

From: Riggins, Patrick
Sent: Thursday, October 18, 2018 5:55 PM
To: Robertson, Joan
Cc: Alicea, Candido
Subject: BL 125683/0 Information Request

Joan,

Please see the information request below. Please acknowledge receipt of this IR and also please respond via email and as an amendment to the BLA by November 1, 2018.

Please provide the detail validation report including image data for validation of the test method
CS-000-BC-041 (b) (4)

Any questions, do not hesitate to let me or Candido know.

Regards,
Pat Riggins

Patrick S. Riggins, PhD
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
Food and Drug Administration
WO 71 Room 4216
10903 New Hampshire Ave.
Silver Spring, MD 20993
Phone: 240-402-8346
Fax: 301-595-1303