DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	02/19/2013 - 02/21/2013
	FEI NUMBER 3002596670

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Warren B. Lee, President and Owner

FIRM NAME	STREET ADDRESS
Lee and Company dba Lee Pharmacy, Inc.	4300 Grand Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Smith, AR 72904-7028	Producer of Sterile Drug Products

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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

A) Your firm's procedures for monitoring the ISO Class 5 are not suitable to ensure the quality of air. For example, your firm conducts no monitoring for viable and non-viable particles during aseptic filling of sterile drug products. The current practice of your firm is to conduct personnel monitoring (b) (4) monitor viable particulates via settling and contact plates (b) (4) and monitor for non-viable particulates (b) (4) all in static conditions.

B) Your firm lacks studies under dynamic conditions to ensure the flow pattern of filtered air in the ISO Class 5 area.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

A) Your firm has not performed any qualification studies on your (b) (4) For example, you have no (b) (4) studies or (b) (4) studies utilizing current loading patterns. (b) (4) are used to sterilize vials, septums, equipments, and drug product. Further, the process of sterilizing suspensions have not been validated.

B) Your firm has not established the process for sterilization of empty vials and septums (stoppers) intended for aseptically filling with sterile drug products. For example, there is no data to support the critical parameters of time (b) (4) exposure necessary to render the materials sterile. Moreover, there is a lack of establishing the loading pattern for vials and septums in the (b) (4)

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OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A) Your firm has no written procedures that establish aseptic technique of the operator while working in the aseptic areas during aseptic filling operations. For example, there are no directions for the changing of sterile gloves or the frequency of sanitization of sterile gloves during set-up and filling operations.

B) Your firm's SOP #7.1, approved 2/2/10, Validation of the Aseptic Technique, provides for filling (b) (4) 10 ml clear vials with media and incubating. However, your firm routinely fills up to (b) vials during aseptic operations, and fills 2, 10, 30 and 50 ml vials, and normally uses amber colored vials. Therefore, your current media fill studies do not represent actual aseptic filling operations.

OBSERVATION 4

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, there is no assurance that your firm has adequate process controls to prevent failures of your sterile drug product. For example, the sterilization processes for suspensions and solutions have not been design following a scientific rationale. Suspensions are (b) (4) sterilized in bulk prior to the aseptic filling process and solutions are filter sterilized with a sterile (b) (4) filter.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

A) Your firm has no scientific data to justify the assigned BUD (six months) at room temperature for any sterile injectable drug product, all of which contain a preservative. None of the formulations that you produce were placed on a stability program to determine an appropriate BUD period.

B) You firm failed to perform any anti-microbial effective testing to determine whether (b) (4) (b) (4) effectively inhibits microbial growth in your sterile injectable drug products through their BUD period. These preservatives are used in the manufacture of all of your sterile drug products.

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OBSERVATION 6

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically, your firm has no program for the evaluation of suppliers test results. Further, you conduct no independent testing of any raw material prior to use in producing sterile drug products.

OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, SOP #9.5, approved 1/22/03, Visual Examination of Sterile Preparation, requires that (b) (4) injectable preparation will be inspected after filling into the sterile vial. However, your firm's current practice is to only visually inspect the bulk product while contained in a IV bag while located in the ISO Class 5 hood.

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."