DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/30/2019-8/7/2019* FEI NUMBER 3004575449

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kristin M. Defife, St. VP of Operations & Site Head

FIRM NAME	STREET ADDRESS
Ajinomoto Althea, Inc.	11040 Roselle St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92121-1205	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

The quality control unit lacks the responsibility and authority to approve and reject all drug products.

Specifically,

The Quality Unit does have responsibility and authority to approve and reject all drug products; However, drug product lots found to be associated with faulty connectors resulting in stainless steel corrosion particulates were not always rejected.

For example, (b) (4) Injectable drug product lots produced from on or about January – February 2018 were investigated due to a higher incidence of particulate rejects found during (b) (4) visual inspection. The firm's investigation into these particulates ultimately determined the root cause to be associated with corroded (b) (4) within connectors used to connect the (b) (4) drug product vessel to the (b) (4) setup and/or filling line. Drug product lots produced during this time were not always rejected.

OBSERVATION 2

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joey V Quitania, Investigator Santiago Gallardo Johnson, Generic Drug User Fee Amendments (GDUFA)	X Joey V Quitania Investigator Signed By: Joey V. Quitania -S Date Signed: 08-07-2019 17:06:48	8/7/2019

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The firm's investigation SOP-0980, Rev 000, "Conducting cGMP Investigations" states in section 7.3.1.2 to assess the impact on other processes, procedures, products, or patients, however, investigation reports reviewed do not always document the assessment of whether this requirement to extend the investigation to other batches of the drug product and/or other drug products which may have been similarly affected was performed.

***DATES OF INSPECTION**

7/30/2019(Tue), 7/31/2019(Wed), 8/02/2019(Fri), 8/05/2019(Mon), 8/06/2019(Tue), 8/07/2019(Wed)

X Santiago Gallardo Johnson
Generic Drug User Fee Amendments (GDUFA)
Signed By: Santiago Gallardo Johnson -S
Date Signed: 08-07-2019 17:07:29

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Joey V Quitania, Investigator Santiago Gallardo Johnson, Generic Drug User Fee Amendments (GDUFA)	X Joey V Quitania Investigator Signed By: Joey V. Quitania -S Date Signed: 08-07-2019 17:06:48	8/7/2019

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."