DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022472/S-017

**SUPPLEMENT APPROVAL**

MannKind Corporation
Attention: Robyn Walsh, M.S.
Senior Manager, Regulatory Affairs
One Casper Street
Danbury, CT 06810

Dear Ms. Walsh:

Please refer to your supplemental New Drug Application (sNDA) dated and received April 19, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Afrezza (insulin human) inhalation powder.

This Prior Approval sNDA provides for proposed modifications to the approved Afrezza risk evaluation and mitigation strategy (REMS). This supplement is in response to our April 17, 2018, 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 REQUIREMENTS

The REMS for Afrezza (insulin human) inhalation powder was originally approved on June 27, 2014, and the most recent REMS modification was approved on April 20, 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 April 17, 2018.

**Communication Plan:** We have determined that the communication plan is no longer necessary as an element of the REMS to ensure the benefits of Afrezza (insulin human) inhalation powder outweigh its risks because the communication plan has been completed and the most recent assessment demonstrated 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 Afrezza (insulin human) inhalation powder.

## REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

## REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Michael G. White, Ph.D., Regulatory Project Manager, at (240) 402-6149.

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/

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JENNIFER R PIPPINS
04/24/2018