

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: January 11, 2007

CBER REPS. Jennifer Ross

SPONSOR REP.(S): Jim Kenimer, PhD

ORGANIZATION: The Biologics Consulting Group LLC
US Agent for Mekos Laboratories AS

TELEPHONE NO.: 703-739-5695

SUBJECT: STN 103738.5031
(panel of rubber patches)

TO: file

I spoke with Dr. Kenimer to let him know that the due date for this supplement is 2/14/07 and that, as with germalls and corticosteroid supplements, we will need 3 lots in support and to know how Mekos intends to comply with PREA.