DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District 6751 Steger Drive Cincinnati, OH 45237 (513) 679-2700 Industry Information: www.fda.gov/oc/industry	06/05/2017 - 06/09/2017
	FEI NUMBER 3005457901

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Adam J. Israel, Manager

FIRM NAME	STREET ADDRESS
Gipsco Investment Corp. dba Lee Silsby Compounding Pharmacy	3216 Silsby Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cleveland Heights, OH 44118	Producer of sterile drug products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1) There is inadequate HEPA-filter coverage or airflow over the area to which sterile product is exposed, specifically, on May 5, 2017, we observed a gap, approximately ¼ inches, across the back of the HEPA screen in the (b) (4) laminar air flow hood which is used to fill syringes of sterile drug products. The gap appears to be larger than the syringes being filled, causing them to be below the level of ISO 5 airflow.

2) Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated and were observed with exposed skin during aseptic processing.
   a. The sterile gowns used by the technician filling syringes of sterile drug products are buttoned using her bare hands before sitting with her entire upper body in the ISO 5 area with exposed skin around her eyes.
   b. The gowns worn by the pharmacist producing sterile drug products are non-sterile, including the sleeves that actually enter the ISO 5 area.
   c. Both types of gown are removed, hung on hooks in the ISO 8 area, and then re-used throughout the day.

3) There is no evidence that the (b) (4) preservative used to provide (b) (4) blanketing for glutathione sterile drug products is of an appropriate quality for its intended use.

4) Personnel failed to disinfect or change gloves frequently enough to prevent contamination. Specifically, on 06/05/2017, the pharmacist producing hydroxycobalamin donned sterile gloves and then touched more than 20 items in the ISO 7 cleanroom before spraying his gloves with (b) (4) and then placing them in the ISO 5 area to produce sterile product without changing his gloves.

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		Matthew Casale, Investigator Jazmine Still, Investigator	06/09/2017

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5) Unsealed, loose ceiling lights were observed in your cleanroom. Specifically, the first light in the ISO 7 cleanroom, when entering from the ISO 8 anteroom, is not fully seated in its housing, causing a gap into the area behind the housing, and is not sealed.

6) Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.
   a. The pressure differentials between the ISO 7 cleanroom and ISO 8 anteroom are not monitored before, during, ~~or after~~ sterile drug production. MS 6/9/17 JMS 06/09/2017.
   b. There is a gap in the doors on both sides of the pass-through between the ISO 7 cleanroom and the supporting unclassified areas that allows palpable airflow between the areas.

7) ISO-5 classified areas were not certified under dynamic conditions. Specifically, the smoke studies performed to demonstrate the laminar air flow in the (b) (4) laminar air flow hood and (b) (4) laminar air flow cabinet used to produce sterile drug products do not have enough smoke to visualize the air flow at critical production areas and do reflect all types of operations performed in the areas.

8) The cycle parameters used for (b) (4) sterilization for products intended to be sterile are not lethal to heat-resistant microorganisms. For instance, the (b) (4) cycles intended to sterilize equipment used in the production of sterile drug products only reached a temperature of (b) (4) degrees Celsius for (b) (4) (b) (4) instead of the intended cycle of (b) (4) degrees Celsius for (b) (4), for (b) (4) cycle runs between 8/10/16 and 3/28/17.

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9) Biological indicators were not used to verify the adequacy of the sterilization cycle. Specifically,

a. The biological indicators that ensure cycle effectiveness in the (b) (4) intended to depyrogenate glassware used in sterile drug production and to (b) (4) sterilize hydroxyprogesterone sterile drug products have been incubated at temperatures of (b) (4) degrees Celsius, despite the fact that the instructions state that they are to incubated at (b) (4) degrees Celsius.

b. The biological indicators that ensure cycle effectiveness of the (b) (4) cycles intended to sterilize equipment used in the production of sterile drug products were incubated at (b) (4) degrees Celsius on 2/6/17, at (b) (4) degrees Celsius on 9/1/16, at (b) (4) degrees Celsius on 9/8/16, and (b) (4) degrees Fahrenheit ((b) (4) degrees Celsius) for (b) (4) different loads on 12/16/16, despite the fact that the instructions state that they should be incubated at (b) (4) degrees Celsius.

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