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SUMMARY

This inspection of Dr. David R. Young, Principal Investigator, was initiated in response to the FACTS Assignment #1303893 issued by the Premarket Compliance and Administrative Actions Team from the Division of Compliance of the Center for Veterinary Medicine. This inspection was conducted in accordance with the inspection assignment, the "Animal Clinical Studies" portion of Compliance Program 7348.811, and (b) (4) , Good Clinical Practice Guidance for Industry.

The inspection assignment directed me to review the data of the following study:

Protocol: (b) (4)

(b) (4)
Study No: (b) (4)
Sponsor: (b) (4)

Study Location: Young Veterinary Research Services (YVRS)
213 S. Roselawn Ave
Turlock, CA 95380

No samples were collected and no refusals were encountered. The previous FDA inspection was conducted in 2003 and was NAI.

ADMINISTRATIVE DATA

Inspected firm:	David R. Young
Location:	213 S Roselawn Ave Turlock, CA 95380-9166
Phone:	209-632-1919
FAX:	209-632-1929
Mailing address:	7243 East Ave. Turlock, CA 95380
Dates of inspection:	10/3/2011, 10/5/2011
Days in the facility:	2
Participants:	Ashar P. Parikh, Investigator

At the initiation of the inspection, I met with Dr. David R. Young, Principal Investigator/DVM, Corinne L. Young, Laboratory Manager, (b) (6), (b) (7)(C), Administrative Assistant, and (b) (6), (b) (7)(C), Assistant Animal Technician. I displayed my credentials and issued an FDA 482, Notice of Inspection, to Dr. Young.

HISTORY

YVRS is a company that conducts research studies on animals. They began their business around 1983. Dr. Young graduated from Veterinary school in 1986 and began conducting research studies on animals. In 1997 Dr. Young took over YVRS from his father.

The 7243 East Ave location is where the home office is located for the company. This is also the location where studies that consist of large animals are conducted. Test articles are received, stored, and shipped back to the sponsor from this location.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

I issued the FDA 482 to Dr. Young as he was the principal investigator for the (b) (4) study and the most responsible individual involved with the study. Dr. Young's duties included allocation of study cats, conducting pretrial physical exams, administering the treatment medications (and controls), and verifying randomization was done properly. Dr. Young was not (b) (4) for this study.

(b) (6), (b) (7)(C), Administrative Assistant, was the backup treatment administrator but she did not administer any medications to the study cats. (b) (6), (b) (7)(C) established the observation time schedule that the technicians were to follow during the study. She was also responsible for reconciling study medications. (b) (6), (b) (7)(C) was not (b) (4) for this study.

(b) (6), (b) (7)(C), (b) (6), (b) (7)(C), (b) (6), (b) (7)(C), and (b) (6), (b) (7)(C), were the study technicians for this study. They were responsible for health observations and counting fleas. The study technicians were (b) (4) for the study.

(b) (6), (b) (7)(C), Technician, was responsible for observing the temperature and conditions of the study articles.

Corinne Young serviced as the verifier during the study. She reviewed data and documents to ensure they were accurate.

FIRM'S TRAINING PROGRAM

The site had protocol training on May 6, 2010. This training included reviewing (b) (4), the study protocol, and study forms. (b) (6), (b) (7)(C) trained the Technician's on the relevant sections of the protocol. The training records I reviewed at the study site were included with the Young CD Package provided to me in the assignment.

STUDY SITE OPERATIONS

The study protocol used at the site was the same protocol that was submitted by the sponsor. The facilities where the study cats were housed are appropriate and during a walkthrough of the facility the cats appeared to be in good health. The cats were identified by (b) (4) on their (b) (4). If the (b) (4) were not easily visible, the cats were given a collar with their ID number on them. The investigators final report was included in the information provided to me by CVM through the assignment therefore I did not collect a copy of it.

The original source data was not present at the site during the inspection. Dr. Young indicated that the source data was stored with the sponsor. The information that I reviewed were compiled by the sponsor after they reviewed the final data. Dr. Young informed me that the information I was reviewing was exact copies of the original source data. He provided me with a copy of the YVRS

Chain-of-Custody page which states that for the data listing "Certified copies of the raw data and Quality Assurance Statement have been retained by YVRS". (Exhibit #1) He also provided me with the YVRS Chain-of-Custody page for the final report. (Exhibit #2)

I obtained a copy of the IACUC submission and approval (Exhibit #3). The protocol was approved and the investigator was notified on May 7, 2010. I also collected a copy of the IACUC organizational chart (Exhibit #4).

Group observations on the cats' health were obtained at the appropriate time intervals during the study. The cats were observed(b) (4) . In the(b) (4) , the cats' health was observed as a(b) (4), and during the(b) (4) , the cats were observed (b) (4) . The cats were observed to determine their(b) (4) and to see if they had(b) (4) . One issue that was observed was that the (b) (4) time observation for Cat #s(b) (4) and (b) (4) was listed as(b) (4) and (b) (4) respectively. According to the Observation Target Times page (Exhibit #5), the times should have been(b) (4) and(b) (4). The times that are listed are out of window. I informed Dr. Young of this issue and he informed me that it must have been an entry error because the times around the observation of these cats were done at the correct time. I obtained a copy of the Treatment Day Animal Observations for the (b) (4) observation timepoint for these two cats (Exhibit #6)

(b) (4) cats were preselected on day (b) (4)) and these cats were(b) (4) These cats were(b) (4) . The(b) (4) . The(b) (4) cats that had the (b) (4) were used in the study. This was documented on the(b) (4) page (Exhibit #7) and this ranking was used to determine the treatment for the cat which is documented on the(b) (4) form (Exhibit #8). I reviewed the ranking and it was done properly. The top(b) (4) cats were(b) (4) and then (b) (4) on day -1. The cats were treated with (b) (4) The dosage amount was determined by each cat's (b) (4) and I did not find any discrepancies with how the dosage was calculated. On day 1 the(b) (4) The(b) (4) . (b) (4) . The(b) (4) were reported accurately for allthedays (day -7, 1, 7, 14, 30, and 37).

The scale was verified prior to cats being(b) (4) . I collected a copy of the Scale Verification Record (Exhibit #9). The animal(b) (4) reported were accurate. I collected a copy of the Animal(b) (4) record (Exhibit #10).

Dr. Young informed me that they do not use cats for studies if they have participated in another study within the past(b) (4) . The vaccination history for the cats included mainly two vaccines, (b) (4)

(b) (4) I collected copies of the package for the (b) (4) (Exhibit #11) and the (b) (4) (Exhibit #12).

Cat ID # (b) (4)

(b) (4)

All the cats in the study met the inclusion/exclusion criteria. None of the cats were given other drugs or vaccinated during the study. (b) (4), and (b) (4) were given (b) (4) the day before they were pre-selected for the study.

The technicians were (b) (4) during the study but Dr. Young and (b) (6), (b) (7)(C) were not. Nothing was observed to indicate that the (b) (4) of the technicians was compromised. The two adverse events that were experienced during the study were reported. During my review, I did not discover any

unreported adverse events. All of the cats that were allocated to the study, completed the study. All of the cats that were used in the study are strictly used for research purpose only. Approximately (b) (4) of the cats were from the YVRS colony and (b) (4) were purchased from an outside supplier, (b) (4).

The study medication was received and stored at the home office located at 7243 East Avenue, Turlock, CA. I reviewed the drug accountability logs and no issues were discovered. The cats were (b) (4) by a (b) (4) to ensure that the study medication was delivered properly.

Two other studies were conducted using (b) (4). These two studies were sponsor study (b) (4) entitled (b) (4) and study (b) (4) entitled (b) (4). I obtained the final study report for both of these studies. (Exhibit #13 and Exhibit #14)

Dr. Young does not conduct any studies that are subject to FDA GLP regulations. There are currently four FDA clinical studies that are being conducted by Dr. Young. Three of the studies are being conducted for (b) (4) and the other study is being conducted for (b) (4).

Study #	Sponsor	Study Title
(b) (4)		

DATA AUDIT

I reviewed animal information (Animal ID#, age, gender), weights, dosing, (b) (4), allocation, adverse events, treatment dosage amount, and disposition. No discrepancies were found.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

There were no objectionable conditions. No FDA 483 was issued to the study site.

REFUSALS

There were no refusals.

GENERAL DISCUSSION WITH MANAGEMENT

The closeout meeting consisted of Dr. Young and I. We discussed the data entry error for Cat #s (b) (4) and (b) (4). Dr. Young reaffirmed that the time was entered incorrectly.

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

1. Chain-of-Custody page for the original raw data and Quality Assurance Statement
2. Chain-of-Custody page for the Final Study Report
3. IACUC Submission and Approval (9 pages)
4. IACUC Organizational Chart dated 26 MAR-09
5. Post-Dose Observation Target Times
6. Treatment Day Animal Observations for (b) (4) Timepoint
7. Animal Ranking by (b) (4)
8. Ranking and Allocation Form
9. Scale Verification Record
10. Animal (b) (4) (2 pages)
11. Copy of (b) (4) Vaccine Box
12. Copy (b) (4)
13. Final Study Report for Study (b) (4) (62 pages)
14. Final Study Report for Study # (b) (4) (86 pages)

ATTACHMENTS

Copy of Assignment, FACTS #1303893
FDA 482, Notice of Inspection

Ashar P. Parikh, Investigator