qualify the AS03 Adjuvant matrix for the bioburden assay, (b)(4) batches (i.e., (b)(4)) were used for Bacteriostasis and Fungistasis (B&F) testing.

(b)(4)

(b)(4)

(b)(4)

- sterility test by -----(b)(4)----- is suitable for testing GSK's H5N1 Antigen and AS03 Adjuvant FC products; and the
- antimicrobial effectiveness test results indicate the 5 µg thimerosal per 0.5 mL dose of Q-Pan H5N1 vaccine is adequate to inhibit the growth of microorganisms that may be introduced inadvertently while repeatedly withdrawing individual doses from a 10 dose vial.