

From: [Gildner, Jean](#)
To: ["jlitalien@avexis.com"](mailto:jlitalien@avexis.com)
Cc: [Jarvis, Candace](#); [Byrnes, Andrew](#)
Subject: BLA 125694/0 Information Request #22
Date: Friday, January 04, 2019 1:04:53 PM
Attachments: [STN 125694 LRP template final.doc](#)
[image002.png](#)
[image004.jpg](#)
[image006.jpg](#)
[image008.jpg](#)
[image010.jpg](#)
[image012.jpg](#)

Dear Dr. L'Italien,

Please see the following Information request for BLA 125694. Please acknowledge receipt of this email and the ability to respond by January 21, 2019.

Please submit a lot release protocol template for the BLA 125694/0, AVXS-101-onasemnogene abeparvovec.

Use the attached lot release protocol template as a guide to develop a template that is suitable for CBER review of all release testing results for Drug Substance and Drug Product. Please submit this information by 21 January 2019.

Manufacturer may not distribute product prior to receiving lot-specific release from CBER.

The template has been attached to this email.

Sincerely, Jean for Candace Jarvis

Jean F. Gildner MSHS, MT (ASCP)
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8296
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.

Lot Number:

Licensed name of product:

Lot Release Protocol

<u>Product Information</u>	
License Name of Product: Trade Name:	Reason for Submission: ___ For Release ___ For Surveillance ___ For Licensing Action STN: ___ Corrected Protocol
License Holder:	Manufacturer:
Date of Manufacturing:	Expiration Date:
Label Strength:	Vector:
<u>Fill Information</u>	
Filling Date:	Location:
Bulk Total Volume:	Nominal Fill Volume per Vial:
Storage Temperature:	Dosage Form:
<u>Visual Inspection Information</u>	
Number of Vials Inspected:	
Number of Vials Rejected:	
<u>Release Statement</u>	
All tests conducted on this lot are reported and pass specifications as required.	
Authorized Official Printed Name:	Title
Authorized Official Signature:	Date

:

Lot Number:

Licensed name of product:

Lot Release Protocol

Result		
--------	--	--

FINAL CONTAINER

Tests	Test Method	Specifications	Results	Date Tested
General:				
Appearance per (b) (4)				
(b) (4)				
pH per (b) (4)				
(b) (4)				
(b) (4)				
Quantity:				
(b) (4)				
Total Protein by (b) (4)				
(b) (4)				
Identity:				
(b) (4)				
Identity by (b) (4)				
Identity (Protein) by (b) (4)				
Identity (Protein) by (b) (4)				
Purity:				
(b) (4)				
(b) (4)				
(b) (4)				
(b) (4)				

Lot Release Protocol

Potency:				
(b) (4)				
(b) (4)				
Safety:				
Sterility per (b) (4)				
Endotoxin per (b) (4)				
Container Closure Integrity per (b) (4)				

3. (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

3. Sterility

Method used: _____

Type: for example, (b) (4), Final Container

On Test Date	Medium/Temperature	Tested Quantity	Off Test Date

Result:

Specification: