DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Inspector: Miriam Ngundi Phone: 240-402-9774 Industry Information: www.fda.gov/oc/industry	April 06-10, 2026 and April 13-14, 2026
	FEI NUMBER 3025268614

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dennis Huang, Chief Technical Operations Officer

FIRM NAME	STREET ADDRESS
Ultragenyx Pharmaceutical Inc.	170 Middlesex Turnpike
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bedford, MA 01730	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

Quality oversight is inadequate to ensure (b) (4) has the (b) (4) (b) (4) it purports or is represented to possess. Specifically, controlled documents such as Master Batch Records (MBRs) are not adequately reviewed before they are approved and put into effect. MBRs have (b) (4) errors identified by operators while using the MBRs. The errors include (b) (4) errors, references to incorrect Standard Operating Procedures (SOPs), and incorrect (b) (4) process hold-times. The errors occur (b) (4) throughout the MBRs. For example,

a. Deviation QE-006853 was opened due to a documentation generation error for MBR (b) (4) This deviation was (b) (4) to a major deviation, because it was considered a repeat deviation. However, corrective and preventive actions from this deviation did not prevent future documentation errors in batch records.
b. MBR for the (b) (4) step (b) (4) is not in alignment with the Manufacturing Process Control Document (MPCD (b) (4) in accordance with change control QE-007097. Due to this misalignment, (b) (4) has (b) (4) for the (b) (4) of the process hold-time for the (b) (4)
c. MBR for the (b) (4) incorrectly listed (b) (4) (b) (4) throughout the document.
d. MBR (b) (4) incorrectly listed (b) (4) (b) (4) throughout the document.

COPY

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Miriam Ngundi, Lead Inspector, CSO Scott Ballard, CSO Jacob Bitterman, Biological Reviewer Edhriz Siraliev-Perez, Staff Fellow	04/14/2026

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Inspector: Miriam Ngundi Phone: 240-402-9774 Industry Information: www.fda.gov/oc/industry	April 06-10, 2026 and April 13-14, 2026
	FEI NUMBER 3025268614

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dennis Huang, Chief Technical Operations Officer

FIRM NAME	STREET ADDRESS
Ultragenyx Pharmaceutical Inc.	170 Middlesex Turnpike
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bedford, MA 01730	Drug Substance and Drug Product Manufacturer

e. MBR (b) (4) incorrectly referenced (b) (4) (b) (4) throughout the document.

OBSERVATION 2

Acceptance criteria for the (b) (4) of the (b) (4) (b) (4) are not adequate. While your (b) (4) states that the (b) (4) shall achieve (b) (4) it also states that (b) (4) (b) (4)

The (b) (4) conducted on September 18, 2025 (b) (4) (b) (4) The study used a (b) (4) A subsequent (b) (4) of the study conducted on September 24, 2025 showed (b) (4) (b) (4) (b) (4) conducted on November 4, 2025 (b) (4)

(b) (4)

OBSERVATION 3

Your manufacturing spaces are not always adequately cleaned for (b) (4) manufacturing. On April 6, 2026, an unknown residue was observed on the ceiling of (b) (4) (b) (4) The residue had a (b) (4) appearance with some areas having a grainy texture. At the time of this observation, the room was in a cleaned status and prepared for manufacturing (b) (4) (b) (4)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Miriam Ngundi, Lead Inspector, CSO Scott Ballard, CSO Jacob Bitterman, Biological Reviewer Edhriz Siraliev-Perez, Staff Fellow	04/14/2026

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Inspector: Miriam Ngundi Phone: 240-402-9774 Industry Information: www.fda.gov/oc/industry	April 06-10, 2026 and April 13-14, 2026
	FEI NUMBER 3025268614

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dennis Huang, Chief Technical Operations Officer

FIRM NAME	STREET ADDRESS
Ultragenyx Pharmaceutical Inc.	170 Middlesex Turnpike
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Bedford, MA 01730	Drug Substance and Drug Product Manufacturer

OBSERVATION 4

(b) (4) is not representative of (b) (4) and manufacturing processes for (b) (4) products. Your (b) (4) for bioburden follows (b) (4) (b) (4) which states to (b) (4) (b) (4) However, your operational procedure (b) (4) titled (b) (4) states to (b) (4) (b) (4)

OBSERAVTION 5

Written production and process control procedures are not followed in the execution of production and process control functions. Specifically, on April 7, 2026, during the (b) (4) (b) (4), a manufacturing operator (b) (4) (b) (4) The manufacturing operator proceeded to conduct the (b) (4) despite instructions provided in (b) (4) (b) (4) (b) (4) in controlled/classified areas.

MN 04/14/2026.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Miriam Ngundi, Lead Inspector, CSO Scott Ballard, CSO Jacob Bitterman, Biological Reviewer Edhriz Siraliev-Perez, Staff Fellow	04/14/2026

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."