

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

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 4/1/2021-4/13/2021*
	FBI NUMBER 1000160561

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Harry T. Fan, Chief Executive Officer

FIRM NAME Stason Pharmaceuticals, Inc.	STREET ADDRESS 11 Morgan
CITY, STATE, ZIP CODE, COUNTRY Irvine, CA 92618-2005	TYPE ESTABLISHMENT INSPECTED 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
 Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

 Specifically, the firm performed quality review for 2020 and identified a trend with 11 deviations due to human errors, but did not provide follow up group training to help minimizing similar deviations from occurring again.

OBSERVATION 2
 The responsibilities and procedures applicable to the quality control unit are not in writing.

 Specifically, the firm uses an outside contract lab for all of their microbiological testing, but the written procedure used to evaluate the contract lab and the on site audit conducted in 2018 failed to include instructions and assessment of the microbiology lab.

***DATES OF INSPECTION**
 4/01/2021(Thu), 4/02/2021(Fri), 4/05/2021(Mon), 4/07/2021(Wed), 4/12/2021(Mon), 4/13/2021(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Truong X Nguyen, Investigator	Truong X Nguyen Investigator Signed By: Truong X. Nguyen-S Date Signed: 04-13-2021 14:12:11 X	DATE ISSUED 4/13/2021

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."