

(System Info - 202324 VALENTI ELIZABETH 06/11/2012 11:50:29 VALENTI)

RECORD OF EMAIL CONVERSATION

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

Product:

[Multiple Products: Allergen Patch Test Kit]

Applicant:

Mekos Laboratories AS

Telecon Date/Time: 11-Jun-2012 11:36 AM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):

1. Advice

Author: ELIZABETH VALENTI

Telecon Summary:

103738/5031.5005 is an Incomplete Response, additional advice and requests for future resubmission.

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: Monday, June 11, 2012 11:36 AM

To: 'Kim Sullivan'

Cc: Valenti, Elizabeth

Subject: Incomplete Response, STN 103738/5031

Dear Kim

We are unable to consider your May 10, 2012, amendment to STN 103738/5031 as a Complete Response (CR) because your three production lots are not available. In our February 12, 2007, CR Letter we asked that you submit three lots of product in your proposed final container configuration and analytical standard raw materials in support of this supplement for lot release testing. In your Complete Response submission you stated that your three production lots will not be available until October 2012.

Please submit an amendment to STN 103738/5031 to withdraw your May 10, 2012, submission.

Please resubmit a Complete Response when your three production lots are available. However, please do not submit the three lots for testing with your Complete Response. Please wait until we request the lots and provide specific information regarding how to submit them.

In addition, we have the following comments that should be addressed prior to your resubmission:

1. Please submit an updated draft Lot Release Protocol (LRP), which should be modeled on your T.R.U.E. TEST LRP. Please advise if your lots in support of this supplement are for exhibit or launch. Please clarify the number of lots in support for exhibit or launch.
2. Please submit a revision to your draft labeling so that "T.R.U.E. TEST" and "Rubber Panel" are not separated by white space or text, as is on your proposed carton labeling.
3. Please submit a revision to your draft labeling to include the NDC. Please see 21 CFR 207.35 to establish your NDC.
4. Please submit your draft package insert in SPL format.
5. We note that your proposed draft labeling is for patients 18 years of age and older. We note that a pediatric study was conducted in children six through 17 years of age, which included the allergens on your T.R.U.E. TEST Rubber Panel.

We suggest that you submit a PREA waiver request for use in children less than six years of age. Please submit the waiver request and a justification that the product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients **and** is unlikely to be used in a substantial number of pediatric patients in this age group.

We suggest that you seek an indication for the T.R.U.E. TEST Rubber Panel in patients six years of age and older. Please submit your pediatric effectiveness and safety data for this population. Please include the pediatric effectiveness and safety data and study summary in your draft package insert in a similar presentation to that of your adult data. Please do not combine the adult and pediatric data within the package insert.

Please see the draft Guidance for Industry How to Comply with the Pediatric Research Equity Act (<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077855.pdf>) for more information.

6. Please submit a list of active and inactive ingredients and corresponding UNII codes.
7. As previously advised, you may submit for a company name change to the Office of Compliance and Biologics Quality (OCBQ). It must be approved prior to use. Once approved, you have 180 days to update all labeling with the change. Please see the Guidance for Industry Changes to an Approved Application: Biological Products (<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM170166.pdf>) for more information.

Please let me know if you have any questions, Betsy

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