



Our STN: BL 125720/0

DOCUMENT REQUEST
ORIGINAL BLA
May 5, 2020

BioMarin Pharmaceutical Inc.
Attention: Robert Baffi
46 Galli Drive
Novato, CA 94949

Dear Mr. Baffi:

Please refer to your original Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (PHS Act) for BMN 270 (Valoctocogene Roxaparvovec) to provide for the manufacturing facility located in Novato, California for the manufacturing and testing of the BMN 270 drug product and associated drug substance.

We are requesting records pertaining to the manufacture of the BMN 270 drug substance and drug product manufactured at the BioMarin Pharmaceutical Inc. facility located in Novato, CA (FEI: 3004079983). These records are described in the attachment to this letter.

Please provide these records in advance of an inspection pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(a)(4)]. The inspection is tentatively scheduled for (b) (4).

If the records requested do not exist, please state that fact in your response. Please submit the records in an Information Amendment to the submission through the Electronic Gateway (3.2.R Regional Information (USA) section of the CTD) by Monday, May 25, 2020.

If you have any questions or concerns regarding your ability to respond to this request by the specified date, please contact me, Marian Ortiz-Rodriguez, at 240-402-9784.

Sincerely,

Marian Ortiz-Rodriguez
Regulatory Project Manager
Division of Manufacturing and Product Quality
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research