

Clarification Request Email, May 15, 2012 - MenHibrix

- **From:** Norris Pyle [mailto:norris.h.pyle@gsk.com]
Sent: Tuesday, May 15, 2012 12:57 PM
To: Temenak, Joseph
Cc: Staten, David; Prutzman, Kirk C; Roecklein, Tina; Jody Gould
Subject: RE: follow up questions...

Hi Joe,

I expect to be able to provide GSK's minutes from the meeting yesterday by early tomorrow. Regarding the auxiliary label information, here is a cut/paste from the draft minutes in the interest of time.

1. **CBER had questions on the demonstration labels that were sent by GSK's Norris Pyle to CBER's David Staten, Kirk Prutzman and Joseph Temenak on May 10, 2012. There was some confusion as CBER stated that the vaccine labels had two lot numbers. CBER asked for re-confirmation that the auxiliary label (that incorporates lot number and expiry dating for combo box) can't be moved so that it is not used as a tamper-evident seal. CBER also asked as to how vaccine vials are received by ----(b)(4)---- from Belgium.**
 - a. The pdf of the demonstration labels sent on May 10, 2012 do have just one lot number for the vaccine vial label, vaccine carton label, and the auxiliary label (Lot ----(b)(4)-----). Note that the expiration dating on the auxiliary label is the shortest dating between the diluent and the vaccine.
 - b. As mentioned in the above referenced email, the auxiliary label could not be moved so as not to be performing the function of a tamper-evident seal without delays beyond June 1, 2012 (physical location of labelling would need to be changed to accommodate a space). Exact timing for this is currently being determined.
 - c. The vaccine vials that come from -----(b)(4)----- are received in ---(b)(4)-- - as unlabeled vials. ---(b)(4)--- performs all labelling and packaging for the vaccine.

For question below on the procedure for labeling vaccine vials with kitted lot numbers, the table below gives an example as to how the combo batch numbers are assigned. The first column is the actual vaccine lot number from manufacturing which is not printed on the labeling. The combo batch number is assigned through SAP (controlled database). Are you looking for an actual SOP or procedure for how the combo batch number is taken from SAP and transferred to the labeling/package batch record, or is this information sufficient?

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)
AHCYA009A	----- (b)(4) -----	----- (b)(4) -----

AHCYA009A	-----(b)(4)-----	-----(b)(4)-----
AHCYA009B	-----(b)(4)-----	-----(b)(4)-----

- Please let me know if you need additional information. Thank you - Norris

From: Temenak, Joseph [mailto:Joseph.Temenak@fda.hhs.gov]

Sent: Tuesday, May 15, 2012 11:47 AM

To: Jody Gould; Norris Pyle

Cc: Staten, David; Prutzman, Kirk C; Roecklein, Tina

Subject: follow up questions...

Norris,

On our telecon yesterday, Tina asked you the following questions:

- Where are the vials labeled?
- What is the procedure for labeling vaccine vials with kitted lot numbers?

Also, I went back to your May 10 email with the 'demo' labels. I made a mistake in what I said yesterday regarding the vaccine vial, carton, and combo labels; you did have the same lot number(s) consistently for each of those. I must have written it wrongly when I went though it earlier. Also, it appears that the expiration dating is correct as well: the vaccine vial and carton is XX/XX/2015, expiration for the diluent vial and carton is XX/XX/2013, and the expiration dating for the outer/kit carton is the lesser of the 2 (XX/XX/2013).

Please answer Tina's questions as quickly/best s you can.

Thanks,

joe

From: Jody Gould [mailto:jody.a.gould@gsk.com]

Sent: Tuesday, May 15, 2012 11:34 AM

To: Temenak, Joseph

Cc: Staten, David; Prutzman, Kirk C; Norris Pyle

Subject: RE: Question or comment from yesterday...?

Importance: High

Hi, Joe –

Can Norris and I give you a call?

Thanks,

Jody

From: Temenak, Joseph [mailto:Joseph.Temenak@fda.hhs.gov]

Sent: Tuesday, May 15, 2012 11:29 AM

To: Norris Pyle

Cc: Jody Gould; Staten, David; Prutzman, Kirk C

Subject: Question or comment from yesterday...?

Hi Norris,

We spoke briefly yesterday on the phone, but I had to end our call somewhat abruptly. I was waiting to speak to Marion Gruber, OVRD director.

Can you please email me with the question/comment you had?

Thanks,
Joe

p.s. Please let us know when you think we'll receive your promised submission for tomorrow (Wed., May 16), i.e., what time of day? that will help us be on the lookout for it.