DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	10/12/12-11/08/12
	FEI NUMBER 3003644883

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Thomas C. Kupiec, Ph.D., CEO & President

FIRM NAME	STREET ADDRESS
ARL Biopharma, Inc. dba Analytical Research Laboratories	840 Research Parkway, #546
CITY, STATE AND ZIP CODE Oklahoma City, OK 75204	TYPE OF ESTABLISHMENT INSPECTED Contract Testing Laboratory

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:

The following observations pertain to the firm's contract testing of human drug products, including compounded drug products.

1. Your firm states on the Microbiology Report that is issued to a client after sterility and/or fungal testing that the Test Method employed was USP <71>. However, your firm is not fully following all parts of USP <71> when performing sterility and/or fungal testing of human drug products. For example,

a. USP <71> requires a Method Suitability Test be performed for all new products tested. Your firm does not have documentation to show that Method Suitability Testing has been performed for all drug products submitted for sterility testing by Ameridose, LLC and New England Compounding Center (NECC), both located in Massachusetts. For those drug products submitted by NECC and Ameridose, LLC, you have some documentation of bacteriostasis/fungistasis testing performed in 2006 & 2008 on a limited number of drug products, however there is no source documentation showing how the tests were performed, lot numbers of organisms or media used, and who performed the testing.

b. USP <71> specifies the number of articles to be tested. While you provide reference to USP <71> for sample sizes, you do not ensure that your clients are submitting the required number of articles for testing. Most clients usually submit only (b) (4) for sterility testing, including NECC and Ameridose.

2. Your firm has no documentation to show that all analytical methods used to test for potency (assay) have been validated for all drug products including drug products submitted for testing by NECC and Ameridose LLC. These include drug products such as Methylprednisolone Acetate, Heparin, Vasopressin, Triamcinolone Acetonide, and products containing Bupivacaine and Epinephrine. Analytical methods that are not validated and/ or not found in the USP that are used for potency testing of human drug products are not written, reviewed and approved.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Margaret M. Cinnes	Margaret M. Annes, CSO	11/8/12

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	10/12/12-11/08/12
	FEI NUMBER 3003644883

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Thomas C. Kupiec, Ph.D., CEO & President

FIRM NAME	STREET ADDRESS
ARL Biopharma, Inc. dba Analytical Research Laboratories	840 Research Parkway, #546
CITY, STATE AND ZIP CODE Oklahoma City, OK 75204	TYPE OF ESTABLISHMENT INSPECTED Contract Testing Laboratory

3. Your firm states on the Microbiology Report that is issued to a client after endotoxin testing that the Test Method employed was USP <85>. Your firm is not fully following all parts of USP <85> when performing endotoxin testing of human drug products.

Specifically, the Maximum Valid Dilution (MVD) is not always calculated using the formula in USP <85>. Your firm does not ensure that each of your clients provides information regarding dosing of the drug product needed to calculate the MVD. For example,

a. An endotoxin limit was not established for Clonidine/Ropivacaine (PF) 1mcg/1mg/ml in 500mL 0.9% Sodium Chloride (injectable) submitted as sample #186092-01 by NECC and tested for endotoxins on 9/4/12.

b. An endotoxin limit was not set for Baclofen PF (STOCK) 5000 mcg/mL Injection submitted as sample #184445-01 by NECC and tested for endotoxins on 9/4/12.

c. An endotoxin limit was not set established for CP2D submitted as sample #176189-01 by Ameridose and tested for endotoxins on 5/18/12.

4. Your firm has had 13 confirmed endotoxin failures for various drug products from October 2010-October 2012. There is no documentation of any investigations conducted into any endotoxin failures, including the failure of sample #186077-01 of Sodium Bicarbonate 150mEq/1000mL in Sterile Water for Injection that was submitted by NECC. SOP MBI-126 Microbiology Out-of-Specification Investigation (OOS), does not address investigation of OOS's for endotoxin testing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes	Margaret M. Annes, CSO	11/8/12