DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	4/7/2026-4/21/2026* FEI NUMBER 2410375

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Paul J. Diolosa, President & CEO

FIRM NAME	STREET ADDRESS
American Regent, Inc.	5 Ramsey Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Shirley, NY 11967-4701	Sterile Drug 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:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

A. Your firm has initiated approximately 29 Investigation reports since April 2024 to present, for microorganisms recovered from the Grade A zone in the aseptic core where sterile injectable drug products are manufactured. These Grade A zones include the Filling Rooms and supporting areas such as Room (b) (4) (b) (4) Injection (b) (4)), Room (b) (4) Grade A storage area, Room (b) (4) filling of (b) (4) Injection (b) (4) USP), Room (b) (4) filling of (b) (4) and operational Room (b) (4) (EM storage/staging area). Since May 2024 organisms recovered included *Aspergillus hiratsukae/shendaweii, Aspergillus versicolor, Staphylococcus species (epidermidis, hominis, capitis, saprophyticus*, and *warneri*), *Corynebacterium tuberculostearicum, Micrococcus luteus*, and other organisms such as *Kocuria palustris, Microbacterium paraoxydans* and *Cococobacillus spp*. These organisms have been identified as either spore forming, or non-spore forming organisms recovered from either surface contact, active air, and/or passive air samples.

Moreover, your Grade B operational Rooms (b) (4)) and area described as operational and/or transitional is separated from the Grade A critical zone with (b) (4) (representing a traditional aseptic manufacturing process), has recovered approximately 167 instances where microorganisms have been recovered. Organisms recovered are the same as in the Grade A area include but not limited to the following additions: *Bacillus cereus group, Moraxella osloensis,*

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Vivin George, Investigator Tanya R Syffrard, Investigator Divek R Jumani, Investigator Simone E Pitts, National Expert X Tanya R Syffrard Investigator Signed By: TANYA R. SYFFRARD -S Date Signed: 04-21-2026 13:03:31	4/21/2026

Sphingomonas sp., Acinetobacter radioresistens, Niallia circulans, Aureobasidium melanogenum Priestia megaterium, Priesta flexa (Bacillus), and *Paenibacillus sp*. These organisms have been identified as either spore forming, or non-spore forming organisms recovered from either surface contact, active air, and/or passive air samples. Your cleaning procedures in the Grade B area do not appear to be adequate for the removal of microorganisms recovered in the area, which led to the subsequent recovery of the same organisms in the Grade A zone.

B. On April 08, 2026, at multiple time points during setup operations at Room (b) (4) Line (b)(4) for (b) (4)) Lot:(b) (4), expiration date:(b) (4) , these deficiencies were observed via livefeed from CCTV(b) (4) and (b) (4):

1. At approximately between 0652 - 0653, an operator blocked the first air and extended their head, torso and arms inside the -Grade A area when connecting the sterile(b) (4) and adjusting the (b) (4) .

    i. In addition, as part of routine personnel monitoring, the head and/or forehead of operators is not sampled

2. At approximately 0705-0706 and 0744-0745 , (b) (4) operators were observed sanitizing their hands with (b) (4)) before being plated for personnel monitoring. In addition, the operators did not allow for the pads of the gloved fingers to come into contact with the media plate but only the gloved fingertips. Furthermore, similar practices were observed during your media fill study on February 06, 2026 at approximately 5 hours and 29 minutes to 5 hours and 30 minutes, 6 hours and 34 minutes to 6 hours and 35 minutes, CCTV (b) (4) review showed operators sanitize their gloved hands with (b) (4) prior to finger plating and only the fingertip was plated on each media plate.

3. At approximately 0742, an Operator was observed using their left leg to push trash down into a trash receptacle in Grade A zone. This type of behavior can agitate particles inside the trash or from the floor making them airborne.

4. At approximately 0714 we observed an operator (b) (4) adjusting the filling needles using gloved hands without hand sanitization prior or using sterile tools such as forceps for the needle adjustment. This intervention is not captured in the media fill exercise.

5. For Filling Line (b) (4) in Room (b) (4) operators did not perform sanitizing of the barrier doors which separates Grade A and Grade B areas after completion of the filling line setup. Also, operators were observed moving in and out of the Grade A and Grade B space during filling to perform interventions without wiping down the barrier doors.

Your July 2024 airflow visualization study (smoke study) in the Grade A (ISO-5) zone of traditional aseptic Filling Line (b) (4) in Room (b) (4) did not demonstrate unidirectional airflow. This line fills sterile injectable products such as (b) (4), Lot: (b) (4); (b) (4), Lot: (b) (4); (b) (4) Injection USP (b) (4)), Lot: (b) (4) for the U.S. market. Airflow was observed to swirl upwards, move towards the open door, and then disperse towards the lower back area of the stopper wheel. Additionally, the smoke nozzles were positioned towards the floor during the study thereby directing the airflow instead of allowing the natural cascade from the HEPA filters to direct the airflow.

When opening the barrier doors on Filling Line (b) (4) in Room (b) (4), during the airflow visualization study- PR-90-762, July, 2024, we observed the following: the laminar air being pulled away from the sterile exposed filling needles and thereby having no first air over the exposed sterile filling needles during any routine and/or non-routine intervention. The laminar air was observed to be hitting the torso/trunk of the operator thereby, reintroducing the air into the Grade A critical zone. The laminar air as it exits Grade A zone into the Grade B area was moving swooping upwards thereby, reintroducing the air into the Grade A area.

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On April 07, 2026, during manufacturing of the sterile injectable drug product, (b) (4) in Room (b) (4) Capping Room), multiple gaps were observed in between the (b) (4) allowing the ingress of particles from the Grade D zone into the laminar flow Grade "A" supply. This gap separation was observed directly above the clean vials exiting the (b) (4) into the (b) (4).

No smoke studies were performed under the laminar flow grade "A" supply area in Room (b) (4), where the stoppered vials are capped.

Goggles donned by operators for aseptic operations within Grade A zones and aseptic production support operations within Grade B zones are not suitably designed and validated to prevent shedding of particulates and other contaminants from personnel to the environment under working conditions. Operators were observed in the Grade A classified areas during aseptic filling operations wearing the (b) (4) and (b) (4) (b) (4) goggles. The (b) (4) " goggles were observed to fog up and not be flush against the operator's face. The (b) (4) (b) (4) goggles were observed to have gaps on the top of the goggles.

During your media fill study conducted on Filling Line (b) (4) in Room (b) (4) on February 06, 2026, at approximately 11 hours and 30 minutes and 11 hours and 34 minutes, CCTV review showed unauthorized activities of (b) (4) operators in the aseptic manufacturing Grade B area playing what appears to be the game "Hangman" on a sterile wipe while undergoing simulating filling operations.

During the manufacture of (b) (4) Injection (b) (4) Lot: (b) (4) Mfg date: (b) (4), exp date: (b) (4), Filling line "A" in Room (b) (4) the following deficiencies at multiple timepoints were observed and following are some examples:

At one hour and forty-nine minutes during setup, the operator was observed to squeeze the (b) (4) bottle holding the unidentifiable liquid on and around the filling

needles after performing an intervention.

At four hours and nine minutes, during a stopper block intervention, the operator was observed to reach over the sterile exposed filling needles and open vials that hold the sterile product.

At thirteen hours and forty-nine minutes, during a stopper height adjustment of the (b) (4) (b) (4) the mechanic was observed to touch the sterile (b) (4) equipment with gloves and wipe using an unidentifiable liquid used in the Grade A zone.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A. There is a failure to adequately investigate and prevent the migration of a mold spore forming organism, *Aspergillus hiratsukae/shendaweii* from the Grade C area, into the Grade B cleanroom and ultimately into the Grade A (ISO 5) critical aseptic processing zone used in sterile manufacturing operations.

1. The organism was initially recovered via Sample #1070426 in Room 105: Equipment Preparation Room, Surface Contact Plate on 03MAR2025. No investigation was initiated as the organism recovered from Grade C and did not exceed the alert and-or action levels.

2. Deviation 59343 (New Deviation #17642) was initiated for Room 124,

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Aseptic Supporting Area, Active Air Sample under Sample #1095215, for the recovery of the organism in Grade B cleanroom during manufacture of (b) (4) Injection, Lot (b) (4) dated 14APR2025.

3. Deviation 17991, was initiated for Room (b) (4), Aseptic Filling Room, Passive Air Sample under Sample #1207328, recovered the organism in Grade A during manufacture of (b) (4) Injection), Lot: (b) (4), dated 29JUN2025.

4. Deviation 17992 was initiated for Room (b) (4) Aseptic Filling Room, Passive Air Sample under Sample #1209304, recovered the organism in Grade A during manufacture (b) (4) Injection), Lot:(b) (4) , dated 30JUN2025.

B. Deviation 18514 initiated 08OCT2025 details the recovery on 1 CFU of mold from an Environmental Monitoring sample (Sample #1325286) in the Grade A area of Room (b) (4) (Staging area for materials and equipment that is utilized in the Grade A areas). Between 24SEP2025 and 07OCT2025, an environmental monitoring trend was identified due to 3 EM OOS recoveries identified within a 1-month period with two bacterial recoveries and the current isolate for *Aspergillus versicolor*. The investigation concludes there is no product impact due to all equipment and materials utilized are (b) (4) and (b) (4) .

C. Room (b) (4) Media Fill Report (LV26-003), Media Fill Master Plan, AR-PROT-0049, Version 13.0, dated: 13Mar2026, one vial representing the setup rejects for fill volume ((b) (4) vials) showed turbidity post incubation. An investigation was initiated under DEV-19088, the organism recovered was identified as

Staphylococcus hominis. There was no corrective and preventative action initiated to address the recovery of Staphylococcus spp. in the Grade A (ISO 5)space.

D. Room (b) (4) Media Fill Report (LV24-003), Media Fill Master Plan, AR-PROT-0049, version 9.0, dated: 18SEP2024, one vial representing the setup rejects for fill volume (b) (4) vials) showed turbidity post incubation. An investigation was initiated under DEV-13258, the organism recovered was identified as *Staphylococcus epidermis*. There was no corrective and preventative action initiated to address the recovery of Staphylococcus spp. in the Grade A (ISO 5) space.

E. There is no non-viable particulate monitoring system that monitors the air quality near the (b) (4) sterile (b) (4) hopper equipment in the Grade A area ,that holds the sterilized stoppers that feeds the stopper bowl in Room (b) (4), Line (b) (4)

OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A. The (b) (4) calibration performed (b) (4) prior to the initiation of the visual inspection was inadequate. While (b) (4) intensity at the center of the (b) (4) is verified during initiation, your firm failed to evaluate (b) (4) intensity across all functional areas used during routine visual inspections.

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B. The discrepancy for the reject counts during the (b) (4) leak detector test, for the (b) (4) Injection) sterile drug product, between the (b) (4) and the (b) (4), was not recorded contemporaneously.

C. Your firm does not perform 100% (b) (4), and/or (b) (4) visual inspection for (b) (4) Injection, USP vials. A destructive test with samples taken at AQL (b) (4) is used in lieu of the 100% visual inspection. This approach excluded the inspection of critical physical container defects during the 100% visual inspection., Your (b) (4) visual inspection process has not been validated to demonstrate adequate detection of visible particulates within a (b) (4) matrix in (b) (4), which is known to (b) (4) particulate matter.

D. Your firm has not established or utilized product-specific defect standard (b) (4) representative of (b) (4) solutions, including particles of varying size, composition, and opacity, to qualify and periodically requalify inspectors.

E. Inspectors performing visual inspection are not adequately qualified or requalified for detection capability in (b) (4) solutions, and training does not include challenges specific to (b) (4) (b) (4) product characteristics.

F. Your firm utilizes the (b) (4) Multisizers, Equipment ID: 317204, S/N (b) (4) and Equipment ID: 316534, S/N: (b) (4) to perform a destructive particulate test in lieu of 100% visual inspection on finished drug product.

   i. The (b) (4) Multisizer is capable of detecting particulates in the (b) (4) -micron range, a baseline of the particle morphology and characterization observed in the (b) (4) Injection) has not been established.

G. Investigations into rejected units containing visible particulates through AQL visual inspection are inadequate in that the firm does not evaluate potential sources, including container closure systems, (b) (4) or aseptic processing operations for all aseptically manufactured sterile drug products including, but not limited to, (b) (4) Injection, USP vials.

H. Process validation studies have not included any headspace analysis to determine whether stoppered vials maintain their (b) (4) until crimping and capping. The following are some examples of sterile drug products with the (b) (4) overlay:
   i) (b) (4)
   ii) (b) (4) vial
   iii) (b) (4) vial
   iv) (b) (4) vial
   v) (b) (4) vial
   vi) (b) (4) vial

OBSERVATION 4

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

Specifically,

A. There is no process to reconcile the CGMP forms printed at your firm to determine whether all issued original CGMP forms are used or returned to QA. Employees are permitted to print excess copies of CGMP forms and discard unused forms. There is no assurance forms with original CGMP data are not destroyed and/or discarded. Additionally, multiple document shredder bins holding what appeared to be CGMP forms were observed around the facility and some of the examples are as follows:

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Building 1:

1. (b) (4) office bin adjacent to copier
2. (b) (4) bin, adjacent to copier
3. (b) (4) backup bin at the head of the packaging corridor
4. (b) (4) Bin

B. After a (b) (4) testing failure, your firm retested sterilizing (b) (4) using (b) (4) Instrument (ID: 9369; S/N: (b) (4)) without initiating an investigation. This deviates from approved procedure AR-SOP-1430, *Integrity Testing of* (b) (4) *via the* (b) (4) *Method*, as evidenced in the following examples:

On March 28, 2026, (b) (4) Injection, USP), Lot: (b) (4) failed post-use (b) (4(b) (4) testing and was retested once with an acceptable result for product release and no investigation was initiated.

2. On April 1, 2026, (b) (4) Injection, USP, Lot: (b) (4), failed post-use (b) (4) testing and was retested five times until reaching an acceptable result for product release and no investigation was initiated

OBSERVATION 5

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.

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Specifically,

A. Your firm failed to adequately investigate the blue peeling paint like particles observed on the filling tubes in the Grade A zone, during the manufacture of the sterile drug product, (b) (4) Injection (b) (4) vial, Lot: (b) (4) mfg date: (b) (4) exp date: (b) (4) , filling line: (b) (4) under Deviation- 17383. The blue residue like particles were generated from the (b) (4) bottles used in both Grade A and Grade B areas. The subject lot of the sterile drug product was released for commercial distribution into the US market.

B. Your firm failed to adequately investigate one reject vial containing a fiber-like particle "hair" during the (b) (4) visual inspection of the sterile drug product, (b) (4) Injection (b) (4) USP), Lot no: (b) (4), mfg date: (b) (4) exp date: (b) (4) filling line: (b) (4) under Deviation- 17967. This fiber-like particle "hair" was greater than 1mm in length and 20 um in width in brown color. The root cause was not determined, and the subject lot was released for commercial distribution into the US market.

OBSERVATION 6

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

A. The (b) (4)) and the (b) (4)) used for the visual inspection program of multiple vials presentations i.e., (b) (4) , and (b) (4) vials, have not been adequately validated for its intended use in identifying critical and major defects for sterile injectable drug products. The (b) (4) is incapable of identifying any defects above the body of the vial, including the neck and shoulder for vial defects. Moreover, this equipment has been qualified to detect only (b) (4) and (b) (4) particulates within the range of (b) (4) to (b) (4) and (b) (4) and (b) (4) fibers. It did not include the (b) (4) particulates and (b) (4) to (b) (4)

(b) (4), which were reported in your deviations. The (b) (4) is not routinely challenged to detect any particulates less than (b) (4) fibers, (b) (4), and/or (b) (4) or longer fibers.

B. The design of the (b) (4) stopper wheel/(b) (4) is inadequate in that the design violates first air principles for stoppers seated on open vials. As stoppers exit the chute to be placed on vials, the shape of the (b) (4) blocks the unidirectional airflow of the incoming vials into the stoppering station until they exit and proceed to capping. The (b) (4) is used on multiple filling lines where sterile injectable drug products are filled including (b) (4) Injection), Line (b) (4) (Room (b) (4)) and (b) (4) Line (b) (4) Room (b) (4)

OBSERVATION 7

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. On April 15, 2026, the following were observed in the equipment prep area, Room 105:

1. The post-use cleaned (b) (4) stopper bowl utilized on Line (b) (4) was observed to have an unknown brownish red residue on the outside of the subject stopper bowl.
2. The post-use cleaned (b) (4) stopper wheel, was observed to have gouges, scratches and excessive wear and tear.
3. The post-use (b) (4) (b) (4) was observed to have brown "rust" like appearance.

B. Additionally, the (b) (4) used in Room (b) (4) Line (b) (4) which separates Grade A from the Grade B zone, during the manufacture of the sterile drug product, (b) (4)) Injection, USP (b) (4)

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(b) (4) (b) (4), were observed to have unknown white residue.

OBSERVATION 8

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

Your firm's audit trail review for the (b) (4) Instrument (ID: 9369; S/N: (b) (4)) is deficient in that:

A. There is no procedure describing the review, evaluation and approval of (b) (4) audit trails to ensure the integrity of testing data from the instrument.

B. There is no individual usernames and passwords attributable to the access of (b) (4) , utilized to conduct (b) (4) test.

C. It does not ensure all (b) (4) testing results are adequately reviewed and verified by the Quality Unit against the (b) (4) usage logbook to ensure all data integrity is maintained.

OBSERVATION 9

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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Your firm failed to submit Field Alert Reports for the below sterile drug product lots manufactured and distributed into the US market when visible particulates were observed during the (b) (4) visual inspection of retain samples:

Name of the product	Lot No- Date of Manufacture	Expiry
(b) (4))	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)

OBSERVATION 10

Your firm failed to establish secure, interoperable, electronic systems and processes necessary to respond with the relevant transaction information (at the package level) and transaction statement for a product upon request by FDA or other appropriate Federal or State official in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product and associate a saleable return product with its applicable transaction information and transaction statement to allow a trading partner to accept the returned product.

Specifically,

While your firm has established interoperable electronic systems ((b) (4) , and (b) (4) system) capable of storing and managing transaction information at the package level, your firm lacks documented procedures for utilizing these systems to comply with the enhanced verification requirements. These systems are used on all human drug products manufactured at your firm that are subject to the DSCSA requirements.

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*DATES OF INSPECTION

4/07/2026(Tue), 4/08/2026(Wed), 4/09/2026(Thu), 4/10/2026(Fri), 4/13/2026(Mon), 4/14/2026(Tue), 4/15/2026(Wed), 4/16/2026(Thu), 4/17/2026(Fri), 4/21/2026(Tue)

X Divek R Jumani
Investigator
Signed By: Divek R. Jumani -S
Date Signed: 04-21-2026 13:04:25

X Simone E Pitts
National Expert
Signed By: SIMONE E. PITTS -S
Date Signed: 04-21-2026 13:05:14

X Vivin George
Investigator
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EMPLOYEE(S) SIGNATURE
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Divek R Jumani, Investigator
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Investigator
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Date Signed: 04-21-2026 13:03:31

DATE ISSUED
4/21/2026

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."