

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

Memorandum

Date: June 14, 2007

To: STN BL125259.0

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

REVIEWED
By Rebecca Olin at 11:22 am, Jun 21, 2007

Subject: Memo of Telecon

APPROVED

By Helen Sullivan Gemignani at 8:40 pm, Mar 11, 2008

Attendees

CBER

Chiang Syin, PhD
Rebecca Olin

GSK

Linda S. Kramer, Manager, US Regulatory Affairs

This telecon occurred on Thursday June 14, 2007, at 10am EST, with representatives from CBER and GSK/US.

The issue being discussed regards the use of filling line (b)(4) located in Rixensart. On June 13, 2007, GSK notified FDA that vial filling line (b)(4) would no longer be used for filling US licensed products. Affected licensed products include Engerix (Hepatitis B Vaccine-Recombinant), HAVRIX (Hepatitis A Vaccine, Inactivated), Infanrix (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine, Adsorbed), Twinrix (Hepatitis A Inactivated and Hepatitis B-recombinant Vaccine), and Pediarix (DTaP, adsorbed, Hepatitis B, recombinant and Inactivated Poliovirus Vaccine Combined).

Dr. Chiang Syin and CSO Rebecca Olin telephoned Linda Kramer on June 14, 2007 to discuss the discontinuation of (b)(4) as it relates to the Cervarix file (STN 125259.0) as well as any other open file currently being reviewed.

During this call we asked the following:

1. Was Cervarix filled on any other filling line in addition to (b)(4)?
2. Are there any other open submissions affected by the closing of (b)(4)?

3. Are the products listed in the June 13, 2007 letter approved for filling on other filling lines?

Preliminary answers:

1. Cervarix is filled on [REDACTED]
2. Other open submissions include Rotavirus and perhaps Kinrix.
3. The currently licensed products are all approved to be filled on additional lines.

To ensure accurate and complete information, Ms. Kramer suggested we have a telecon at a later date to discuss these issues. To accommodate everyone's schedule, plans were made to conduct the telecon at 10am on Monday, June 18, 2007.