



Inspection Report

Par Sterile Products Llc
6 Ram Ridge Road
Chestnut Rdg, NY 10977

Customer ID: **41952**

Certificate: **22-R-0141**

Site: 001

JHP PHARMAETICALS LLC

Type: ROUTINE INSPECTION

Date: 11-JUN-2015

2.32(c)(1)(1)

PERSONNEL QUALIFICATIONS.

At about 7:15 am on May 27th, animal facility workers found 35 dead guinea pigs in two rooms at the facility. The facility had increased temperature alarms starting at about 11:13 pm the night of May 26th. Security had informed facility maintenance of the increased temperature situation and maintenance worked to resolve the situation by around 6:00 am the morning of May 27th. Despite the high temperatures in a building housing animals, animal care personnel were not notified and no thought was given to the fact the guinea pigs were being exposed to high, potentially life threatening temperatures for an extended period of time. Records showed that temperatures were elevated for around 7 hours and peaked at a high of about 38 degrees Celsius. This is above the 85 degree Fahrenheit maximum mandated for indoor housing facilities for guinea pigs. One more guinea pig was found dead on May 28th and three more guinea pigs were euthanized. Necropsy reports showed gross pathology consistent with heat stress. It is the responsibility of the research facility to ensure that all personnel involved in animal care be trained in the basic needs of each species of animal housed or utilized at the facility. This lack of training resulted in unnecessary animal suffering and death. This training needs to be provided to facility personnel.

Correct by: Correct from this time forward. The facility has put in place immediate and long term corrective actions to ensure that this does not happen again.

3.26(a)

FACILITIES, INDOOR.

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Prepared By: KURT HAMMEL, D V M USDA, APHIS, Animal Care

Date:
15-JUN-2015

Title: VETERINARY MEDICAL OFFICER 1023

Received by Title: ASSOCIATE DIRECTOR QUALITY CONTROL

Date:
15-JUN-2015



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Correct by: Correct from this time forward. The facility has put in place immediate and long term corrective actions to ensure that this does not happen again.

This focused inspection was to address a facility self-reported incident resulting in the death of 39 guinea pigs.

Inspection and initial exit interview conducted on 6-11-15 with JHP responsible personnel. Formal exit interview conducted on 6-15-15 with PAR (JHP) responsible personnel.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
41952	22-R-0141	001	JHP PHARMAETICALS LLC	11-JUN-15

Count	Scientific Name	Common Name
000373	<i>Cavia porcellus</i>	DOMESTIC GUINEA PIG
000373	Total	