

From: Coats, Richard Heath
Sent: Friday, April 22, 2016 4:00 PM
To: 'sullivan@smarthealth.com'; 'kp@smartpractice.dk'
Subject: RE: Additional Information request regarding Rubber Panel T.R.U.E. Test

Dear Kim,

I forgot to add a follow up question from a previous information request on December 11, 2015.

Pages 24 and 25 of the executed batch record appear to document reconciliation of used foil and calculation of yield. The written notes are barely legible, however it appears a 97% deviation is noted for the pouches when the limit is specified as (b) (4). It also appears that of the (b) (4) pouches manufactured, (b) (4) of the pouches were rejected, (b) (4) were sampled, (b) (4) pouches were considered the yield, and the total number of pouches produced was below the specified mean. Please elaborate on the following items:

- a. Please confirm a pouch at this step contains a test strip
- b. Calculations regarding the deviation of the number of pouches manufactured and whether 'Double pouches – empty' are retained or discarded
- c. Any investigations performed assessing the documented low yield

Please provide an explanation of why (b) (4) pouches rejected is acceptable.

Regards,
Heath

From: Coats, Richard Heath
Sent: Friday, April 22, 2016 7:47 AM
To: 'sullivan@smarthealth.com'; 'kp@smartpractice.dk'
Subject: Information request regarding Rubber Panel T.R.U.E. Test

Dear Kim,

I am sending this email as a follow up to our conversation yesterday regarding additional information needed to complete my review for the Rubber Panel T.R.U.E. Test application. I have also included the email address for your colleague in Denmark.

Please provide the following information regarding the polyester (b) (4) used as backing for the allergen gel (b) (4):

- The material specification (b) (4) for the polyester (b) (4)
- A description of the process of receiving shipments of polyester (b) (4). Please include any inspections or testing performed and the frequency of these tests during the receipt, inspection, and release of material for use in commercial manufacturing
- Please describe the vendor qualification process for the vendor(s) of the polyester (b) (4). Please include what periodic reassessment or requalification of the vendor(s) is planned.

As we discussed yesterday, time is of the essence in getting responses to these requests. I understand that a holiday in Denmark will delay the response of your colleagues until next week. I appreciate your assistance in providing this information.

Regards,

Heath

Richard Heath Coats
Biologist



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