DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/DMPQ 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Room 4042 Telephone: 240.402.7343 Industry Information: www.fda.gov/oc/industry	December 5, 6, 7, 8 and 9, 2022
	FEI NUMBER 3004079983

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. David Fein, VP Novato Site Head

FIRM NAME	STREET ADDRESS
BioMarin Pharmaceuticals, Inc.	46 Galli Drive, Novato Campus
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Novato, CA 94949	Drug Substance and Drug Product Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Procedures are incorrect and lack specific instruction to perform operations consistently, in the (b) (4) manufacturing building. For example,

a. SOP- (b) (4) effective July 13, 2022, Use of (b) (4) in the Novato Manufacturing Facilities, Table (b) (4) incorrectly states that product contacting (b) (4) and WFI (b) (4) have an (b) (4) and are (b) (4) prior to use for a final formulation lot.
b. SOP- (b) (4) effective April 25, 2022, WFI (b) (4) and Usage, lacks specific instruction for WFI (b) (4) use and flushing for manual outlets.
c. SOP- (b) (4) effective November 29, 2022, Dispensing of Water for Injection (WFI) lacks specific instruction for dispensing WFI for (b) (4) in the (b) (4)
d. SOP- (b) (4) effective September 16, 2022, Operation of the (b) (4) in (b) (4) step (b) (4) states to place items onto the appropriate shelf labeled with a status for clean storage.
e. SOP- (b) (4) effective November 24, 2020, (b) (4) using the (b) (4) (b) (4) step (b) (4) states to place items onto the appropriate shelf labeled with a status for clean storage.
f. SOP- (b) (4) effective March 28, 2022, Cleaning and Sanitation Program for (b) (4) cGMP Manufacturing Facility, lacks specific instruction to ensure duration of contact time is maintained for the (b) (4) used in facility cleaning.

Observation 2

(b) (4) approved July 2, 2013, Process Validation of the (b) (4) does not acceptably represent the (b) (4) time storage of (b) (4) manufacturing facility. Specifically,

a. The validation was executed in the (b) (4) manufacturing facility.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	/S/	Laura Fontan, CSO, Kula Jha, Biological Reviewer, Andrew Harmon, Lead Biologist, Emmanuel Adu-Gyamfi, Biologist, Thomas Ryan Withers, CSO	12/09/2022

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b. The validation presented lacks any specific detail regarding the storage conditions.

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SEE REVERSE OF THIS PAGE	/S/	Laura Fontan, CSO, Kula Jha, Biological Reviewer, Andrew Harmon, Lead Biologist, Emmanuel Adu-Gyamfi, Biologist, Thomas Ryan Withers, CSO	12/09/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."