



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Our STN: BL 103738/5031

Mekos Laboratories AS
Attention: Bo Poulsen
Herredsvejen 2
3400 Hillerod
DENMARK

FEB 12 2007

Dear Mr. Poulsen:

This letter is in regard to your supplement to your biologics license application for a new panel, T.R.U.E. Test Rubber Panel, containing five rubber related allergen patches (Carba Mix, Black Rubber Mix, Mercaptobenzothiazole, Mercapto Mix, and Thiuram Mix) plus a negative control to be manufactured at your Hillerod, Denmark location submitted under section 351 of the Public Health Service Act.

We have completed the review of all submissions made relating to this BLA supplement. In our review, we find that the information and data submitted are inadequate for final approval action based on the deficiencies outlined below.

1. We request that you propose a postmarketing study to obtain additional information on the safety and effectiveness of patches to be contained in T.R.U.E. Test Rubber Panel. This study is needed for compliance with the Pediatric Research Equity Act of 2003. Please include in your response the following:
 - A detailed protocol or, at a minimum, a detailed outline describing all design features of each study including sample size and justification, eligibility criteria with rationale, dosing regimens and duration, clinical assessments to be performed and their timing, and endpoints to be analyzed.
 - A proposed schedule for conducting the study, including all major milestones for the study, e.g. submission of finalized protocol to us, initiation of study, completion of patient accrual, completion of the study, and submission of the final study report, SAS datasets and applicable revised labeling to us.

Please submit a complete protocol for review and comment to your IND 2466. You may cross-reference the IND in your response to this letter.

2. Please submit three lots of product in your proposed final container configuration and analytical standard raw materials in support of this supplement for lot release testing.

3. We acknowledge your commitment in your August 14, 2006, response to our June 30, 2006, Complete Response letter to perform stability studies through 24 months on the first three commercial batches. You state in your response that “[t]he rubber panel has not yet been produced.” We understand that you have acquired stability data on the component rubber patches in configurations other than those proposed in this supplement and that these data may provide supportive information regarding expiration dating. However, we reiterate that final expiration dating will be based upon real-time stability data of the rubber panel in the final product configuration. Please acknowledge.

We reserve comment on the final proposed labeling until the supplement is otherwise acceptable.

Within 10 days after the date of this letter, you should take one of the following actions: (1) amend the supplement; (2) notify us of your intent to file an amendment; (3) withdraw the supplement; or (4) request a hearing on the grounds for denying approval of the supplement.

We stopped the review clock with the issuance of this letter. We will reset and start the review clock when we receive your complete response.

If you have any questions, please contact the Regulatory Project Manager, Dr. Jennifer Ross, at (301) 827-3070.

Sincerely yours,

/s/

Richard I. Walker, Ph.D.
Director
Division of Bacterial, Parasitic
and Allergenic Products
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

cc: James Kenimer, Ph.D.
The Biologics Consulting Group, LLC