

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE February 18, 2016

FROM Colonious King, Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 240-402-8759 Fax: 301-595-1304

THROUGH Patricia Holobaugh, Chief, Bioresearch Monitoring Branch

THROUGH Gilliam Conley, Director, Division of Inspections and Surveillance

TO Elizabeth J. Valenti Chair, Review Committee
Christina Houck RPM
Joohee Lee Clinical Reviewer

SUBJECT Bioresearch Monitoring Discipline Review Memo
BLA/STN: 125579/0
IND: 2466
Sponsor: SmartPractice
Product: Thin-layer Rapid Use Epicutaneous (T.R.U.E.) Test Panels 1.1,
2.1, and 3.1

FINAL SUMMARY STATEMENT:

The Bioresearch Monitoring clinical investigator inspection did not reveal problems that impact the data submitted in this Biologics Licensing Application (BLA).

BACKGROUND

A clinical investigator was inspected in support of the BLA and was conducted in accordance with FDA's Compliance Program Guidance Manual (CPGM) 7348.811, Inspection Program for Clinical Investigators. The inspection assignment included specific questions related to the study protocols and verification of the study data on safety and efficacy endpoints submitted by the sponsor in the BLA. The completed inspection conducted for data verification represented the only pediatric study for the BLA application. The data audit portion of the inspection focused on the verification of the study data on safety and efficacy endpoints for the rubber panel T.R.U.E. Test submitted by the sponsor in the BLA for 65% of the enrollees at site 01.

PROTOCOL AUDITED

Clinical evaluation of T.R.U.E. TEST[®] panel 1.1, 2.1 and 3.1 in children and adolescents. (Protocol Mekos 07 29P1/2/3 401)

The table below summarizes the inspection results:

Site Number	Study Site	Location	Enrolled Subjects	483 Issued	Classification
01	Rady Children’s Hospital	San Diego, CA	102	Yes	VAI

VAI = Volunteer Action Indicated

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when s/he disclosed information about her/his financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children including if and when the information was updated. The inspected study site did not have a copy of the financial disclosure forms on hand for the clinical investigator and sub-investigators. A copy of the financial disclosure form was submitted with the submission.

INSPECTIONAL FINDINGS

Sponsor/Monitor Issues

There were no sponsor/monitor issues identified at the study site audited.

Clinical Investigator (CI) Study Site Issues

Study Site 01: The FDA investigator noted a few minor problems during the inspection. A review was conducted of testing records, regulatory binders, study specific standard operating procedures, and general study conduct. The investigational product accountability was not documented and accountability records were not maintained during the study of investigational products. There were no records for storage conditions and temperature monitoring log of investigational products. In addition, source documents were reviewed and the information was compared to the data tables submitted by the sponsor in the application. No discrepancy was found between source documents at the site and the data submitted by the sponsor in the application.

BIMO ADMINISTRATIVE FOLLOW-UP

An information letter will be issued for the study site inspected.

Please contact me should you have any questions about this memo or any aspect of Bioresearch Monitoring.

Colonious King
Consumer Safety Officer

Distribution

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EDR	STN 125579/0
Elizabeth J. Valenti	Chair
Christina Houck	RPM
Joohee Lee	Clinical Reviewer
Linda Thai	FDA Investigator

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