

**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
s.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

Table of Contents

Table of Contents	2
Chemistry Review Data Sheet.....	3
The Executive Summary	7
I. Recommendations.....	7
A. Recommendation and Conclusion on Approvability	7
B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable.....	7
II. Summary of Chemistry Assessments.....	7
A. Description of the Drug Product(s) and Drug Substance(s)	7
B. Description of How the Drug Product is Intended to be Used.....	8
C. Basis for Approvability or Not-Approval Recommendation.....	9
III. Administrative.....	9
A. Reviewer's Signature: in DAARTS	9
B. Endorsement Block: in DAARTS.....	9
C. CC Block: in DAARTS	9
Chemistry Assessment	10
I. Review of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body of Data	10
S DRUG SUBSTANCE.....	10
P DRUG PRODUCT	10
A APPENDICES	22
R REGIONAL INFORMATION	22
II. Review of Common Technical Document-Quality (Ctd-Q) Module 1	23
A. Labeling & Package Insert.....	23
B. Environmental Assessment or Claim of Categorical Exclusion	28
List of Deficiencies To Be Communicated	29

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

N/A

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Original NDA

Document Date

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.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.