

UNII Code Assignment Request Email, March 11 2013 - Novoeight

From: Ananyeva, Natalya
Sent: Monday, March 11, 2013 4:02 PM
To: Pracht, Leigh
Subject: FW: UNII Code Assignment Request for STN 125466/0

Dear Leigh,

Below, I concur with Frank Switzer on the UNII code assignments.

Natalya

From: UNII_REQUEST
Sent: Friday, March 01, 2013 10:39 AM
To: Pracht, Leigh; CBER SRS
Cc: Callahan, Lawrence; Borodina, Yulia; Perkins, Vada
Subject: RE: UNII Code Assignment Request for STN 125466/0

Hi Leigh,

Here are the UNIIs

Ingredient	Preferred Substance Name	UNII
turoctocog alfa	TUROCTOCOG ALFA	969NZA3X9T
L-Histidine	HISTIDINE	4QD397987E
Sucrose	SUCROSE	C151H8M554
Polysorbate 80	POLYSORBATE 80	6OZP39ZG8H
Sodium Chloride	SODIUM CHLORIDE	451W47IQ8X
L-Methionine	METHIONINE	AE28F7PNPL
Calcium chloride dihydrate	CALCIUM CHLORIDE	M4I0D6VV5M
Water for injections	WATER	059QF0KO0R
----- (b)(4) -----	----- (b)(4) -----	----- (b)(4) -----
----- (b)(4) -----	----- (b)(4) -----	----- (b)(4) -----
----- (b)(4) -----	----- (b)(4) -----	----- (b)(4) -----

Regards,

Frank

Frank L Switzer, PhD

Chemist, FDA Substance Registration System
WO 32 Room 4156
10903 New Hampshire Ave
Silver Spring, MD 20993
Office: 301.796.8506
Mobile: 240.401.5897

I concur on the above UNII code assignments.

Natalya
Review Committee Chair

*Natalya Ananyeva, Ph.D.
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FDA/CBER/OBRR/DH/LH
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From: Pracht, Leigh
Sent: Thursday, February 28, 2013 2:27 PM
To: CBER SRS
Subject: UNII Code Assignment Request for STN 125466/0

<< File: STN 125466.0 Annotated-draft-labeling.doc >>

Please provide a UNII Code assignment for:

STN: 125466/0
Applicant: NOVO NORDISK INC.

Product: Antihemophilic Factor (Recombinant), Plasma/Albumin Free
[NovoEight]

Short Summary: Original Biologics License Application (BLA) for NovoEight, Antihemophilic Factor (Recombinant), Plasma/Albumin-Free for the following proposed indications:

- Control and prevention of bleeding episodes in adults, adolescents and children with hemophilia A
- Perioperative management of patients with hemophilia A
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults, adolescents and

children

Table 1 Composition of turoctocog alfa drug product 250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU and 3000 IU

Name of components	Quantity per mL before lyophilisation	Quantity (nominal) per vial of lyophilised powder ²	Quantity per mL in the withdrawal volume	Function	Reference to standards
Active substance					
turoctocog alfa drug substance	250 IU ¹	250 IU	62.5 IU	Active ingredient	Novo Nordisk A/S
turoctocog alfa drug substance	500 IU ¹	500 IU	125 IU	Active ingredient	Novo Nordisk A/S
turoctocog alfa drug substance	1000 IU ¹	1000 IU	250 IU	Active ingredient	Novo Nordisk A/S
turoctocog alfa drug substance	1500 IU ¹	1500 IU	375 IU	Active ingredient	Novo Nordisk A/S
turoctocog alfa drug substance	2000 IU ¹	2000 IU	500 IU	Active ingredient	Novo Nordisk A/S
turoctocog alfa drug substance	3000 IU ¹	3000 IU	750 IU	Active ingredient	Novo Nordisk A/S
Excipients					
L-Histidine	6 mg	6 mg	1.5 mg	--(b)(4)--	Ph Eur, USP, JP
Sucrose	12 mg	12 mg	3 mg	--(b)(4)--	Ph Eur, USP, JP
Polysorbate 80	0.4 mg	0.4 mg	0.1 mg	--(b)(4)--	Ph Eur, USP, JP
Sodium Chloride	36 mg	36 mg	18 mg ³	--(b)(4)--	Ph Eur, USP, JP
L-Methionine	0.22 mg	0.22 mg	0.055 mg	--(b)(4)--	Ph Eur, USP, JP
Calciumchloride dihydrate	1.0 mg	1.0 mg	0.25 mg	--(b)(4)--	Ph Eur, USP, JP
Water for injections	To final volume	-	To final volume	Solvent	Ph Eur, USP, JP

Name of components	Quantity per mL before lyophilisation	Quantity (nominal) per vial of lyophilised powder ²	Quantity per mL in the withdrawal volume	Function	Reference to standards
-----(b)(4)-----	(b)(4)	-	-	------(b)(4)--	--(b)(4)--
------(b)(4)-----	(b)(4)	-	-	--(b)(4)----- --	--(b)(4)--
----- (b)(4) -----					
--(b)(4)--	-	+	-	------(b)(4)-----	--(b)(4)--

1An overage of (b)(4) turoctocog alfa drug substance is added, see details in 3.2.P.2.3 Manufacturing Process

Development for Drug Product and3.2.P.2.2 Drug Product

2Nominal quantity per vial refers to the quantity per 4 mL

3The amount of sodium chloride originates from 9 mg from the formulation and 9 mg from the solvent 0.9% Sodium Chloride Solution used for reconstitution

------(b)(4)-----

------(b)(4)-----

Thank you,

Leigh A. Pracht

Regulatory Project Manager

FDA/CBER/OBRR/DBA

WOC1; RM 572N; HFM-380

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Page Last Updated: 11/15/2013

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