DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Ann Robards Manager
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

**RE: BLA 125469**
TRULICITY® (dulaglutide) injection, for subcutaneous use
MA 1035

Dear Ms. Ann Robards:

The Food and Drug Administration has completed evaluation of your firm's response to our Untitled Letter dated February 8, 2022. Based on our evaluation, it appears that you have addressed the violation(s) contained in this Untitled Letter.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority. The Agency expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should violations be observed during subsequent surveillance or through other means.

If you have any questions or comments, please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. To ensure timely delivery of your submissions, please use the full address above and include a prominent directional notation (e.g. a sticker) to indicate that the submission is intended for OPDP. Please refer to MA 1035 in addition to the BLA number in all future correspondence relating to this particular matter.

Sincerely,

{See appended electronic signature page}

Samantha Bryant, PharmD, BCPS
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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SAMANTHA E BRYANT
02/22/2022 08:27:17 AM