

(System Info - 238876 VALENTI ELIZABETH 06/07/2013 15:52:50 VALENTI)

RECORD OF TELEPHONE CONVERSATION

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

Product:

[Multiple Products: Allergen Patch Test Kit]

Applicant:

SmartPractice Denmark ApS

Telecon Date/Time: 07-Jun-2013 02:10 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Other -

Author: ELIZABETH VALENTI

Telecon Summary:

Sponsor informed of the conversion to BLA, request to propose new proprietary name.

FDA Participants: E. Valenti

Non-FDA Participants: K. Sullivan

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

LCDR Valenti called Ms. Kim Sullivan to inform her of future changes to STN 103738/5031, SmartPractice's Rubber Panel. LCDR Valenti asked and Ms. Sullivan confirmed that the Rubber Panel will be sold and marketed separately from the existing T.R.U.E. TEST product under STN 103738. LCDR Valenti explained that much has changed since this Prior Approval Supplement (PAS) was issued a Complete Response (CR) Letter in 2007, including the implementation of FDAAA, recent and pending T.R.U.E. TEST CMC changes, and the company name change from Mekos Laboratories AS to SmartPractice Denmark ApS.

LCDR Valenti explained that it is difficult to track two products under one parent STN, especially two products with different package inserts (PI). LCDR Valenti advised Ms. Sullivan that; therefore, upon receipt of SmartPractice's response to CBER's Complete Response, we will convert the Rubber Panel PAS to a new BLA. Ms. Sullivan agreed and stated that having the Rubber Panel under a separate parent STN will ease confusion. With recent CMC PAS submissions she has been concerned with ensuring changes to the

T.R.U.E. TEST panels are accurately reported, the PI properly updated, etc., and noting whether these changes are necessary and applicable to the Rubber Panel. In addition, Ms. Sullivan believes having separate parent STNs will alleviate confusion for future products such as a Metal or Nickel Patch. Ms. Sullivan expressed her appreciation that we did not request that she withdraw the PAS and resubmit it as a new BLA.

LCDR Valenti also explained that we would like SmartPractice to propose a new proprietary name for the Rubber Panel in the response to our CR Letter. LCDR Valenti stated that SmartPractice was welcome to propose any new name; however, she explained that CBER will not accept a name that leads with "T.R.U.E. TEST." Ms. Sullivan clarified and LCDR Valenti concurred that "T.R.U.E. TEST" may be acceptable as part of the proprietary name; however, it cannot be the first two words of the name. LCDR Valenti also reiterated that SmartPractice was welcome to submit a proprietary name review (PNR) for an entirely new name if she desired. Ms. Sullivan stated that T.R.U.E. TEST was part of the company's identity so it was likely to remain; however, she understood that it cannot lead in the proprietary name. Ms. Sullivan expressed her appreciation that we did not request a new name for the existing T.R.U.E. TEST panels.

LCDR Valenti requested a timeframe for SmartPractice's response to our CR Letter. Ms. Sullivan stated she was leaving the following day to work with her colleagues in Denmark. She will brief her colleagues and gather information regarding the response to CBER's CR Letter. She asked if a brief telecon was possible next week to clarify questions from her colleagues in Denmark regarding the BLA conversion. LCDR Valenti stated she was available to answer follow-up questions or have a brief telecon.

The telecon ended at 2:10pm EDT.