CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-341

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

4 MARCH 2009

NDA: 22-341

Drug Product Name
Proprietary: Victoza
Non-proprietary: liraglutide
Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
5/23/2008	5/23/2008	6/5/2008	6/9/2008

Submission History (for amendments only): N/A

Applicant/Sponsor
Name: Novo Nordisk Inc.
Address: 100 College Road West, Princeton, NJ 08540
Representative: Mary Ann McElligott
Telephone: 609-987-5831

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

A. 1. **TYPE OF SUBMISSION:** Original NDA 505(b)(1)

2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product

3. **MANUFACTURING SITE:** Novo Nordisk
Bagsvaerd, Denmark

4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile preserved aqueous solution in a 3 mL glass pen-fill cartridge for SC injection, 6 mg/mL.

5. **METHOD(S) OF STERILIZATION:** ——— Fill

b(4)

6. **PHARMACOLOGICAL CATEGORY:** Control of Type 2 Diabetes.

B. **SUPPORTING/RELATED DOCUMENTS:** DMFs 21494 and ———.

C. **REMARKS:** This was an eCTD submission. An IQA was performed by ONDQA (dated 7/2/2008). The majority of the sterility assurance information was provided in Type V DMF 21494 (Novo Nordisk). The submission also contained a Comparability Protocol for the Addition of Clayton, NC as an additional manufacturing site (see Section R. Regional Information).

b(4)

filename: N022341R1.doc

Executive Summary

I. Recommendations

A. Recommendation on Approvability – This submission is recommended for approval on the basis of product quality microbiology.

B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable – N/A

II. Summary of Microbiology Assessments

A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology – The drug product is sterile [redacted] filled. b(4)

B. Brief Description of Microbiology Deficiencies – N/A

C. Assessment of Risk Due to Microbiology Deficiencies – N/A

III. Administrative

A. Reviewer's Signature _____
Bryan S. Riley, Ph.D.

B. Endorsement Block _____
James L. McVey
Microbiology Team Leader

C. CC Block
N/A

5 Page(s) Withheld

√ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Microbiology- 1

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/s/

Bryan Riley
3/5/2009 01:01:27 PM
MICROBIOLOGIST

James McVey
3/10/2009 10:50:47 AM
MICROBIOLOGIST
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-341 **Applicant:** Novo Nordisk Inc **Letter Date:** 5/23/2008

Drug Name: Victoza **NDA Type:** 505(b)(1) **Stamp Date:** 5/23/2008

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		Information provided in the NDA and in DMF 21494
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		Information provided in the NDA and in DMF 21494
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		Information provided in DMF 21494
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		Information provided in the NDA and in DMF 21494
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		Information provided in the NDA and in DMF 21494
7	Has the applicant submitted the results of analytical method verification studies?	X		Information provided in DMF 21494
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The application includes a Comparability Protocol for an additional manufacturing site for the drug product (Novo Nordisk, Clayton, NC, USA).

23 June 2008

Bryan S. Riley, Ph.D. Date
Senior Review Microbiologist, OPS/NDMS

James L. McVey Date
OPS/NDMS Team Leader

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/s/

Bryan Riley
6/23/2008 11:30:42 AM
MICROBIOLOGIST

James McVey
6/23/2008 01:54:22 PM
MICROBIOLOGIST
I concur