



Inspection Report

Portola Pharmaceuticals Inc.
270 East Grand Avenue, Ste. 22
South San Francisco, CA 94080

Customer ID: **24058**

Certificate: **93-R-0486**

Site: 002

PORTOLA PHARMACEUTICALS, INC.

Type: ROUTINE INSPECTION

Date: 07-FEB-2019

2.31(e)(2)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A newly approved protocol, number PPI-010-18 regarding the collection of blood for use in drug development studies and procedures, does not contain an adequate rationale to explain the number of guinea pigs and rabbits requested annually.

The protocol specifies that 36 rabbits and 75 guinea pigs are needed annually for the next three years. The rationale given for these numbers in the proposal states: "Although few animals were used under this protocol in the past year, it remains important to be able to supply blood and plasma upon request for the various research programs at Portola. The numbers of animals cited in this protocol reflect the expected use in 1 year's time based on previous years records." The protocol lists previous animal use numbers: 2017-2018: 0 guinea pigs and 0 rabbits; 2016-2017: 0 guinea pigs and 6 rabbits; and 2015-2016: 0 guinea pigs and 2 rabbits. There is no explanation as to how it was determined that they would need 36 rabbits and 75 guinea pigs per year.

The Institutional Animal Care and Use Committee (IACUC) should not approve a proposal to conduct an activity involving animals unless that proposal contains a rationale for the numbers of animals to be used. It is the role of the IACUC to be thoughtful about requests to use animals for studies. Failure to ensure that the protocol contains a clear explanation for the number of animals requested could result in unnecessary acquisition and usage of animals.

To be corrected from this time forward.

This inspection and exit interview were conducted with the facility representative.

Prepared By:

SMITH PAMELA, D V M

SMITH PAMELA, D V M USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL OFFICER 6036

Date:

07-FEB-2019

Received By:

Title:

Date:

07-FEB-2019



Species Inspected

| Cust No | Cert No | Site | Site Name | Inspection |
|---------|-----------|------|-------------------------------|------------|
| 24058 | 93-R-0486 | 002 | PORTOLA PHARMACEUTICALS, INC. | 07-FEB-19 |

No Animals were Inspected.

| Count | Scientific Name | Common Name |
|--------|-----------------|-------------|
| 000000 | NONE | NONE |
| 000000 | Total | |