BLA 761184/S-001

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Heather Hufnagel, MS
Senior Manager, Global Regulatory Science
66 Hudson Boulevard East
New York, NY 10001

Dear Heather Hufnagel:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received August 30, 2023, submitted under section 351(a) of the Public Health Service Act for Ngenla (somatrogon-ghla) injection.

We also refer to our approval letter dated December 27, 2023, which contained the following error: incorrect list of the change in anion-exchange (AEX)-HPLC identity release test acceptance criteria (b) (4)

This replacement approval letter incorporates the correction of the error. The effective approval date will remain December 27, 2023, the date of the original approval letter.

This Prior Approval sBLA provides for the following changes:

1. Addition of an independent somatrogon drug substance (DS) manufacturing process (b) (4) at Pfizer Grange Castle (FEI: 3004145594).

2. Addition of (b) (4) a new DS container closure system for storage of DS manufactured (b) (4)

3. Change of long-term storage temperature (b) (4) for DS stored (b) (4)

4. Update of the (b) (4) analytical method (b) (4) (b) (4)

5. Update to the anion-exchange HPLC (AEX-HPLC) release method acceptance criteria for identity testing (b) (4) (b) (4)

6. Editorial update to the bioburden sample volumes for (b) (4) cell culture samples (b) (4)

7. Update to the endotoxin procedure for DS [redacted]

8. Addition of an alternative testing site, [redacted] for the rabbit pyrogenicity test.

9. Pfizer Grange Castle [redacted] DS commercial scale concurrent validation protocols for: [redacted]

10. Pfizer Grange Castle [redacted] DS expiry [redacted] protocol [redacted]

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, please contact Shazma Aftab, PharmD, Regulatory Business Process Manager, at shazma.aftab@fda.hhs.gov or (301) 796 - 3138.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, PhD
Division Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Susan Kirshner

Digitally signed by Susan Kirshner
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