

RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125579/0.0
Review Office	OVRR
Applicant	Smart Practice Denmark ApS
Product	Rubber Panel T.R.U.E. TEST
Trans-BLA Group:	No

Telecon Details

Telecon Date/Time	August 10, 2017
Author	Khurana, Taruna
EDR	No
Post to Web	Yes
Outside Phone Number	NA
FDA Originated?	Yes
Communication Categories	Other (labeled storage conditions)
Related STNs	None
Related PMCs	None
Telecon Summary	Storage condition for Rubber Panel T.R.U.E. TEST
FDA Participants	Taruna Khurana, Jennifer Bridgewater, Elizabeth Valenti, Jay Slater
Applicant Participants	Kim Sullivan, Michael Nielsen, Kirsten Paulsen

Telecon Body:

SmartPractice (the Applicant) originally proposed to label their Rubber Panel product as follows: “Store Rubber Panel T.R.U.E. TEST (b) (4) 25°C (77°F). Do not freeze.” In April, 2016 CBER requested that the Applicant update their package insert as follows: “Store Rubber Panel T.R.U.E. TEST between 20°–25°C (68°–77 °F). Do not freeze.” This teleconference was held to determine the appropriate labeled storage temperature for

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the Rubber Panel product. SmartPractice proposed an alternate storage temperature of (b) (4) - 25 °C. CBER informed the Applicant that the proposed storage condition of (b) (4) -25°C for the Rubber Panel T.R.U.E. TEST product was not acceptable based on available stability data. CBER asked the Applicant if stability data was available for (b) (4) °C. The Applicant indicated that data is available only for the (b) (4) °C range, but not for the Rubber Panel T.R.U.E. TEST. Stability studies for the Rubber Panel product were performed only at 25°C (b) (4) relative humidity. The Applicant asked if the (b) (4) guidelines suggesting storage of (b) (4) 25°C would apply. CBER replied that (b) (4) guidelines were not applicable to their product. The Applicant stated that they plan to store and ship Rubber Panel T.R.U.E TEST (b) (4). CBER stated that this proposal would be acceptable to the Agency if the Applicant can generate data for the proposed storage and shipping conditions. However, the current data was not supportive of these conditions. SmartPractice asked the Agency if the (b) (4)

(b) (4)

Stability data in this configuration is required for storage and expiry of the Rubber Panel. The Applicant stated that they might have stability data for the Rubber Panel at (b) (4) °C but at different time points. CBER stated that the Applicant can submit these data. The data will be reviewed for acceptability and CBER will consider the proposal. No further discussion occurred and the call ended.