DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	5/18/2026-5/20/2026
	FEI NUMBER 3032349813

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Gregory A Rockers, Chief Quality and Strategy Officer

FIRM NAME	STREET ADDRESS
Belmar Labs, LLC	150 Capital Dr Ste 430/440
CITY, STATE, ZIP CODE, COUNTRY Golden, CO 80401-5611	TYPE ESTABLISHMENT INSPECTED Contract Testing Facility

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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Your firm failed to conduct adequate investigations, identify true root causes, and implement effective corrective and preventive actions (CAPAs) for recurring deviations associated with incubation process failures, resulting in the irreversible loss of at least (b) (4) client samples across multiple events.

On January 5, 2026, your firm opened DEV26001 to investigate three over-incubation events that resulted in the complete and irreversible loss of (b) (4) client environmental monitoring (EM) samples. Your investigation concluded that "manpower" (analyst oversight) was the root cause; however,

- The investigation stopped at "human error" without further inquiry into why (b) (4) trained analysts failed to follow the same procedure across multiple events within a 10-day period.
- Your firm concluded that the method (TM-MB-012 v1.0) was not a contributing factor, yet the replacement CAPA (CAPA26007, opened March 3, 2026) implemented method-level improvements, including an incubation-specific (b) (4) labeling system, (b) (4) whiteboard inspection and notation of samples, and revision of (b) (4) procedures to incorporate incubation tracking controls
- Your trending deviation (DEV26020, opened March 3, 2026) further contradicts the original root

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Nelson N Ayangho, Investigator X Nelson N Ayangho Investigator Signed By: 2004144302 Date Signed: 05-20-2026 19:24:44	5/20/2026

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cause determination, concluding that "Method is determined to be the main contributing factor and manpower is considered a secondary contributing factor."

Secondly, your firm failed to recognize CAPA Failure in a Timely Manner.

On January 12, 2026, your firm opened CAPA26001 in response to DEV26001. The stated corrective actions included implementation of a centralized incubation calendar system and (b) (4) reviews of in-process testing. However,

- DEV26017 (February 23, 2026): EM samples were over-incubated by (b) (4) occurred 42 days after CAPA26001 implementation—with the same root cause of inadequate incubation tracking. Your firm did not reassess CAPA26001 effectiveness following this recurrence.
- DEV26019 (March 3, 2026): Client samples were under-incubated in two separate events, resulting in the irreversible loss of an additional (b) (4) client samples occurred 50 days after CAPA26001 implementation. Your firm did not recognize CAPA26001 as ineffective until after this third incubation failure.

CAPA26001 was not closed as ineffective until March 3, 2026, after two additional deviations had already occurred.CAPA26001 was replaced with CAPA26007 on March 3, 2026; yet, incubation-related failures have continued. At least two additional deviations involving microbiology incubation events—DEV26025 (opened May 7, 2026) and DEV26028 (opened May 14, 2026)—indicate that samples and/or data were not incubated or documented per requirements, suggesting that CAPA26007 has also not been demonstrated to be effective in preventing recurrence.

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OBSERVATION 2

Laboratory controls do not include the establishment of scientifically sound and appropriate standards designed to assure that conform to appropriate standards of identity, strength, quality and purity.

Specifically,
Your firm uses a (b) (4) reference standard from (b) (4) without verification against the United States Pharmacopeia (USP) reference standard.
Specifically:
During the inspection on 05/18/2026, your lab analyst stated that the (b) (4) reference standard is obtained from (b) (4) because the firm does not have the storage capability required for the USP reference standard.
Your analyst further stated that the firm has not compared the (b) (4) reference standard to the USP (b) (4) reference standard to verify equivalency.
Your firm has perfomerd (b) (4) potency testing using the (b) (4) reference standard for numerous batches from January 2026 through May 2026, including but not limited to:

Lot (b) (4) tested January 2026)
Lot (b) (4) (tested January 2026)
Lot (b) (4) (tested January 2026)

OBSERVATION 3

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,
Your firm's practice of accepting materials from suppliers during initial qualification without conducting identity testing or verification against the Certificate of Analysis fails to provide adequate assurance that:

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a) The materials received are what they purport to be (identity verification)
b) The materials meet the specifications claimed in the Certificate of Analysis
c) The materials are suitable for their intended use in testing operations that support product release decisions for finished drug products (testosterone pellets, estradiol pellets) and incoming material qualification.
Examples include but not limited to,
Your firm received at least 2 lots (b) (4) Lot (b) (4) (Expiration: (b) (4) (b) (4)), Lot (b) (4) (Expiration:(b) (4)) but fail to conduct verification tests to confirm the material was (b) (4) as claimed eventhough your fail did not test this(b) (4) during vendor qualification process to acertain the accuracy of the certificate of analysis

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Investigator
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X

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5/20/2026

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 judgment, 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."