DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

March 17, 2020

Updated Instructions for Submitting Lot Release Samples and Protocols During the COVID-19 Pandemic

Dear Lot Release Authorizing Official,

In response to the ongoing COVID--19 pandemic, the Center for Biologics Evaluation and Research (CBER) intends to significantly scale back our lot release activities and will not be receiving biological product samples or protocols *in physical form* (paper or CD-ROM) at the FDA White Oak campus in Silver Spring, Maryland beginning March 23, 2020, until further notice. CBER's Office of Compliance and Biologics Quality (OCBQ) is providing you with logistical information to assist with continuation of the lot release process during this period.

Lot Release Samples

Please note that we will not be able to receive lot release **samples** or protocols in physical form beginning March 23, 2020. Once CBER is able to receive lot release samples and protocols in physical form, we will notify you that we have resumed receiving samples and protocols at our current address:

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

Lot Release Protocols

Electronic lot release protocols submitted through the FDA Gateway will *not* be impacted during this period and may continue to be submitted at any time.

Lot release protocols submitted in physical form (paper or CD-ROM electronic format) will not be received for processing by CBER during this period. In order to continue with the release of new lots whose protocols are in paper or CD-ROM, manufacturers should convert their lot release protocol to PDF and submit it to the following email address using "Submitting Scanned LRP for STN: 000000_0" in the subject line:

- Please submit to: CBERLotRelease@fda.hhs.gov

Please note: More than one protocol can be sent via email, as long all of the documents attached to the email are for the same STN number.

Naming the Lot Release Protocol (LRP) File

Electronic LRPs currently submitted on CD-ROM can use the current filename convention.

Paper LRPs that are scanned and converted to PDF must be assigned a unique filename for each product lot. The filename is composed of alphanumeric characters. You should not use any special characters in the filename. The first four numbers represent the year of the submission (e.g., 2020). The fifth number is "9," which will be used to identify a submission normally in paper format that has been converted to PDF. The next three numbers represent the sequential lot submitted for that year (e.g., 001, 002, 003, etc.), and these 8 numbers are followed by a period. The final two to three alphanumeric characters represent the type of submission (.P0 (zero).pdf specifies an original protocol, and .PC specifies a corrected protocol). Thus, 20209003.P0.pdf. represents the original protocol for the third lot submitted in the year 2020.

A corrected lot release protocol is a submission to correct minor clerical or transcription errors or to clarify lot release information in response to questions by FDA. For submissions under a corrected lot release protocol, designate each corrected protocol using ".PC," followed by the correction number (i.e., .PC1 represents the first corrected protocol, .PC2 represents the second corrected protocol, etc.). Thus, 20209003.PC1.pdf represents the first correction of the original protocol for the third lot submitted in the year 2020. Convert to PDF and set filename as described above.

Release Notifications

Normally the final release notification is faxed with a follow-up copy mailed to the manufacturer. Under this temporary process, we will not be able to fax the final release notices, and there will be a delay in sending the mailed copy. For this reason, we request that you provide the FDA with an email address that will serve as the point of contact. We will send the final release notices to the email address you specify during this time period

Additional Information

FDA staff names should NOT be placed on the document address. Addressing documents to individual FDA staff members will result in a delay in CBER receiving the documents, and a delay in processing.

In order to ensure continued release of products during this period, it is essential that you share this information with the appropriate personnel at your firm who are associated with your lot release submission process.

When we resume normal operations, we will send an updated notice and post information on CBER's website.

Sincerely,

John A. Eltermann -S

Digitally signed by John A. Eltermann -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300049305, cn=John A. Eltermann -S
Date: 2020.03.17 14:57:13 -04'00'

John A. Eltermann, Jr., R.Ph., M.S.
Director
Division of Manufacturing and Product Quality
Office of Compliance and Biologics Quality
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