DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707 ORAPHARM1_RESPONSES@fda.hhs.gov	9/27/2021-10/8/2021* FEI NUMBER 3013352224

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Rebecca L. Harris, MBA, BSN, RN, Senior Director of Operations

FIRM NAME	STREET ADDRESS
InfuScience, Inc. dba Bioscrip Infusion Services	4151 Lafayette Center Dr Ste 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chantilly, VA 20151-1230	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

The ISO 5 classified aseptic processing areas had particle-generating and visibly dirty equipment or surface.

Specifically, on September 27, 2021, and October 4, 2021, we observed white spots on the HEPA diffuser screens of all (b) (4) laminar air flow hoods in the buffer room. The ISO 5 classified hoods supply (b) (4) HEPA airflow through the respective HEPA diffuser screens.

The white spots were not removed before or in between aseptic processing of all products produced in those hoods, such as Rx (b) (6) "TPN 3:1 1460 mL IV 15 Hours 6/week", Rx(b) (6) " (b) (4) b) (4)mg / (b) (4)ml NS Wk 0,2,6, then Q8wk", and Rx (b) (6) "DAPTOmycin 770mg in NS (b) (4)ml Q24H EP".

OBSERVATION 2

Personnel conducted aseptic manipulations in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, we observed purportedly sterile connections being made, in order to setup the ACD or replace empty product vials, in front of other component materials. For example, on September 27, 2021, the component product " (b) (4) " tubing connection was made in front of mounted vials containing (b) (4) and (b) (4) , blocking fist pass air. Similarly, on September 29, 2021, the component product (b) (4) " was made in front of mounted vials containing (b) (4) and (b) (4) .

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sena G Dissmeyer, Investigator Marcia D Fields, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 10-08-2021 15:54:28	10/8/2021

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Furthermore, your smoke studies do not provide assurance that first pass air is maintained for purportedly sterile connections made in front of other component materials.

OBSERVATION 3

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under dynamic operational conditions representative of your aseptic processing practices. Air visualization studies ("smoke studies") performed in your ISO 5 classified laminar airflow hoods, (b) (4) of which (Hoods (b) (4) are designated for total parenteral nutrition (TPN) preparations, did not demonstrate unidirectional airflow, for example, around hanging IV bags, and component materials such as vials and syringes mounted on the metal rack of the (b) (4) automatic compounding device (ACD). The metal rack consists of approximately (b) (4) poles and additionally, bags are hung on the bar within the hood. Your standard configuration setup for this ACD contains (b) (4) component product port connections, approximately (b) (4) of which are mounted to the metal poles. The smoke studies conducted in August 2021 were conducted with tubing connections made to one vial, one IV bag, and manipulation on the hood deck with one syringe. The ACD, including the metal rack, occupies approximately half the width of the respective hoods. The respective ACDs have been in use for the production of TPN products since installation in June 2021.

OBSERVATION 4

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

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Specifically,

A. Your facility's media fills do not represent the quantity and type of connections used to produce total parenteral nutrition (TPN) drug products using the (b) (4) automatic compounding device (ACD) as observed during production.

B. Your facility does not incorporate positive and negative controls to demonstrate growth promotion within your media fills.

***DATES OF INSPECTION**
9/27/2021(Mon), 9/28/2021(Tue), 9/29/2021(Wed), 9/30/2021(Thu), 10/01/2021(Fri), 10/04/2021(Mon), 10/05/2021(Tue), 10/08/2021(Fri)

X Marcia D Fields
Investigator
Signed By: Marcia D. Fields -S3
Date Signed: 10-08-2021 16:04:51

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Sena G Dissmeyer, Investigator Marcia D Fields, Investigator	X Sena G Dissmeyer Investigator Signed By: Sena G. Dissmeyer -S Date Signed: 10-08-2021 15:54:28	10/8/2021