



Inspection Report

PORTOLA PHARMACEUTICALS, INC.

Customer ID: **24058**

Certificate: **93-R-0486**

Site: 002

270 EAST GRAND AVENUE, STE. 22

PORTOLA PHARMACEUTICALS, INC.

Type: ROUTINE INSPECTION

Date: Aug-27-2009

SO.SAN FRANCISCO, CA 94080

No noncompliant items were identified during this inspection.

Note:

This inspection was focused on regulated animals and their housing.

Prepared By:

MARCY E ROSENDALE, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Aug-31-2009

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Aug-31-2009



Inspection Report

PORTOLA PHARMACEUTICALS, INC.

Customer ID: 24058

Certificate: 93-R-0486

Site: 002

PORTOLA PHARMACEUTICALS, INC.

270 EAST GRAND AVENUE, STE. 22

Type: ROUTINE INSPECTION

Date: Jul-14-2008

SO.SAN FRANCISCO, CA 94080

2.31 (c) (7)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(c) IACUC Functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall: (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

Procedures were conducted on animals without IACUC approval as written in the amendment of Protocol PPI-005-08. A tracheotomy and euthanasia were performed on at least 2 animals without written approval or documentation from the IACUC allowing such procedure.. The amendment did not include the above mentioned procedure yet records indicated that it was performed. All procedures on animals must be approved prior to implementation. The IACUC would have required an alternatives search for the tracheotomy, as it a potential painful procedure. An alternative search may have lead to the procedure being conducted on a non animal substitute, reducing the number of live animals being utilized.

Correct by August 15, 2008.

2.31 (e) (2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used.

Protocol PPI-005-08 had an amendment covering training for procedures conducted within the protocol but did not include a justification for the number of animals that were used. In order for an IACUC to adequately review and approve amendments such as this, a justification for the numbers of animals should have been provided. The IACUC is required to determine and ensure that an appropriate numbers of animals are used in any procedure. The amendment reviewed and approved by the IACUC did not provide that information.

Prepared By:

MICHAEL J SMITH, D.V.M. USDA, APHIS, Animal Care

Date:

Title: SUPERVISORY ANIMAL CARE Inspector 5019

Jul-15-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jul-15-2008



Inspection Report

Correct by August 15, 2008

2.31 (e) (3)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following : (3) A complete description of the proposed use of the animals;

The amendment to Protocol PPI-005-08 did not include procedures that were performed during the training. The protocol stated that only two procedures would be performed 1) endotracheal intubation and 2) percutaneous catheter placement. These procedures would lead the IACUC to believe the procedures were survival and that the animals could be used in the actual protocol. Records reviewed indicated that other procedures were performed on the animals without IACUC approval. There were tracheotomies performed with subsequent euthanasia of the animals. Descriptions must be complete and contain all procedures performed on the animals.

Correct by August 15, 2008

Prepared By:

MICHAEL J SMITH, D.V.M. USDA, APHIS, Animal Care

Date:

Title: SUPERVISORY ANIMAL CARE Inspector 5019

Jul-15-2008

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jul-15-2008



Inspection Report

PORTOLA PHARMACEUTICALS, INC.

Customer ID: **24058**

Certificate: **93-R-0486**

Site: 002

PORTOLA PHARMACEUTICALS, INC.

270 EAST GRAND AVENUE, STE. 22

Type: ROUTINE INSPECTION

SOUTH SAN FRANCISCO, CA 94080

Date: Jul-18-2007

2.31 (d) (1) (ix)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(ix) Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions.

Surgical area for non-rodents is not operated nor maintained under aseptic conditions. The surgical room was used for storage of material and equipment and cleaned prior to a surgical procedure. In order to follow this section of the regulations surgical rooms must be operated and maintained under aseptic conditions.

Correct by September 1, 2007.

Prepared By:

MICHAEL J SMITH, D.V.M. USDA, APHIS, Animal Care

Date:

Title: SUPERVISORY ANIMAL CARE Inspector 5019

Jul-18-2007

Received By:

(b)(6), (b)(7)(c)

Date:

Title:

Jul-18-2007