CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206321Orig1s000

CHEMISTRY REVIEW(S)

MEMORANDUM

Date: 21-Oct-2014
From: Joseph Leginus, Review Chemist, Branch VII/DNDQA III/ONDQA
To: NDA 206321, Saxenda™ (Liraglutide [rDNA origin] Injection)
Subject: CMC Approval Recommendation

Background:

- In Chemistry Review #1 (14-May-2014), the recommendation from the standpoint of chemistry, manufacturing and controls was Approval for NDA 206321. However, at that time, a recommendation from the Office of Compliance was pending.
- On 16-Jan-2014, a recommendation for Approval was provided by the Microbiology Reviewer, B. Riley.

Update:

- On 10-Oct-2014, a recommendation of Acceptable was provided by the Office of Compliance for NDA 206321.

Conclusion:

- NDA 206321 is recommended for Approval from the standpoint of chemistry, manufacturing and controls. A recommendation for Approval has been provided from Microbiology and an overall Office of Compliance recommendation of Acceptable has been provided.

Joseph Leginus, PhD
Review Chemist

joseph.leginus@fda.hhs.gov

Digitally signed by joseph.leginus@fda.hhs.gov
DN: cn=joseph.leginus@fda.hhs.gov
Date: 2014.10.21 07:25:44 -04'00'

NDA 206321
Saxenda™
(Liraglutide [rDNA origin] Injection)

Novo Nordisk Inc.

Joseph Leginus, PhD
Division of Pre-Marketing Assessment III, Branch VII, ONDQA

For the Division of
Metabolism and Endocrinology Products

CHEMISTRY REVIEW #1

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Chemistry Review Data Sheet

1. NDA 206321

2. REVIEW #: 1

3. REVIEW DATE: 14-May-2014

4. REVIEWER: Joseph Leginus, PhD

5. PREVIOUS DOCUMENTS:

Previous Documents	Document Date
N/A	

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed	Document Date
Original NDA	20-Dec-2013

7. NAME & ADDRESS OF APPLICANT:

Name:	Novo Nordisk Inc.
Address:	PO Box 846, Plainsboro NJ, 08536
Representative:	Robert B. Clark, VP, Regulatory Affairs
Telephone:	609-786-4690

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: Saxenda™
b) Non-Proprietary Name (USAN): Liraglutide
c) Code Name/# (ONDC only): Liraglutide 3 mg
d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: Type 1
- Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION: This NDA is submitted as a 505(b)(1) application.

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