CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206321Orig1s000

MICROBIOLOGY / VIROLOGY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 14 January 2014

TO: NDA 206321

FROM: Bryan S. Riley, Ph.D.
Team Leader (acting)
OPS/New Drug Microbiology Staff

THROUGH: Stephen E. Langille, Ph.D.
Master Review Microbiologist
OPS/New Drug Microbiology Staff

CC: Patricia Madara
Regulatory Project Manager
OND/DMEP

Priyanka Kumar
Regulatory Project Manager
OPS/ONDQA

SUBJECT: Product Quality Microbiology review of NDA 206321, Liraglutide injection (submission date 20 December 2013).

This submission is recommended for approval from a product quality microbiology standpoint.

This NDA refers to approved NDA 22-341 for Victoza (liraglutide injection 1.8 mg). (b) (4) [redacted]. The only significant difference from a product quality microbiology standpoint is the proposed maximum dose for the subject NDA is greater (3.0 mg/day) than for the approved NDA 22-341 (1.8 mg/day). However, the proposed endotoxin specification ((b) (4) IU/mL) is acceptable for the maximum dose of 3.0 mg/day.

ADEQUATE

Reviewer Comments – The proposed drug product is identical to an approved drug product from a product quality microbiology perspective. Therefore, no additional product

quality microbiology assessment is necessary.

END

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/s/

BRYAN S RILEY
01/15/2014

STEPHEN E LANGILLE
01/16/2014