



Inspection Report

BRIDGE GLOBAL PHARMACEUTICAL

Customer ID: **21555**

610 PROFESSIONAL DRIVE

Certificate: **51-R-0079**

Site: 001

BRIDGE GLOBAL PHARMACEUTICAL

GAITHERSBURG, MD 20879

Type: ROUTINE INSPECTION

Date: Jan-22-2009

NO NON-COMPLIANT ITEMS IDENTIFIED THIS INSPECTION.

Prepared By:

GLORIA S MCFADDEN, D V M USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jan-22-2009

Received By:

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

Date:

Title:

Jan-22-2009



Inspection Report

BRIDGE GLOBAL PHARMACEUTICAL SERVICES INC

Customer ID: 21555

Certificate: 51-R-0079

Site: 001

BRIDGE GLOBEL

610 PROFESSIONAL DRIVE

Type: ROUTINE INSPECTION

GAITHERSBURG, MD 20879

Date: Jan-17-2008

2.31 (d) (1) (ii)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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:

- 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; (Also refer to Policy 12, Written Narrative for Alternatives to Painful Procedures)

***Protocol 1648-06300: The literature search statement is "none exist for the type of test article used". There is no supporting documentation that an adequate literature search was performed. A literature search must be performed for alternatives to ensure that animals are not unnecessarily subjected to pain and distress. Correct with all subsequent protocols from this client. NOTE: This study was completed in March 2007.

2.31 (e)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

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

*** Protocol 1648-06300: The number justification simply states "sufficient to determine biological/statistical significance". This justification is insufficient to determine that the minimum number of animals necessary will be used. A justification of numbers must address reduction to ensure appropriate animal use and/or should reference the study design and statistical analysis process/program. Correct with all subsequent protocols from this client.

Prepared By:

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Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jan-23-2008

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

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Jan-24-2008



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NOTE: This study was completed in March 2007.

2.33 (a) (2)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

***SOP 0301.01/4 Request for Veterinary Care outlines the chain of command for the veterinary care of animals. It includes a statement regarding study director approval and IACUC approval when there is a difference of opinion regarding appropriate veterinary care for a study animal. The attending veterinarian must have the appropriate authority regarding veterinary care to ensure compliance with the regulations of the Animal Welfare Act that mandates that animals are not subjected to unnecessary pain/distress. The veterinarian must be given authority regarding veterinary care to ensure animals do not suffer unnecessarily and that authority must be reflected in the facility standard operating procedures and followed accordingly. Correct by January 31, 2008.

***Protocol 1619-06691 Animal #14853: On 9/4/07, the attending veterinary developed a care plan for this animal, which included IM buprenorphine to start on 9/5/07. Buprenorphine treatment did not start until 9/7/07, after study director consultation and approval. The current practice of obtaining study director approval resulted in a delay in carrying out the prescribed treatment plan and unnecessary suffering for the animal. The attending veterinarian must have the authority to ensure adequate veterinary care for the well-being of the animal. The veterinarian must be given the authority to relieve pain and suffering unless prior IACUC protocol review and approval indicates differently for scientific reasons. A mechanism that ensures the attending veterinarian has the appropriate authority must be established. Correct by January 31, 2008.

2.36 (b) (1)

ANNUAL REPORT.

The annual report shall assure that professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by the research facility.

***Two (2) animals under protocol 1648-06300 were reported on the FY07 annual report under pain and distress category D. Based upon notations in the daily observations and veterinary request forms, these animals should have been reported under category E for pain and distress. Research facilities must have a mechanism in place for ensuring that animals are reported in the appropriate pain and distress category on the Annual Report (APHIS Form 7023). To correct this non-compliant item, an amended annual report must be sent to the USDA Administrator for the Eastern Region by February 24, 2008.

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Date:

Title: VETERINARY MEDICAL OFFICER Inspector 1048

Jan-23-2008

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

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Jan-24-2008



Inspection Report

2.36 (b) (7)

ANNUAL REPORT.

The annual report shall state the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report.

***Two (2) animals under protocol 1648-06300 experienced study compound related affects that resulted in some degree of pain and or distress. No treatment was administered to relieve these symptoms. Neither the protocol nor any amendments provided justification for withholding veterinary care for these animals to minimize pain and distress. These animals fall under Category E for pain and distress, not category D, as indicated in IACUC records and the annual report for FY07. The animal study protocol should be amended to reflect any change in the pain and distress category to ensure the annual report to the USDA is accurate. To correct this non-compliant item, a mechanism must be established to ensure animals are reported under the appropriate pain/distress category on the annual report and an amended annual report must be sent to the USDA Administrator for the Eastern Region by February 24, 2008.

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GAITHERSBURG, MD 20879

Date: Jul-24-2007

2.31 (e) (1)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the identification of the species and the approximate number of animals to be used.

***Protocols 1675-06989 and 1619-06843: The justification of numbers respectively states "sufficient number to determine biological significance" or "number of animals is the minimum necessary by the study director for statistical evaluation of the data?". The statement of justification is insufficient to determine that the minimum number of animals necessary will be used. A justification of numbers must address reduction to ensure appropriate animal use and/or should reference the study design or statistical analysis process/program. Correct by August 2, 2007 and with all subsequent studies.

2.131 (b) (1)

HANDLING OF ANIMALS.

Handling of all animals shall be done as expeditiously and carefully as possible in a manner that does not cause trauma, overheating, excessive cooling, behavioral stress, physical harm, or unnecessary discomfort.

***Four animals (A16955, A17925, A18099, A18287) were diagnosed with a broken arm. The incidences occurred during the process of dosing or weighing on 3/24/2007, 5/15/2007, and 6/07/2007. It is unknown if the animal on 4/09/2007 was injured during handling or while in its cage. Animals should be handled in such a manner to prevent trauma, physical harm, or unnecessary discomfort. Procedures to ensure animals are handled in a manner that prevents trauma or physical harm to the animals must be established and practiced for the animals comfort and well-being. Correction: This NCI was corrected through appropriate personnel changes, revision of handling procedures, and training.

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Jul-27-2007

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