DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 60 Eighth Street NE<br>Atlanta, GA 30309<br>(404) 253-1161 Fax:(404) 253-1202<br>Industry Information: www.fda.gov/oc/industry | 03/08/2012 - 03/09/2012 |
| | FEI NUMBER<br>1048698 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Matthew J. Ressner, Interim Plant Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| Hospira, Inc. | 8484 Us 70 Bus Hwy W |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Clayton, NC 27520-9465 | 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**

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.

Specifically,

A. Final Field Alert Report, dated 07/19/11, is associated with the presence of a particle in a vial identified during the (b) (4) retain inspection of Hospira Propofol (NDA 77-908) with Lot # 02-268-DJ. The aforementioned particle was retrieved from the product and submitted to the Hospira particle identification laboratory. The particle was identified to be a 1,200 micron size stopper particle. Additionally, a medical assessment provided by the Medical Director from Global Product Safety revealed the 1,200 micron size particle is not likely to result in patient injury in the absence of any smaller particles and could not be injected into the patient because of its size. Your firm failed to assess the potential of smaller particles being introduced into the product.

B. Final Field Alert Report, dated 02/24/12, is associated with the presence of a particle in a vial of Hospira Propofol (NDA 77-908), with Lot # 02-221-DJ, identified by a customer. The aforementioned particle was retrieved from the product and submitted to the Hospira R&D laboratory. The particle was identified to be a 3,950 micron size stopper particle. Additionally, a medical assessment provided by the Medical Director from Global Product Safety revealed the 3,950 micron size particle is not likely to result in patient injury in the absence of any smaller particles and could not be injected into the patient because of its size. Your firm failed to assess the potential of smaller particles being introduced into the product.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Viviana Matta, Investigator | 03/09/2012 |