DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration

Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

MEMORANDUM

DATE December 8, 2011

FROM Janet White, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

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

TO Mark Lee, HFM-715, Chair, BLA Committee
Terrolyn Thomas, HFM-700, RPM, BLA Committee

SUBJECT Bioresearch Monitoring Inspection Results
BLA STN: 125400/0
Sponsor: Organogenesis, Inc.
Product: Apligraf (Oral), Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen

SUMMARY STATEMENT

The bioresearch monitoring (BIMO) inspections of three clinical investigator sites did not reveal problems that impact the data submitted in the Biologics Licensing Application (BLA).

BACKGROUND

Three clinical investigator inspections were performed in support of this BLA. The pivotal study protocol, study subject enrollment, clinical investigators not previously inspected, and number of serious adverse events were among the factors used to select the inspected sites. The inspections focused on specific questions concerning the study protocol and the comparison of information from the BLA to source documents.

Study Site	**Site #**	**Location**	**Number Of Subjects Enrolled**	**Form FDA 483 Issued**	**Inspection Final Classification**
Perio Health Professionals	010	Houston, Texas	34	No	NAI
University of Michigan School of Dentistry	016	Ann Arbor, Michigan	29	No	NAI
Boston Periodontics & Dental Implants	017	Boston, Massachusetts	30	NO	NAI

STUDY TITLE

Protocol 06-PER-002-CTX: *A Clinical Trial to Evaluate CelTx (Apligraf®) as an Alternative to Tissue from the Palate to Enhance Oral Soft Tissue Regeneration and Wound Healing*

FINANCIAL DISCLOSURE

The Clinical Investigator Compliance Program directs the FDA investigator to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any subinvestigators, spouse(s) and dependent children, and if and when the information was updated. The information submitted to the BLA was verified for the clinical investigator at each of the three sites.

SPONSOR/MONITOR ISSUES

No sponsor or monitoring issues were noted.

NOTEWORTHY INSPECTINAL FINDINGS

The inspections at the three sites revealed no deviations from applicable regulations.

BIMO ADMINISTRATIVE FOLLOW-UP

We issued letters to the clinical investigators at the three sites. Please contact me at (301) 827-6336 if you have any questions about this memorandum or any aspect of Bioresearch Monitoring.

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Janet K. White
Consumer Safety Officer