

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
Division of Vaccines and Related Products Application
Bacterial Vaccines and Allergenic Products Branch, HFM-481

TELEPHONE CONVERSATION RECORD

DATE: March 14, 2007

CBER REPS. Jennifer Ross, PhD

SPONSOR REP.(S): Kim Sullivan
ORGANIZATION: Vice President Regulatory-Mekos
Laboratories/Smart Practice/Smart
Health

TELEPHONE NO.: 602-225-0595 x 274

SUBJECT: STN 103738.5031
(panel of rubber patches)

TO: file

K.Sullivan phoned J.Ross.

Mekos requested clarification on whether they could submit stability data from Panel 2, which contains the rubber allergen patches in the Rubber Panel, to establish expiry dating in support of the approval of this supplement. CBER stated "no". CBER recommends that Mekos submit exposed expiry dating and data to support the dating. Stability data of the actual product and configuration for approval need to be submitted. Mekos may use data from Panel 2 to propose that a shorter real time stability data with the Rubber Panel, such as maybe 3 months, would support the proposed expiry dating period of Rubber Panel.