

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 12, 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 left a message for Dr. Kenimer in response to his email copied below.

1. I fixed the address in the system and let those involved know to send things to the new address, so hopefully this fixes the ongoing problem.
2. Supplements will be processed no matter who they are addressed to. I'm not aware of the specific reason that Dr. Baylor is listed in the acknowledgement letters rather than a division director.
3. The PREA proposal sent 12/22/06 to file 103738/5019 (germall) is generally acceptable with regard to ages for waiver and deferral. We will look at clinical protocol to be submitted in March. Mekos is likely to send same proposal to all supplements, and that is acceptable/desirable.

From: Jim Kenimer [mailto:jkenimer@bcg-usa.com]
Sent: Thursday, January 11, 2007 1:05 PM
To: Ross, Jennifer
Subject: Mekos

Jennifer,
We received a supplement receipt letter today for 103738/5032 addressed to our old mailing address. Is it possible for you to change our address in the system?

Also, I note that the letter requested that all future correspondence for this supplement should be addressed to Norman. Does all correspondence go the Office Director now (we've been addressing most things to the Division Directors) or does it really matter?
Also I left a message asking about the review process for the PREA waiver request that was submitted by Mekos for one of the other supplements. What's the review timeframe on that?

Jim

James G. Kenimer, Ph.D.
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