

Department of Health and Human Services  
Public Health Service  
Food and Drug Administration  
Center for Biologics Evaluation and Research

Memorandum

Date: June 18, 2007

To: STN BL125259.0

From: Rebecca Olin, CBER/OCBQ/DMPQ/MRBII *Rebecca Olin*

REVIEWED  
By Rebecca Olin at 11:39 am, Jun 21, 2007

Subject: Memo of Telecon

APPROVED

By Helen Sudran, Consultant at 2:28 pm, Mar 11, 2008

Attendees

CBER

Chiang Syn, PhD  
Rebecca Olin

GSK

Linda S. Kramer, US Regulatory Affairs Assistant Director  
Teresa Ward, US Regulatory Affairs Director  
Weining Hu, US Regulatory Affairs CMC Assistant Director  
Donna Boyce, US Regulatory Affairs, Executive Director (Kinrix File)  
Johann Deman, Rixensart, for Cervarix file

On Monday, June 18, 2007, at 10am, a telecon was held with the above named people regarding the removal of filling line (b)(4) for Cervarix and other products currently under review at CBER/DMPQ. The (b)(4) line will be used as a dedicated filling line for non-US licensed products.

On Friday, June 15, 2007, Linda Kramer submitted a fax containing information regarding the consistency lots for Cervarix and Kinrix. The tables identified the lot numbers, presentation, filling facility and filling line for each product. The fax is attached to this memo. One of the (b)(4) lots submitted in support of the Cervarix file was filled on (b)(4), Lot (b)(4). Please note the filling line identified as (b)(4) is located (b)(4).

(b)(4) lots of Cervarix were produced in support of the Cervarix BLA (STN 125259.0). Each lot was filled on (b)(4) different filling lines; (b)(4) pre-filled syringe lines and (b)(4) vial lines. The (b)(4) lots of Kinrix manufactured in support of BLA 125260 were filled on (b)(4) different filling lines, (b)(4) syringe lines and (b)(4) vial lines.

The June 18, 2007 telecon concerned the issue of using the data from the lots of Cervarix and Kinrix filled on (b)(4). One lot of each product was filled on this line. The other outstanding file for Rotovirus is not affected by this change.

Although one lot of Kinrix was filled on (b)(4), the removal of the line was identified in the BLA file therefore no other action is required for this file.

GSK would like to use the data from the lot of Cervarix filled on (b)(4) in support of the process validation for the product.

Dr. Syin replied that we would discuss this with Laurie Norwood and the Product Office and Rebecca Olin would contact them with the decision.