

(System Info - 204646 VALENTI ELIZABETH 07/06/2012 12:54:05 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: 06-Jul-2012 12:00 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s):

1. Advice

Author: ELIZABETH VALENTI

Telecon Summary:

Name change, NDCs, license number

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: Friday, July 06, 2012 12:00 PM

To: 'Kim Sullivan'

Cc: Valenti, Elizabeth

Subject: Name Change, NDCs, and License Number

Dear Kim,

My responses to your questions are imbedded in your email below.

Your NDCs will not change due to a name change. You will need to send in an updated NDC Labeler Code Request with the newly approved name. This is a separate activity from the name change request and approval and it should not be requested before your new name is approved by CBER.

For additional information regarding the name change, please refer to SOPP 8403:
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073468.htm>

For additional information regarding SPL, please see:
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>
or email cberspl@fda.hhs.gov

For additional information regarding Registration and Listing, please see:
<http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234625.htm>

For additional information regarding your DUNS, please see:
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm307027.htm>
and
<http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162544.htm>

Please let me know if you have additional questions, Betsy

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From: Kim Sullivan [mailto:sullivan@smarthealth.com]
Sent: Tuesday, July 03, 2012 10:54 AM
To: Valenti, Elizabeth
Subject: Re: Questions related to upcoming submissions for TRUE Test

Thanks Betsy!

All of these are original allergens under IND 2466.

Additionally we have questions about the proper procedures for the following. I have tried to contact other individuals in the registration and compliance divisions, but was unable to find someone to provide answers. I am sorry to trouble you with this but we are struggling to put these actions in the proper sequence so as not to complicate matters.

This communication is intended to seek guidance regarding the timing of the following submissions and activities:

- 1) Name Change from Mekos Laboratories AS to SmartPractice Denmark.
 - a) What form(s) is required to submit the name change? 356h and a General Correspondence Cover Letter? A PAS? I read the *Guidance for Industry- Changes to an Approved Application: Biological Products* that you forwarded to me, but the practical matter of sequence of submissions and proper form is not detailed. Please see SOPP 8403 VII B 1 f.
 - b) Will we need a new DUN # for the new name? Please follow-up with D&B.
 - c) It is my understanding that we will be assigned a new license number-correct? Whether a new license number will be assigned it to the discretion of the team

reviewing your proposed name change. It is likely that you will receive a new license number; however, you will be advised at the time of approval.

- d) Will we need to reapply for a new NDC? No, your NDCs will not change.
- e) We will need to receive the new license number and new NDC before we can submit the updated labelling-correct? You will receive your new license number, if necessary, at the time of the name change approval. Your NDCs will not change. For draft labeling in regard to your license number for the name change, please see SOPP 8403 VII 3. For draft labeling in regard sBLAs (i.e. 103738/5031), please use your current license number, NDCs, and create new NDCs as necessary.

2) Rubber Panel

a) May we apply for the NDC for this product under the new name SmartPractice Denmark before we receive official approval? No. Once the name change is approved you have 180 days implement the change. The name change cannot be proposed with the Complete Response for the Rubber Panel. It must be a separate submission. You should generate your NDCs for the Rubber Panel based upon the labeler codes you have already been assigned.

b) What license number should we use or must we wait for the assignment of the new one? Please use your existing license number until you are notified that it has changed.

c) We need the Name, License # and DUN to apply for the new NDC for the Rubber Panel and will also need these to submit the UNII codes electronically. Please create your NDCs for the Rubber Panel based on your current labeler codes. Please use your current name and license number until any changes have been approved.

d) We will need all of this before we can submit the labeling electronically. Draft labeling should be submitted to this file electronically in Word and SPL for review (on CD). Until the Rubber Panel is approved, it does not need to be submitted electronically for Registration and Listing.

If there is someone at the Agency you recommend to help with these questions, please let me know.

Many Thanks,
Kim

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Kim M. Sullivan
SmartPractice
(602) 225-9090 X7274

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