

From: [Switzer, Frank](#)
To: [Cagungun, Nannette](#); [UNII_REQUEST](#); [Jarvis, Candace](#)
Cc: [Byrnes, Andrew](#); [Vincent, Carla](#); [Callahan, Lawrence](#)
Subject: RE: Original BLA 125694 | AveXis, Inc | UNII Code Request (3rd attempt)
Date: Wednesday, April 24, 2019 8:19:58 AM **Attachments:**
[image001.png](#)

Candace and Nannette,

Here are the requested UNIIIs.

Frank

Active Ingredient

ONASEMNOGENE ABEPARVOVEC (b) (4)

Inactive Ingredients

TROMETHAMINE (b) (4)
(b) (4) (b) (4) MAGNESIUM CHLORIDE
(b) (4)
SODIUM CHLORIDE (b) (4)
POLOXAMER 188 (b) (4)
(b) (4) (b) (4)
(b) (4) (b) (4)

20 mM tris (pH 8.0), 1 mM magnesium chloride (MgCl₂),
200 mM sodium chloride (NaCl) containing 0.005% poloxamer 188; sterile filtered (b) (4)
vials. The product contains no preservative.

From: Cagungun, Nannette
Sent: Tuesday, April 23, 2019 6:21 PM
To: UNII_REQUEST <UNII_REQUEST@fda.hhs.gov>
Cc: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>; Byrnes, Andrew <Andrew.Byrnes@fda.hhs.gov>;
Vincent, Carla <Carla.Vincent@fda.hhs.gov>; Switzer, Frank <Frank.Switzer@fda.hhs.gov>;
Callahan,
Lawrence <Lawrence.Callahan@fda.hhs.gov>
Subject: FW: Original BLA 125694 | AveXis, Inc | UNII Code Request (3rd attempt)
Importance: High

Good afternoon.

I would like to follow up on our request for UNII Codes. Please see the active and inactive ingredients for this product below. Note that this BLA's targeted due date is May 17, 2019.

Active:

onasemnogene abeparvovec (adeno-associated virus serotype 9 vector containing the human survival of motor neuron gene)

Inactive:

Tromethamine
Magnesium chloride
Sodium chloride
Poloxamer 188

(b) (4)

We look forward to hearing from you soon.

Thank you.

Nannette

Sincerely,
Nannette Cagungun, MS, PD, RAC
Chief, Branch I

**Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
Division of Regulatory Project Management
U.S. Food and Drug Administration**
Tel: 240-402-8267

nannette.cagungun@fda.hhs.gov



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From: Jarvis, Candace
Sent: Thursday, April 11, 2019 11:14 AM
To: UNII_REQUEST <UNII_REQUEST@fda.hhs.gov>
Cc: Jarvis, Candace <Candace.Jarvis@fda.hhs.gov>; Byrnes, Andrew <Andrew.Byrnes@fda.hhs.gov>;
Cagungun, Nannette <Nannette.Cagungun@fda.hhs.gov>
Subject: Original BLA 125694 | AveXis, Inc | UNII Code Request (3rd attempt)

Good morning,

I would like to request a UNII code review for BLA 125694 as submitted by AveXis, Inc. For your reference, I have provided

- The annotated word and PDF version of the draft labeling
- The link to the submission to find the draft carton and container labels can be found in Module 1.14.1.1

(b) (4)

- Description and Composition of the Drug Product
- General Properties of the Drug Product
- Structure of the Drug Product
- Structure Elucidation

INN: onasemnogene abeparvovec
Proprietary Name: ZOLGENSMA
Product code: AVXS-101

Please let me know if there is anything else that is needed for this request.
Please acknowledge receipt.

Regards,

Candace N. Jarvis
Regulatory Project Manager
Center for Biologics Evaluation and Research
Office of Tissues and Advanced Therapies
U.S. Food and Drug Administration
Tel: 240-402-8315
candace.jarvis@fda.hhs.gov



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