

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 9, 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 103738.5027, 5019, and 5031

TO: file

Entered in BIRAMS under IND 2466

J. Ross left a voice message for K. Sullivan to follow-up on conversation on 3/5/07. During the conversation, Mekos proposed eliminating the pregnancy test for ages 12, 13, 14. In follow-up email the same day from K. Sullivan, they propose eliminating the pregnancy test for ages 12, 13, 14, and 15 to help ensure adequate enrollment. CBER agreed. Please send a revised study protocol to IND 2466.

Mekos requested an update on pending supplements during the 3/5/07 telecon also.

5019--germalls and quinoline is coming due June 5, 2007.

This would be the latest date for CBER to take action.

5027--coming due Aug. 10, 2007.

Lots in support of these supplements were received and Mekos will be notified if there are any problems in testing.

5031--a CR letter was sent 2/12/07. CBER received via Jim Kenimer (previous US Agent for Mekos) a letter indicating intent to respond to the CR letter. That is all that has been sent thus far.

3/9/07, K. Sullivan called J.Ross regarding the following:

1. Mekos does not have stability data in the final configuration for the rubber panel. Mekos is unsure how to respond to item #3 in CR letter of 2/12/07. K. Sullivan proposed revising the rubber panel to have patches in configuration that they are in panel 2 so that Mekos would not need to submit stability data. J. Ross will get back to K. Sullivan.
2. K. Sullivan would like to request a Type A meeting and asked where to send the meeting request. Please fax meeting request to J. Ross and send hard copies to the appropriate file.
3. K. Sullivan switched from (b) (4) for shipment of samples from Denmark. She would like to send a "trial run" of samples not to be thrown out. J. Ross indicated that CBER cannot just throw out samples. They would be logged and normal administrative processes would occur. Even if one shipment was sent successfully, it would not assure that future shipments would be either, given changing import and homeland security measures. CBER does not tell sponsors they cannot send samples, but does not recommend trial runs either.
4. Mekos would like to send lots in support of the rubber panel supplement this April. Can Mekos send samples without foil pouches? We do not encourage shipments of anything except the marketable form, but if the form is that of the previous samples for 5019/5027 then this is likely fine. J. Ross will check and respond back to Mekos.

J. Ross noted that as the supplement action dates approach, the package inserts may need minor adjusting on tight deadlines, depending on which supplements are approved/not approved at a specific time.