



Inspection Report

ELAN PHARMACEUTICALS, INC.

Customer ID: 1117

Certificate: 93-R-0280

Site: 001

800 GATEWAY BLVD.

ELAN PHARMACEUTICALS, INC.

Type: ROUTINE INSPECTION

Date: Feb-04-2010

SOUTH SAN FRANCISCO, CA 94080

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 the appropriateness of the species of animals to be used.

Protocols GP-130-05-09 and GP-PK-02-07 did not contain rationales for the appropriateness of the species of the animals to be used in the study.

A system should be in place to ensure that a rationale for the appropriateness of the species of animals to be used in an activity is included in proposals to conduct activities involving animals in order that the IACUC may assess said rationale.

Correct by April 8, 2010.

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.

IACUC approved protocol GP-PK-02-07 did not provide a maximum quantity of blood that could be safely withdrawn over the entire course of the study. A 24 hour maximum was provided, however the written protocol did not provide a definitive end-point for blood withdrawal. A maximum total amount of blood that may safely be withdrawn for the animals being used in the study should be included in the description provided by the investigator.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5039

Feb-05-2010

Received By:

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

Date:

Title:

Mar-08-2010



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A system should be in place to ensure that a complete description of the proposed use of animals is included in protocols prior to being approved by the IACUC.

Correct by April 8, 2010.

Sec. 2.31 Institutional Animal Care and Use Committee (IACUC).

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing; Further, the IACUC shall determine that the proposed activities or significant changes in ongoing activities meet the following requirements:

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e. g., the Animal Welfare Information Center, used to determine that alternatives were not available.

Two IACUC approved protocols did not include written narrative descriptions of the methods and sources used to determine that alternatives were not available. Protocols GP-130-05-09 and GP-PK-02-07 included procedures that may cause more than momentary or slight pain or distress to the animals yet did not provide a written narrative description of searches for alternatives to those procedures.

Failure to include this information limits the IACUCs ability to determine whether or not the investigator has made an adequate effort to determine the availability of alternatives to the activity. A system should be in place to ensure that searches for alternatives are included in protocols so that they may be considered by the IACUC prior to protocol approval.

Correct by April 8, 2010.

Prepared By:

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

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Feb-05-2010

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Mar-08-2010



Inspection Report

ELAN PHARMACEUTICALS, INC.

Customer ID: **1117**

800 GATEWAY BLVD.

Certificate: **93-R-0280**

Site: 001

LABORATORY ANIMAL FACILITY

SO.SAN FRANCISCO, CA 94080

Type: ROUTINE INSPECTION

Date: May-07-2008

No non compliances identified during this inspection.

Prepared By:

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

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 5019

May-07-2008

Received By:

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Date:

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May-07-2008