Our STN: BL 125400/81

NOTIFICATION OF NON-COMPLIANCE WITH PREA
June 29, 2017

Organogenesis, Inc.
Attention: Patrick Bilbo
150 Dan Road
Canton, MA 02021

Dear Mr. Bilbo,

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen (GINTUIT).

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR #1, identified in our approval letter of March 9, 2012. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment.

You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with FDASIA, FDA will post this letter and your response on the website located at: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm448393.htm, with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please submit your response to this letter within 45 days to this STN, BL 125400/81. Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit a cross-reference letter to the IND to which your protocol has been submitted.

If you do not submit electronically, please send 3 copies of the submission to the following address:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
Bldg. 71, Rm. G112
Silver Spring, MD 20993-0002

If you have any questions, please contact the Regulatory Project Manager, Bennett Irons, at (240) 402-8311.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research