

Bioresearch Monitoring Midcycle Review Memo, April 19, 2011 - EVARREST

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

DATE: April 19, 2011

FROM: Dennis T. Cato, Bioresearch Monitoring, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

Telephone: 301-827-2588 Fax: 301-827-6748

THROUGH: Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

SUBJECT: Bioresearch Monitoring Midcycle Review Memo

BLA/STN: 125392/0

Sponsor: Omrix Biopharmaceuticals, Ltd.

Product: Fibrin Pad

TO: Sonday Kelly HFM-380
Natalya Ananyeva HFM-392
Kimberly Lindsey HFM-392

BIMO issued inspection assignments for three Clinical Investigators at the following study sites:

Site Number	Study Site	Location	Number of Subjects	Form FDA 483 Issued
Site 011	R. Adams Cowley Shock Trauma Center	Baltimore, MD	18	Yes
Site 014	Medical College of Georgia, Section of Urology	Augusta, Georgia	28	No
Site 022	University of Alabama, Division of Cardiothoracic Surgery	Birmingham, Alabama	32	Yes

All three of the above inspection assignments have been completed. Two of the three Establishment Inspection Reports (EIRs) are pending receipt and review. We will update the review committee with the pending results as soon as they are available.

Dennis T. Cato
Consumer Safety Officer

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HFM-380 Sondag Kelly

HFM-392 Natalya Ananyeva

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