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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 158-15 Liberty Avenue<br>Jamaica, NY 11433<br>(718) 340-7000 Ext:5301 Fax:(718)662-5661 | 1/18/2017-1/25/2017*<br>FEI NUMBER<br>3011773798 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ajoy Joshi , CEO/ President

| FIRM NAME | STREET ADDRESS |
|---|---|
| Spirit Pharmaceuticals | 2004 Orville Dr N Ste 2 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Ronkonkoma, NY 11779-7645 | Pharmaceutical Packager/ Distributer |

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 fully followed.

Specifically:

1) Review of the firm's qualification report for bottle packaging line (b)(4) found that the performance qualification failed to identify the lot number of product used in the qualification operations. Further, when the rejection log was examined for a recording of the lot used in the qualification, there was no record of the rejected product. Finally, review of the inventory card which was requested found that the responsible individual reportedly recorded the wrong lot number.

2) The firm has had a large number of complaints of cloudiness/ crystallization in the softgel product (b)(4) and for specific lots such as manufacturer lot (b)(4) there was a large percentage of rejects and four customer complaints for lot (b)(4) However, although Spirit Pharmaceuticals, LLC internal communication dated April 5, 2016 states in reference to the supplier efforts that "Based on the evaluation done so far they have found the root cause that might be causing the re-crystallization and are in the process of making permissible manufacturing changes on (b)(4) and will implement the required changes to manufacturing process after evaluating pilot scale batches", review of quality system files found no documentation regarding communication of the results of the process changes and validation by the supplier. Spirit Pharmaceuticals, LLC quality management stated that they believe this has been done but would have to contact the supplier to confirm this and obtain supporting documentation to add to the file.

3) Review of randomly selected training reports for several employees who have supervisory roles found that recording of training on a number of procedures (SOPs) showed the training on those SOPs for

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Robert C Horan, Investigator<br>1/25/2017<br>X Robert C Horan<br>Robert C Horan<br>Investigator<br>Signed by: Robert C. Horan -S | 1/25/2017 |

those individuals was dated after the start of the current inspection. The current QA Director who has been at the firm for only one month stated that upon review of the training files, he wanted to insure that there was a record that those employees had been trained on the applicable procedures. It is also noted that this was not handled through a gap analysis/ CAPA procedure.

---

**OBSERVATION 2**

Routine checking of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically:

(b)(4) checking of the metal detectors employed on packaging lines does not employ non-ferrous metal challenges.

---

***DATES OF INSPECTION**

1/18/2017(Wed),1/19/2017(Thu),1/23/2017(Mon),1/24/2017(Tue),1/25/2017(Wed)

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."