

APPROVED

By Jean Gildner at 3:03 pm, Dec 12, 2016

From: Gildner, Jean
To: maquilera@vcel.com
Cc: larmour@vcel.com
Subject: Tcon with FDA Wednesday August 10 @ NOON
Date: Monday, August 08, 2016 1:55:00 PM

Dear Margarita,

FDA is requesting a tcon with you on Wednesday August 10 @ noon EST. Please send in a call-in number.

The agenda will include the following:

(b) (4) sterility testing method validation- expected completion date
Request for additional media fill study
Submission of an amendment providing details of responses to PLI form 483 observation 4
Acceptable studies for (b) (4) testing
Update of progress on other membrane related IRs
Submission of amendment for categorical exclusion from environmental assessment
Request for HCP training materials.

Please acknowledge receipt of this email.

Jean F. Gildner MSHS, MT (ASCP), CQA (ASQ)

Regulatory Project Manager
FDA/CBER/OCTGT
10903 New Hampshire Avenue
Bldg. 71, RM. 5222
Silver Spring, MD 20993-0002
Phone: (240) 402-8296
Fax: (301) 595-1303
jean.gildner@fda.hhs.gov

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender by e-mail or phone.