NDA 212097/S-001

SUPPLEMENT APPROVAL

Xeris Pharmaceuticals, Inc.
Attention: Michele Yelmene
Vice President, Regulatory Affairs and Quality Assurance
180 N. LaSalle Street, Suite 1600
Chicago, IL 60601

Dear Ms. Yelmene:

Please refer to your Supplemental New Drug Application (sNDA) dated and received November 12, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for GVOKE (glucagon) injection.

This "Changes Being Effected" supplemental new drug application provides for updates to the carton labels to be consistent with the 1-pack carton label artwork.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your October 2, 2019, submission containing final printed carton and container labels.

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 Christopher LaFleur, Regulatory Business Process Manager, at (240) 402 - 4724.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling

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Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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