

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: 2/14/07 TIME: 2:30 pm

CBER REPS. Jennifer Ross, PhD

ORGANIZATION REP.(S): Jim Kenimer, PhD
The Biologics Consulting Group Ltd
(US Agent for Mekos)

ORGANIZATION: Mekos Laboratories, AS

TELEPHONE NO.: (703) 739-5695

SUBJECT: STN 103738/5031
Proposed T.R.U.E. Test Rubber Panel

TO: file

In response to email below from Dr. Rodgers and voice message on the same date, Dr. Ross spoke with Dr. Kenimer. A CR letter has been signed for the supplement. Therefore, there is no rush to submit the revised package insert. The CR letter contains more items than just a request for revised labeling; items that have been discussed with Dr. Kenimer many times previous in connection with supplements 5019 and 5027 (for example, lots in support). In addition, it would be an unusual course of business to alert the Agency on the due date for a supplement that additional materials for review were coming that may necessitate the rewriting and sign-off of a CR or approval letter. Dr. Kenimer would communicate the information to Dr. Rodgers, as Dr. Rodgers has not been listed as a representative on the file and the Agency is unfamiliar with her involvement in the file.

From: Pamela Rodgers [mailto:parodger@smarthealth.com]
Sent: Wednesday, February 14, 2007 2:15 PM
To: Ross, Jennifer
Cc: Kim Sullivan
Subject: RE: Revised package insert per comments on STN 103738/5031

Dear Jennifer,

Per CBER's response letter of January 18, 2007, we would like to submit the revised package insert for the T.R.U.E. TEST Rubber Panel (BLA 1623; Manufacturer- Mekos Laboratories, Denmark) for review and per CBER's action date of February 14, 2007.

Jim Kenimer, Biologics Consulting Group, has indicated that due to the severe winter weather, it will not be possible to submit a hard copy to your office today.

Therefore, we would like to submit the revised document with all requested changes, and a completed Form 2567 via email today. Jim Kenimer indicated that we should contact you prior to emailing these documents.

We hope that you are able to respond, and that we can proceed with the submission via email, which can be supported by hard copy delivered via FedEx tomorrow.

Regards,
Pamela Rodgers, Ph.D.
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