

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

| | |
|---|--|
| DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA 4040 North Central Expressway #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 10/3-5/11; 10/13/11; 2/3/12 |
| | FEI NUMBER 3008790859 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Joseph M. Landers, President and owner

| | |
|---|--|
| FIRM NAME Weatherford Compounding Pharmacy LLC | STREET ADDRESS 175 College Park Drive #175 |
| CITY, STATE AND ZIP CODE Weatherford, TX 76086 | TYPE OF ESTABLISHMENT INSPECTED Veterinary Compounding Pharmacy |

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION#1

Documentation was not provided to demonstrate that your firm has conducted media fills to validate the sterilization process for compounded sterile preparations (CSP's) for parenteral use. Some recent examples of compounded sterile preparations shipped to consignees consist of the following:

- A. Enrofloxacin 150mg/Flunixin 17mg/Vitamin B12 500mcg/ml, lot #EFB0911 (Expiration date: 3/12) was compounded on 9/6/11 and shipped to a consignee on the same date.
- B. Ceftiofur 150mg/ml/Enrofloxacin 200mg/ml/Vit. B12 1000mcg/ml, lot #CFE110110 (Expiration date: 11/1/2011) was compounded on 11/30/10 and shipped to a consignee on the same date.
- C. Tulathromycin 50mg/ml/Ceftiofur 150mg/ml/Flunixin 25 mg/ml, lot #TCF111810 (Expiration date: 11/18/2011) was compounded on 2/17/11 and shipped to a consignee on the same date.

OBSERVATION #2

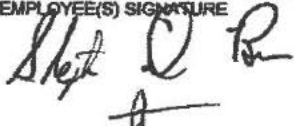
Your firm failed to provide data to demonstrate that the depyrogenation of glass vials and closures used in the compounding of sterile preparations has been conducted.

OBSERVATION #3

Documentation was not provided to demonstrate that your firm has conducted (b) (4) after compounding of sterile preparations has been performed.

OBSERVATION #4

Your firm failed to conduct investigations of potency failures for the following compounded sterile preparations:
 A. Ceftiofur 200mg/Flunixin 50mg/Vitamin B-12 1000mcg/ml, lot #CEF091010, had potency results of 73.9%

| | | | |
|--------------------------|--|---|---------------------------|
| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE  | EMPLOYEE(S) NAME AND TITLE (Print or Type) Stephen D. Brown, Investigator Anh Lac, Investigator | DATE ISSUED 02/03/2012 |
|--------------------------|--|---|---------------------------|

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

FDA
4040 North Central Expressway #300
Dallas, TX 75204
(214) 253-5200

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

10/3-5/11; 10/13/11; 2/3/12

FEI NUMBER

3008790859

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Joseph M. Landers, President and owner

FIRM NAME

Weatherford Compounding Pharmacy LLC

STREET ADDRESS

175 College Park Drive #175

CITY, STATE AND ZIP CODE

Weatherford, TX 76086

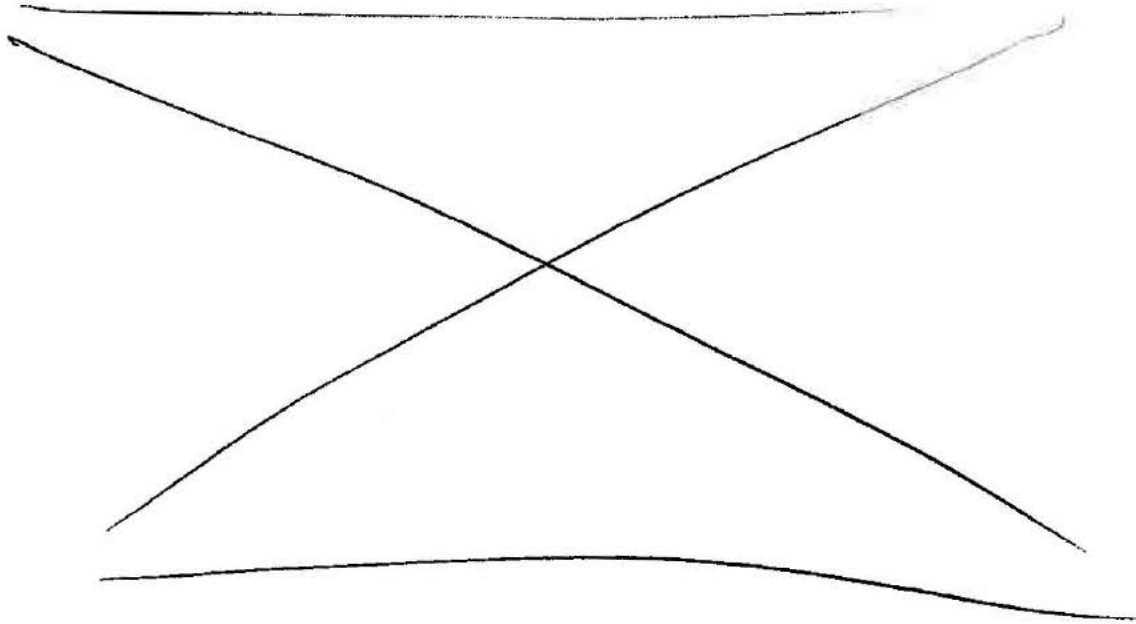
TYPE OF ESTABLISHMENT INSPECTED

Veterinary Compounding Pharmacy

(Specification: (b) (4) %) for Ceftiofur and 71.9% (Specification: (b) (4) %) for Flunixin Meglumine.
B. Tulathromycin 50mg/Ceftiofur 150mg/Flunixin 25mg/ml, lot #100814/20100502/70452C had potency results
of 132.8% (Specification: (b) (4) %) for Ceftiofur and 114.2% (Specification: (b) (4) %) for Tulathromycin.

OBSERVATION #5

Your firm failed to calibrate the (b) (4) scale (Manufacturer: (b) (4)) used in the weighing of raw materials and active pharmaceutical ingredients which are included in compounded sterile preparations.



SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

Stephen D. Brown
Anh Lac

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Stephen D. Brown, Investigator
Anh Lac, Investigator

DATE ISSUED

02/03/2012