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  

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

FIRM NAME  
Weatherford Compounding Pharmacy LLC  

CITY, STATE AND ZIP CODE  
Weatherford, TX 76086  

STREET ADDRESS  
175 College Park Drive #175  

TYPE OF ESTABLISHMENT INSPECTED  
Veterinary Compounding Pharmacy  

DATE(S) OF INSPECTION  
10/3-5/11; 10/13/11; 2/3/12  

FEI NUMBER  
3008790859  

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 #CEF110110 (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%
TO: Mr. Joseph M. Landers, President and owner

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(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.

Stephen D. Brown, Investigator
Anh Lac, Investigator

02/03/2012