DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Dr., Suite 205 Lenexa, KS 66214 913-495-5100	04/27/2026 to 05/06/2026
	FEI NUMBER 1950348
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Richard A. Gilbert, President,	
FIRM NAME Marcus Research Laboratory, Inc.	STREET ADDRESS 1820 Delmar Blvd
CITY, STATE, ZIP CODE, COUNTRY Saint Louis, MO 63103-1712, USA	TYPE ESTABLISHMENT INSPECTED API 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 WE OBSERVED:

Quality Unit

OBSERVATION 1

There are inadequate systems used for maintaining and calibrating critical equipment.

Specifically,

The mixer's ribbon blade appears to be in a state of disrepair. This mixer is used to manufacture every lot of API made at your facility. Since the previous inspection in August 2024 your firm has distributed approximately (b)(4) lots of (b)(4) USP human drug API, (b)(4) lots of (b)(4) Available animal drug API, and (b)(4) lots of (b)(4) animal drug API.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Matt Schuckmann, CSO	Matthew M. Schuckmann, CSO	05/06/2026

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."