

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 19, 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 103738.5019 and 5027 (germalls and
quinoline, corticosteroids)
STN 103738.5032
(OOS supplement, Microbial Limits Test)

TO: file

On 1/17/07 J.Ross called J. Kenimer to ask whether the 1/10/07 submission STN 103738/5027.5004 was meant to be a complete response or just a notice of intent to respond to CBER's CR letter. CBER views this as an intent-to-respond notice. It would be a partial or incomplete response because PREA protocols have not been submitted in enough detail yet to IND 2466 and lots are not at CBER yet. J. Kenimer would talk with Mekos.

I notified Dr. Kenimer that I left a message with (b) (4) about Mekos lots in support of 5019 and 5027 held at Kennedy Airport and will follow-up.

J. Kenimer left a message for J.Ross on 1/18/07.

1. Response STN 103738.5027.5004 was an intent to respond only.

2. Where/what file should Mekos send protocol for PREA study to satisfy supplements 5019/5027 and 5031?
3. Mekos can supply 2 lots of Rubber Panel quickly, but there will be a delay if 3 lots are necessary. If there is any way 2 lots would be adequate, then let us know.
4. Regarding the OOS supplement 5032, please note that the dating period expires before or close to time that the supplement would be coming due. If the supplement could be reviewed sooner, that would be nice.

Responses by J. Ross to J. Kenimer on 1/19/07

1. Agreed.
2. Please submit proposed protocol to comply with PREA for 5019 and 5027 to IND 2466. CBER will discuss with J. Kenimer at a later time how to comply with PREA for Rubber Panel supplement 5031.
3. 3 lots are required in support of supplement 5031 for Rubber Panel. Therefore, supplement will get a CR letter, due on Feb. 14, 2007. Letter will have a comment regarding PREA too.
4. Thanks for notifying CBER of the issue with the due date of supplement 5032 and expiry date of lots. I will notify reviewers.
5. OCBQ coordinated with FDA district office in Jamaica, NY on the lots for 5019 and 5027 that were held at Kennedy Airport. At this point CBER has done what we can and we do not know whether the lots in support of 5019 and 5027 will clear customs or not. The lots may be sent back to Mekos. Mekos sent these lots to me, instead of to the CBER sample custodian. They will send to sample custodian in the future.

The following were emails from Mekos staff about the lots in question:

From: Ross, Jennifer
Sent: Thursday, January 18, 2007 10:25 AM
To: 'Marianne Andersen'; Michael Nielsen; kim.sullivan@allerderm.com; Bridgewater, Jennifer
Subject: RE: Mekos Laboratories

We are aware of the problem and will be trying to do what we can. We will be in touch with Jim Kenimer once we know any outcome.
Jennifer

Jennifer Ross, Ph.D.
Biologist
FDA/CBER

OVRD/DVRPA
tel: 301-827-3070

From: Marianne Andersen [mailto:marianne.andersen@mekos.dk]
Sent: Thursday, January 18, 2007 10:05 AM
To: Michael Nielsen; kim.sullivan@allerderm.com; Bridgewater, Jennifer; Ross, Jennifer
Subject: FW: Mekos Laboratories, TRUE Test Panel 3, additional samples, Ref. no. BL 103-738-5019

From: Marianne Andersen
Sent: 18. januar 2007 16:00
To: Michael Nielsen; 'kim.sullivan@allerderm.com'; 'jennifer.bridgewater@fda.hss.gov'; 'jennifer.ross@fda.hss.gov'
Subject: FW: Mekos Laboratories, TRUE Test Panel 3, additional samples, Ref. no. BL 103-738-5019

Dear all

Could any of you try to contact (b) (4) in US, as you probably know (see (b) (4)) the second shipment for the extra 20 pcs. panel 3 is on hold in customs clearance. I hope that it's only a little explanation of the product.

(b) (4) 4799219961

Look forward to hear good news.

Best regards & have a nice day

Marianne Andersen

Mekos Laboratories ApS

Tel : +45 48 20 71 11

Personal E-Mail : marianne.andersen@mekos.dk

Fax : +45 48 20 71 01

From: Kirsten Paulsen
Sent: 16. januar 2007 10:29
To: Ross, Jennifer
Cc: Bridgewater, Jennifer; (kim.sullivan@allerderm.com); Michael Nielsen
Subject: Mekos Laboratories, TRUE Test Panel 3, additional samples, Ref. no. BL 103-738-5019

Jennifer Ross,

Additional 20 pcs. TRUE Test samples were shipped yesterday on (b) (4) 479 9219 961 with expected delivery on Wednesday (01-17-2007). The lot No. is (b) (4).

Best Regards
Kirsten Paulsen

J. Kenimer called J. Ross on 1/19/07 to double check that IND 2466 was the appropriate IND for submission of PREA protocol. That IND is for parent TRUE Test development, but it may be easier for CBER to have one IND, then to open a new IND each time a patch is added to the kit and PREA needs to be satisfied. J. Ross will double-check with CBER management that using IND 2466 is appropriate.