



MEMORANDUM

To Administrative file for STN 125858/0

Date 08/14/2026

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Office of Compliance and Biologics Quality (OCBQ)
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Through Muhammad Shahabuddin, Ph.D.
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Applicant Ultragenyx Pharmaceutical Inc.

Product Genglycos (Pariglasgene breCAParvovec, DTX401, AAV8G6PC)

Subject Review of analytical methods

Recommendation: Approval

Summary:

The following analytical methods used for lot release of Genglycos drug substance (DS) for the treatment of Glycogen Storage Disease Type Ia (GSDIa) in adult and pediatric patients from Ultragenyx Pharmaceutical Inc., and associated validations for detection of impurities were reviewed:

(b) (4)

A large rectangular area of the document is redacted with a solid gray box. The redaction covers several lines of text, likely containing sensitive information related to the analytical methods and validations mentioned in the summary.

Conclusion: Based on the review of the analytical methods and associated validation reports in this submission, these methods are acceptable for lot release testing of Genglycos DS.

13 pages have been determined to be not releasable: (b)(4)