DATE: December 18, 2020

FROM: Haecin Chun, M.S., Bioresearch Monitoring Branch
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

THROUGH: Dennis Cato, Branch Chief, Bioresearch Monitoring Branch

THROUGH: Carrie Mampilly, M.P.H., Director, Division of Inspections and Surveillance

TO: Steven Bauer, Ph.D., Chair
Rosa Sherafat-Kazemzadeh, M.D., Clinical Reviewer
Candace Jarvis, RPM

SUBJECT: Bioresearch Monitoring Final Review Memo
SPONSOR: Stratatech Corporation
PRODUCT: StrataGraft skin tissue [Allogeneic Keratinocyte Cell Line (NIKS), Seeded on Rat Collagen ((b) (4)) Conditioned with Human Dermal Fibroblasts ((b) (4))]
BLA: STN 125730/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were conducted for the sponsor of this original Biologics License Application (BLA) and five clinical study sites that participated in the conduct of studies, STRATA 2011 or STRATA 2016. The inspections did not reveal substantive issues that impact the data submitted in the BLA.

BACKGROUND

A sponsor inspection was conducted in accordance with FDA's Compliance Program (CP) 7348.810, Inspection Program for Sponsors, Contract Research Organizations and Monitors. The inspection assignment included specific questions concerning the information submitted in this BLA.

Additionally, a total of five BIMO clinical investigator inspection assignments were issued to evaluate the study conduct of the two protocols.

Protocol STRATA2011, "*Open-label, controlled, randomized, multicenter, dose escalation study evaluating the safety and efficacy of StrataGraft® skin tissue in promoting the healing of the deep partial-thickness component of complex skin defects as an alternative to autografting*," was a multi-center study conducted at a total of six (6) clinical study sites in the United States. A total of 30 subjects received the investigational StrataGraft skin tissue.

Protocol STRATA2016, "*A Phase III Open-Label, Controlled, Randomized, Multicenter Study Evaluating the Efficacy and Safety of StrataGraft Skin Tissue in Promoting Autologous Skin Tissue Regeneration of Complex Skin Defects Due To Thermal Burns That Contain Intact Dermal Elements and For Which Excision and Autografts Are Clinically Indicated*," was a multicenter study conducted at a total of 12 clinical study sites in the United States, according to the information submitted in the BLA. A total of 71 subjects received the investigational StrataGraft skin tissue.

Both inspected clinical sites were selected for inspection based on subject enrollment, previous inspectional history, adverse events, protocol deviations and other information submitted in the BLA. The inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Clinical Investigators. The inspection assignments included specific questions concerning the clinical study. Information submitted in the BLA was compared to source documents at each selected study site.

BIMO INSPECTIONS SUMMARY:

No significant inspectional findings were noted from the BIMO inspections. Site 5 that conducted Study STRATA2011 was issued a Form FDA 483. The table below summarizes the site information and the outcome of the BIMO inspections:

Entity	Protocol ID	Site #	Study Site Name and Location	Final Classification
Sponsor	STRATA2011 and STRATA2016	N/A	Stratatech Corporation Madison, WI	No Action Indicated (NAI)
Clinical Investigators	STRATA2011	5	University of Colorado Department of Surgery Aurora, CO	Voluntarily Action Indicated
Clinical Investigators	STRATA2011	4	JBSA-Fort Sam Houston in TX	NAI
Clinical Investigators	STRATA2016	1	University of Wisconsin Hospital and Clinics Madison, WI	NAI
Clinical Investigators	STRATA2016	10	Tampa General Hospital Tampa, FL	NAI
Clinical Investigators	STRATA2016	12	University of California Irvine Orange, CA	NAI

- SPONSOR/MONITORING ISSUES:
  No significant sponsor or monitoring issues were identified during the clinical study site inspections nor from the BIMO inspection of the sponsor.

- 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 sub-investigators, spouse(s) and dependent children, and if and when the information was updated. The information submitted to the BLA was verified for each of the inspected clinical sites.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at 240-402-8038.

Haecin Chun
Consumer Safety Officer