

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 22, 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)
STN 103738.5032
(OOS supplement, Microbial Limits Test)
STN 103738.5027

TO: file

J. Ross called J. Kenimer on 1/22/07

1. PREA protocol can be sent to IND 2466
2. For Rubber Panel supplement 5031, it is adequate to use PREA study with parent TRUE Test and 5 new patches. A separate PREA study just with Rubber Panel is not required. Request same waiver and deferral of pediatric studies in age groups as proposed for 5019 and 5027.
3. We recommend withdrawal of supplement 5032, OOS. This is not appropriate as a supplement - the firm needs to handle it through their QA process. The firm has a confirmed OOS for their microbial limits test, their laboratory investigation was inconclusive and the root cause of the OOS could not be identified. There is nothing in the supplement that would allow us to approve it. Mekos cannot release the product for market.

J. Kenimer emailed J. Ross 1/22/07 asking for an update on lots of Panel 3 held up by (b)(4) at Kennedy airport. J. Ross left a message for J. Kenimer that CBER did not have any new information and (b)(4) tracking information shows that the lots are still in NY. J. Kenimer was given the tracking number so that he could also follow the shipment using the (b)(4) website.

J. Kenimer left a message for J. Ross 1/22/07 with concern that submitting an outline for a PREA study, but not a detailed protocol, to IND 2466 would result in the study being placed on clinical hold. J. Ross left a message for J. Kenimer that Mekos could either wait until they had a detailed protocol to submit or include a statement in the cover letter that Mekos commits to hold off starting the study until a detailed protocol is submitted and reviewed.