

Information request Email, November 13, 2012 - Novoeight

From: Pracht, Leigh

Sent: Tuesday, November 13, 2012 12:50 PM

To: 'CDCA (Cindy Cao)'

Subject: Information request re: 7-Nov-12 STN 125466/0 CE request

Dr. Cao,

We have received Novo Nordisk's reply to the November 7, 2012 request for information, and have these comments below in regard to this submission (amendment #1):

The CE request referencing 21 CFR Part 25.31(c) has been reviewed and it has been determined to not be complete.

- 21 CFR Part 25.15 (d) states that "A person submitting an application or petition of a type subject to categorical exclusion under 25.30, 25.31, 25.32, 25.33, or 25.34, or proposing to dispose of an article as provided in 25.30(d) or 25.32(h), is not required to submit an EA if the person states that the action requested qualifies for a categorical exclusion, citing the particular categorical exclusion that is claimed, and states that to the applicant's knowledge, no extraordinary circumstances exist."

Please update the CE to comply with the regulation, and provide in the conclusion why you are eligible for CE according to 25.31(c).

The introduction of the original submitted CE stated that no extraordinary circumstances exist, however this was removed that from the updated CE submission.

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

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Leigh.Pracht@fda.hhs.gov

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From: Pracht, Leigh

Sent: Wednesday, November 07, 2012 3:44 PM
To: 'CDCA (Cindy Cao)'
Subject: RE: Information request re: STN 125466/0

Cindy,

As a clarification of this request, please provide a new CE referencing 21 CFR Part 25.31(c), and justifying why is that applicable to your BLA.

21 CFR Part 25.31(c) does not require "Expected Introduction Concentration (EIC)" that is discussed in the currently submitted BLA. Overall, it is best to send a new request (Title page, TOC, Text).

Thank you,

Leigh A. Pracht

Regulatory Project Manager

FDA/CBER/OBRR/DBA

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1401 Rockville Pike

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Leigh.Pracht@fda.hhs.gov

From: Pracht, Leigh

Sent: Wednesday, November 07, 2012 2:47 PM

To: CDCA (Cindy Cao)

Subject: Information request re: STN 125466/0

Our Reference: BL 125466/0

Novo Nordisk Inc.

Attention: Cindy Cao, PhD

November 7, 2012

Sent by email

Dear Dr. Cao:

We are reviewing your October 15, 2012 biologics license application (BLA) for Antihemophilic Factor (Recombinant), Plasma/Albumin Free [NovoEight]. We determined that the following information is necessary to continue our review:

1. Your request for Categorical Exclusion (CE) to omit preparation of an Environmental Assessment, under 21 CFR Part 25.31(b) as part of the original BLA STN 125466/0 for NovoEight (Antihemophilic Factor (Recombinant), Plasma/Albumin Free) is not applicable to a marketing application of a biologic product. Please submit the applicable exclusion for your product - 21 CFR Part 25.31(c) as soon as possible.

The review of this submission is on-going and issues may be added, expanded upon, or modified as we continue to review this submission.

The action due date for this file is October 15, 2013.

If you have any questions, please contact me at (301) 827-6116.

Sincerely,

Leigh A. Pracht
Regulatory Project Manager
FDA/CBER/OBRR/DBA
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Page Last Updated: 11/15/2013

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