



Date: July 28, 2009

To: The File

From: Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review
Point of Contact: LCDR Elizabeth J. Valenti, REHS
Regulatory Project Manager

Subject: Teleconference Memo

STN: 103738/5031
Product: Multiple Products: Allergen Patch Test Kit
Sponsor: Mekos Laboratories AS
Summary: Stability Questions for Rubber Test Patch

CBER/FDA Attendees

LCDR Elizabeth Valenti, REHS, Regulatory Project Manager, DVRPA/OVRR

Mekos/SmartHealth Attendees

Kim Sullivan, SmartHealth, Inc., Vice President, Regulatory, Mekos Laboratories ApS, U.S. Agent

June 26, 2009

Ms. Sullivan called LCDR Valenti to inquire about stability data of the rubber test patch. Ms. Sullivan stated that Mekos had discussions with Drs. Slater and Ross a few years ago regarding the stability data needed for the rubber patch. CBER then requested 24-months of stability data. Ms. Sullivan stated that Mekos is proposing (b)(4) of stability data and a PMC for the remainder of the 24-months.

Mekos contends that they have valid stability data on the allergens (on Test Patch 2.1) and that the configuration of the allergens on a panel (the rubber only panel in this supplement) does not alter the stability. Also, Mekos has (b) (4) of stability data for the rubber allergen test patch product. The product is in the same foil and on the same tape as their other products; however it is not imprinted with the logo. In the past Dr. Ross raised some concern that it was not exactly like their other products.

Ms. Sullivan wanted to know the best way to proceed. LCDR Valenti stated that she would contact the review team for advice and respond to Ms. Sullivan and Mekos' request.

July 29, 2009

LCDR Valenti called Ms. Sullivan to inform her that Mekos should submit a proposed expiration period based upon the amount of stability data on this specific product. CBER will not accept stability data from another test patch that contains these allergens (i.e. T.R.U.E. Test Patch 2.1). Ms. Sullivan asked if CBER would accept a 24-month expiration date based upon (b) (4) of stability data and LCDR Valenti replied that a 24-month expiration period was not feasible based upon only (b) (4) of data. Ms. Sullivan stated that she would speak with Mekos and inform them that the expiry period must be in closer proximity to the stability data.