



Inspection Report

CHARLES RIVER LABORATORIES INC

Customer ID: 1799

Certificate: 14-R-0144

Site: 016

CHARLES RIVER LABORATORIES - REDFIELD

251 BALLARDVALE ST

Type: ROUTINE INSPECTION

WILMINGTON, MA 01887

Date: Dec-07-2007

2.31 (d) (1) (iv) (A)

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

Section 2.31(d)(1)(iv)(A) - IACUC review of activities involving animals. The IACUC shall conduct a review of those components of the activities related to the care and use of animals. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedatives, analgesics or anesthesia, 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.

- The justification for withholding agents to relieve more than momentary pain or distress was not adequate in at least six protocols. The justification for study PIJ00002 read as follows: "(AN2690) is being evaluated for the treatment of Onychomycosis. The Food and Drug Administration, and comparable regulatory agencies in other countries, provide guidance on the conduct of single and repeat dose nonclinical toxicity studies needed to support human clinical trials of various durations. The guidance indicated that single and repeat dose toxicity studies should normally be conducted in two mammalian species (one non-rodent). This study is being conducted to support a clinical trial, and as such, a nonclinical toxicity of at least (9 months) in a (non-rodent) species is required. Refer to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use: Guidance for Industry, M3(R1) Nonclinical Safety Studies for the Conduct of Human Clinical Trials for Pharmaceuticals (<http://www.ich.org/LOB/media/MEDIA506.pdf>)." The other protocols reviewed had similar statements. These statements were not clear to the two inspectors present as to how this scientifically justifies not relieving more than momentary pain or distress. The document cited does not implicitly state that pain and distress cannot be relieved. Two IACUC members were asked where this document stated that pain and distress cannot be relieved, and neither of them had knowledge of this. The IACUC should insure that all protocols that do not allow for relief of more than momentary pain and distress be scientifically justified. The protocols reviewed during this inspection were NQS00036, WKP00009, HJE00004, XZA00017, PIJ00032, JUC00005.

To be corrected by: The next IACUC meeting for any protocol currently ongoing and on all future protocols.

Prepared By:

JEFFREY T BAKER, D.V.M. USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL OFFICER Inspector 4052

Dec-11-2007

Received By:

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

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Jan-07-2008



Inspection Report

2.33 (b) (3)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

Section 2.33(b)(3) - Attending veterinarian and adequate veterinary care. Daily observation of all animals to assess their health and well-being; provided, however, that daily observation of animals may be accomplished by someone other than the attending veterinarian; and provided, further, that a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

- There were at least nine animals with injuries that were not being treated at the time of inspection. Seven pigs on the same study had scratches and scrapes along the dorsum. One dog had an abnormality of the left eye that appeared similar to what is commonly called a 'cherry eye'. One rabbit had an ear with thickened and reddened skin. The ear also was warm to the touch and had multiple scabs. There was no documentation present that addressed these injuries or indicated that the attending veterinarian had been contacted. All animals should be observed daily and any veterinary care issues should be timely and accurately relayed to the attending veterinarian. The facility should insure that a program is place to insure that all injured animals receive prompt and adequate veterinary care. To be corrected immediately.

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