

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 12, 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

J.Ross called K.Sullivan and left a voice message in response to questions raised on 3/9/07 by Mekos.

What stability data is required based on item #3 in CR letter of 2/12/07 to the supplement? In previous discussions with Mekos on May 15, 2003 regarding germalls patches, CBER indicated that 12 months of stability data would be considered to support 24 months of expiry dating. In a meeting between CBER and Mekos on 5-2-06, CBER stated that CBER noted that stability studies conducted on Panel 3.1 with patches in the final configuration are likely to be required prior to licensure each time a new allergen is added to the Panel. Mekos may submit a request for exemption from complete stability studies, including information on accumulated experience demonstrating the absence of interactions effecting stability among patches. CBER suggests that Mekos submit a proposed amount of stability data to support a requested expiry dating period. J. Slater provided the same advice to C. Hamann 3/9/07.

Can Mekos send samples in support of the supplement that are not in the foil pouch?

CBER stated that this question may not be an issue since Mekos has not made lots and will be conducting a stability study.

CBER recommends that the sponsor choose one representative to interact with one representative of CBER, which would be J.Ross rather than J.Slater. Generally we find communication works better this way than multiple people talking back and forth in parallel. Please call J.Ross with additional questions.