DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 125469/S-021

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Ingrid Hensley, PhD
Consultant, Global Regulatory Affairs - U.S.
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Dr. Hensley:

Please refer to your supplemental Biologics License Application (sBLA), dated and received December 5, 2017, submitted under section 351(a) of the Public Health Service Act for Trulicity (dulaglutide) injection.

This Prior Approval sBLA provides for proposed modifications to the approved Trulicity risk evaluation and mitigation strategy (REMS). This supplement is in response to our December 1, 2017, REMS Modification Notification letter.

We have completed our review of this supplemental application. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Trulicity was originally approved on September 18, 2014, and the most recent REMS modification was approved on July 27, 2015. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS. In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated December 1, 2017.

Communication Plan: We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Trulicity outweigh its risks because the communication plan has been completed and because the most recent assessment demonstrates that the communication plan has met its goals. No further assessments are necessary to assess the current communication plan.

Therefore, because the communication plan is no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for Trulicity.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, call Marisa Petruccelli, Regulatory Project Manager, at (240) 402-6147.

Sincerely,

{See appended electronic signature page}

Jennifer Rodriguez Pippins, M.D., M.P.H.
Deputy Director for Safety
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

MARY T THANH HAI
12/12/2017