

From: Riggins, Patrick
To: ["James Maloney"](#)
Subject: 125590/0.42 Information Request
Date: Friday, November 2, 2018 2:15:00 PM

APPROVED

By Patrick S. Riggins, PhD at 5:13 pm, Nov 16, 2018

Jim,

I have an information request below. We ask that you please respond no later than Tuesday November 20, 2018. Please confirm receipt of this request.

1. Response to CR Item # 13 letters A and B, re: Identity test of RI-002

We disagree with your new proposal to use the (b) (4) test for Identity testing of RI-002. To reiterate our past concerns about the inclusion of (b) (4) without substantial clinical efficacy data, please remove any reference to (b) (4) from your product Certificate of Analysis, product release specifications, lot release protocol, labeling, and promotional materials.

2. Response to CR Item # 18 letter B, re: removal of (b) (4) from the LRP template

You retained the (b) (4) reporting for the purpose of Identity testing, which is unacceptable. Please remove the test for (b) (4) from the Lot Release Protocol template.

Regards,

Pat Riggins

Patrick S. Riggins, PhD
Division of Regulatory Project Management
Office of Tissues and Advanced Therapies
WO 71 Room 4261
10903 New Hampshire Ave.
Silver Spring, MD 20993
Phone: (240)402-8346
Fax: (301)595-1303