

From: Cagungun, Nannette
Sent: Tuesday, June 06, 2017 3:43 PM
To: Michele.Walsh@csibehring.com
Subject: Information Request: Lot Release Protocol Template

Our Reference: BL 125606

Dear Ms. Walsh,

This is in reference to your biologics license application for C1 Esterase Inhibitor Subcutaneous (Human) submitted on June 30, 2016. We have the following information request:

1. Please provide a revised Lot Release Protocol Template using specifications proposed in Amendment 24 dated 5/26/17.

2. Please provide 2 samples of each of the following lots (b) (4)

with the corresponding Lot Release Protocols to the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Sample Custodian
10903 New Hampshire Avenue
W075-G707
Silver Spring, MD 20993-0002

Please submit your response to this information request as an amendment to this file by June 8, 2017, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If you have any questions, please contact me at (240) 402-8267 or nannette.cagungun@fda.hhs.gov.

Sincerely,
Nannette Cagungun, MS, PD, RAC
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8267
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