DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/2/2026-3/5/2026
	FEI NUMBER 3003433784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Eamonn M. McMahon, Senior Director of Quality Affairs - Ohio Sites

FIRM NAME	STREET ADDRESS
American Regent, Inc.	960 Crupper Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Columbus, OH 43229-1109	Control Testing Laboratory

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

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A) Your quality unit does not clearly document that data review is performed and verified as outlined in the Laboratory Documentation Checklist form prior to approval of the Finished Product Test Summary form for the 1) review of electronic raw data, including but not limited to high-performance liquid chromatography (HPLC), Ultraviolet–visible (UV-Vis) spectra, bacterial endotoxin testing (BET), and particle size analysis, 2) review of file or run level audit trails for laboratory instruments such as HPLCs, 3) verification of all calculations when excel worksheets are used, and 4) review and resolution of out-of-specification (OOS) or other laboratory non-conformances associated with chemistry or microbiological testing.

B) Your quality unit does not document review of 1) (b) (4) standard checks for expiration date as outlined in SOP AR-SOP-0462 *Receipt, Handling, and Storage of Reference Standards* (version 11.0, effective 09/07/2022) and 2) the review of reagents and discarding of expired reagents from laboratory inventory as outlined in SOP AR-SOP-0437 *Preparation, Documentation, and Storage of Solutions, Mobile Phase, and Reagents* (version 16.0, effective 07/16/2025).

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lisa R Hilliard, Investigator	X Lisa R Hilliard Investigator Signed By: Lisa R. Hilliard -S Date Signed: 03-05-2026 10:57:15	3/5/2026

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FIRM NAME American Regent, Inc.	STREET ADDRESS 960 Crupper Ave
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43229-1109	TYPE ESTABLISHMENT INSPECTED Control Testing Laboratory

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your out-of-specification (OOS) investigations do not clearly document the laboratory investigation process to determine whether an OOS is valid or invalid and the justification for retesting. For example:

A) Your OOS investigation DEV-10843 was opened on 06/29/2023 and closed on 06/19/2024 for (b) (4) USP test results for particle size distribution (Batch (b) (4) and Batch (b) (4)), (b) (4) (Batch (b) (4)), (b) (4) (Batches (b) (4), (b) (4) and (b) (4)), and impurities (Batch (b) (4) and Batch (b) (4)). As part of the investigation for the invalidated OOS, you did not clearly document the 1) the Phase I laboratory investigation to determine that the OOS was invalid prior to approving the test plan for retesting, 2) the justification for the lack of an official or numbered CAPA, and 3) the justification of the lack of training for the revised wettability and impurities test methods. (b) (4), USP is used in the production of (b) (4) and (b) (4), USP.

B) Your OOS investigation DEV-12336 was opened on 03/14/2024 and closed on 05/02/2024 for the retesting of (b) (4) Solution, NF Batch (b) (4). As part of the investigation, you did not clearly document the 1) justification for not conducting the Phase I investigation analyst interview prior to approving the test plans for retesting, 2) justification for the retesting of the samples following (b) (4) different test plans, 3) lack of an official or numbered CAPA, and 4) documentation of the retraining of the analyst (as referenced in analyst interview). (b) (4) (b) (4) Solution, NF Batch (b) (4) was used in the production of (b) (4) (b) (4) and (b) (4) Suspension, USP, including Lot (b) (4) (manufactured (b) (4) expiration date (b) (4)) and Lot (b) (4) (manufactured (b) (4) expiration date (b) (4)).

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C) Your OOS investigation DEV-18488 was opened on 10/09/2025 and closed on 11/07/2025 for particulate matter test results for (b) (4) Injection, USP Lot (b) (4) (manufactured (b) (4) expiration date (b) (4) . The OOS was invalidated due to the formation of air bubbles during sample preparation. As part of the investigation, you did not document a justification for the lack of a CAPA, such as re-training or review of the testing method.

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."