

CBER Question on Kit Carton Email, May 4, 2012 - MenHibrix

From: Norris Pyle [mailto:norris.h.pyle@gsk.com]

Sent: Friday, May 04, 2012 9:46 AM

To: Staten, David

Cc: Temenak, Joseph; Prutzman, Kirk C; Jody Gould

Subject: Hiberix/MenHibrix: CBER Question on Kit Carton

Hi David,

In the teleconference yesterday, you asked for a written explanation on how the kit lot number and expiration date were assigned for MenHibrix and Hiberix.

The Kit carton (or combo box) will have an expiration date that is the earliest between the diluent and the vaccine.

The lot number used on the kit carton will be a unique lot number – see example below.

The kit carton is imprinted with all labeling except the lot and expiry dating. The lot number and expiry dating are printed on an auxiliary label which is applied to the kit carton and remains intact for the life of the kit (is not destroyed by opening the kit box).

The kitting process for both Hiberix and MenHibrix takes place in –b(4)--- on a semi-automatic packaging line which does not have imprinting capabilities.

Please let me know if you have any additional questions. Thank you - Norris

We will use a specific batch number for each combination antigen/diluent

Example

Final container antigen batch number (not printed)	Diluent batch number	Combo batch number (would be printed on both antigen and combo boxes)
---b(4)----	---b(4)----	---b(4)----
---b(4)----	---b(4)----	---b(4)----
---b(4)----	---b(4)----	---b(4)----