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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
 6. **PHARMACOLOGICAL CATEGORY:** Control of Type 2 Diabetes. b(4)
- 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 _____ 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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