

(System Info - 204509 VALENTI ELIZABETH 07/03/2012 14:26:09 VALENTI)

RECORD OF EMAIL CONVERSATION

Submission Type: BLA Submission ID: 103738/5031 Office: OVRR

Product:

[Multiple Products: Allergen Patch Test Kit]

Applicant:

Mekos Laboratories AS

Telecon Date/Time: 03-Jul-2012 02:22 PM Initiated by FDA? No

Telephone Number:

Communication Category(ies):

1. Advice

Author: ELIZABETH VALENTI

Telecon Summary:

Submit one lot in full printed foils and two lots in plain foils for testing.

FDA Participants: E. Valenti

Non-FDA Participants: K. Sullivan

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Valenti, Elizabeth

Sent: Tuesday, July 03, 2012 2:22 PM

To: 'Kim Sullivan'

Cc: Valenti, Elizabeth

Subject: RE: Incomplete Response, STN 103738/5031

Dear Kim,

Yes, you may submit one lot in full printed foils and two lots in plain foils.

Betsy

From: Kim Sullivan [mailto:sullivan@smarthealth.com]

Sent: Friday, June 29, 2012 2:42 PM

To: Valenti, Elizabeth

Cc: Kirsten Paulsen; kirsten.moesgaard@mekos.dk
Subject: Re: Incomplete Response, STN 103738/5031

Hello Betsy,

Regarding the Rubber Panel Submission- when the time is appropriate for us to submit the 3 batches, will it be acceptable that we submit 2 batches for support analysis in plain foil and the 3rd lot in full printed foil as the first commercial batch as we did for the last TT approval?

Thanks, once again, for your advice,
Kim