



Inspection Report

GENEVA LABORATORIES, INC.

Customer ID: **639**

Certificate: **35-R-0034**

Site: 001

GENEVA LABORATORIES

P.O. BOX 140

Type: ROUTINE INSPECTION

ELKHORN, WI 53121

Date: Jun-22-2010

No non-compliant items identified during this inspection.

Inspection and exit briefing conducted with the Quality Assurance Director.

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Jun-23-2010

Received By:

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

Date:

Title:

Jun-23-2010



Inspection Report

GENEVA LABORATORIES, INC.

Customer ID: 639

Certificate: 35-R-0034

Site: 001

GENEVA LABORATORIES

P.O. BOX 140

Type: ROUTINE INSPECTION

ELKHORN, WI 53121

Date: Apr-29-2010

2.31 (d) (1) (ii)

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; Provided, however, That field studies as defined in part 1 of this subchapter are exempt from this requirement. 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;.....

**Question #9 in Protocol CL1003 indicates there was no search for alternatives performed although the procedure has the potential to cause more than momentary pain and/or distress to the animal(s). The principal investigator having not conducted an alternative search does not assure that there are less painful procedures available.

**It is the responsibility of the IACUC to ensure that the principal investigator has considered alternatives to procedures that may cause more than momentary pain and/or distress to the animals as set forth in this section in order to promote the health and well-being of the animals.

Correct by June 14, 2010

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Apr-30-2010

Received By:

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

Date:

Title:

Apr-30-2010



Inspection Report

2.31 (d) (1) (iv) (A) **REPEAT**

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;.....

.....**Although the reviewed protocol (CL1003) contained several changes, Question #9 still indicated no pain even though there is the potential for more than momentary pain and/or distress to the animal(s). The principal investigator must properly classify the pain category in order to assure that the potential for pain and/or distress will be appropriately minimized with the appropriate sedatives, analgesics and/or anesthetics.

**It is the responsibility of the IACUC to review those activities involving animals that may cause more than momentary pain and/or distress to ensure the appropriate anesthetics and analgesics are utilized in order to promote the health and well being of the animals as set forth in this section.

Inspection and exit interview conducted with the Director.

THIS IS AN AMENDED COPY OF INSPECTION REPORT #119100636490397 DATED APRIL 29, 2010.

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Apr-30-2010

Received By:

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

Date:

Title:

Apr-30-2010



Inspection Report

GENEVA LABORATORIES, INC.

Customer ID: 639

Certificate: 35-R-0034

Site: 001

GENEVA LABORATORIES

P.O. BOX 140

Type: ROUTINE INSPECTION

ELKHORN, WI 53121

Date: May-26-2009

2.31

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

**Although the reviewed protocol (CL1003) indicated an agent may be used to relieve pain and/or distress to the animal(s), several discrepancies were noted:

-Question #9: no pain was marked although there is the potential for more than momentary pain and/or distress to the animal(s).

-Question #9.4 in the protocol refers to the possible use of anesthetics prior to the procedure, however, use of analgesics after the procedure is performed to relieve pain and/or distress to the animals is not addressed.

-Question #13.3 in the protocol refers to withdrawing animals that have experienced significant symptoms, however, does not address the relief of pain and/or distress for animals that do not fall in that category.

**It is the responsibility of the IACUC to review those activities involving animals that may cause more than momentary pain and/or distress to ensure the appropriate anesthetics and analgesics are utilized in order to promote the health and well-being of the animals as set forth in the section.

Correct by June 26, 2009

Inspection conducted with the Director.

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

May-26-2009

Received By:

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

Date:

Title:

May-26-2009



Inspection Report

GENEVA LABORATORIES, INC.

Customer ID: **639**

Certificate: **35-R-0034**

Site: 001

GENEVA LABORATORIES

P.O. BOX 140

Type: ROUTINE INSPECTION

ELKHORN, WI 53121

Date: Jun-05-2008

No non-compliant items identified during this inspection.

Inspection conducted with the study director and inspector of record.

Prepared By:

DAWN E BARKSDALE, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1062

Jun-05-2008

Received By:

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

Date:

Title:

Jun-05-2008