

**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](http://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.

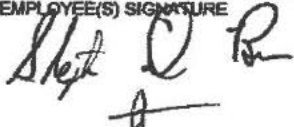
**OBSERVATION #3**

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

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

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

Stephen D. Brown, Investigator  
Anh Lac, Investigator

DATE ISSUED

02/03/2012