

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857	DATE(S) OF INSPECTION 10/23/2023-10/27/2023
	FEI NUMBER 3002809620

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Tadshi Hakomori , General Manager

FIRM NAME Astellas Pharma Inc.	STREET ADDRESS 180, Ozumi
CITY, STATE, ZIP CODE, COUNTRY Yaizu, Shizuoka, 425-0072 Japan	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:
OBSERVATION 1
Complaint records are deficient in that they do not include the findings of the.

Specifically,

A review of your market complaints revealed a lack of scientifically sound justification for the root cause. For example, the following market closed complaints for (b) (4) mg and (b) (4) mg were related to lack of effect in which the root cause could not be identified:

* 11/24/2022, market complaint #373593, (b) (4) mg, bulk batch # (b) (4) This bulk batch number (b) (4) had 4 market complaints reported on the following dates 11/24/2022, 01/05/2023, 01/24/2023, and 02/07/2023. Additionally, the market complaint investigation did not include any batch review, no analytical data review, and there was no review of the retain sample trending data.

* 05/21/2021, market complaint #316281, (b) (4) mg, bulk batch # (b) (4) This bulk batch number has had 5 market complaints reported on the following dates 05/19/2023, 05/21/2023, 06/06/2023, 07/11/2023, 07/28/2023, and 07/28/2023. Additionally, the market complaint investigation did not include any batch review, no analytical data review, and there was no review of the retain sample trending data.

* 07/28/2023, market complaint #397814, (b) (4) mg, bulk batch (b) (4) This bulk batch number had 2 complaints reported. However, the initial complaint for this bulk batch was on 07/04/2023. The stability data from March 2023 was utilized to determine “no root cause” for the 2 market complaints without conducting a comprehensive investigation. Additionally, the market complaint investigation did not include any batch review, no analytical data review, and there was no review of the retain sample trending data.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Michele Gottshall, Investigator	Michele Gottshall Investigator Signed By Michele Gottshall-0 Date Signed 10-27-2023 00 57 43 X	DATE ISSUED 10/27/2023