DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District Office 6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	1/12-14,16,20,21,26/2015
	FEI NUMBER 3011299928

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Amandeep Sharma, Pharmacist In Charge

FIRM NAME	STREET ADDRESS
Jungle Jim's Pharmacy	5440 Dixie Hwy
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fairfield, OH 45014	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 (I) (WE) OBSERVED:

OBSERVATION 1

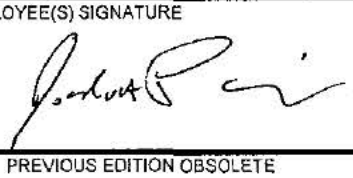
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

A. Specifically, validation studies have not been performed on the (b) (4), which is used to (b) (4) sterilize the pellet drug products such as Testosterone 100 mg. Studies utilizing (b) (4) have not been conducted to demonstrate the equipment's ability to adequately sterilize product.

According to the Log Report for 10/12/14 through 1/12/2015, batches of Testosterone 100 mg pellets vary in quantity from (b) (4) pellets; however the firm does not have validation studies that demonstrate consistency and repeatability with varying sized batch loads.

B. Specifically, according to the firm's Standard Operating Procedures for Pellet Compounding, the (b) (4) is (b) (4). The pharmacist stated that typically (b) (4) but there is no documentation of (b) (4).

C. Specifically, the (b) (4) used to assess (b) (4) do not accurately reflect the sterilization conditions of the pellet drug products, as the (b) (4) have a (b) (4) medium and the pellet products have an air medium.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Joshua P. Wireman, Investigator	01/26/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District Office 6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	1/12-14,16,20,21,26/2015
	FEI NUMBER 3011299928

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Amandeep Sharma, Pharmacist In Charge

FIRM NAME	STREET ADDRESS
Jungle Jim's Pharmacy	5440 Dixie Hwy
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Fairfield, OH 45014	Producer of Sterile Drug Products

OBSERVATION 2

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

Specifically, there is no written stability testing program in place to set appropriate expiration dates, continuously monitor the stability of batches on the market, and assess the on-going state of control of aseptic processing operations.

During the inspection, the firm was unable to provide data regarding the long term sterility and potency of drug pellet products to support the 6 month product expiration dates.

OBSERVATION 3

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, smoke studies were performed on the (b) (4) located in the clean room which was used in the production of sterile injectable products such as 17 Hydroxyprogesterone Caproate 250 MG/ML up until November 2014, and the vertical flow hood ((b) (4)) which was used to produce pellet ingredients such as Testosterone 80 mg. However, these smoke studies were not performed under dynamic conditions to verify that there is no obstruction or alteration of air that may contaminate the product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Joshua P. Wireman, Investigator	01/26/2015

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."