

# 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.  
Senior Staff Fellow  
FDA/CBER/OBRR/DH/LH  
WOC-1, Office # 382N  
1401 Rockville Pike  
Rockville, MD 20852  
Office: 301-827-6165  
E-mail: Natalya.Ananyeva@fda.hhs.gov*

---

**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 <sup>2</sup> | Quantity per mL in the withdrawal volume | Function          | Reference to standards |
|--------------------------------|---------------------------------------|--|--|-------------------|------------------------|
| <b>Active substance</b>        |                                       |  |  |                   |                        |
| turoctocog alfa drug substance | 250 IU <sup>1</sup>                   | 250 IU   | 62.5 IU                                  | Active ingredient | Novo Nordisk A/S       |
| turoctocog alfa drug substance | 500 IU <sup>1</sup>                   | 500 IU   | 125 IU                                   | Active ingredient | Novo Nordisk A/S       |
| turoctocog alfa drug substance | 1000 IU <sup>1</sup>                  | 1000 IU  | 250 IU                                   | Active ingredient | Novo Nordisk A/S       |
| turoctocog alfa drug substance | 1500 IU <sup>1</sup>                  | 1500 IU  | 375 IU                                   | Active ingredient | Novo Nordisk A/S       |
| turoctocog alfa drug substance | 2000 IU <sup>1</sup>                  | 2000 IU  | 500 IU                                   | Active ingredient | Novo Nordisk A/S       |
| turoctocog alfa drug substance | 3000 IU <sup>1</sup>                  | 3000 IU  | 750 IU                                   | Active ingredient | Novo Nordisk A/S       |
| <b>Excipients</b>              |                                       |  |  |                   |                        |
| 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 <sup>3</sup>                       | --(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 <sup>2</sup> | 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) -----<br>-- | -- (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 and 3.2.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

1401 Rockville Pike

Rockville, MD 20852

Telephone: 301-827-6116

Fax: 301- 827-2857

[Leigh.Pracht@fda.hhs.gov](mailto:Leigh.Pracht@fda.hhs.gov)

Page Last Updated: 11/15/2013

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [اڤيريغلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [عسراف](#) | [English](#)