DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd, Parsippany NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	06/19/17, 06/21/17, 08/02/17, 08/09/17, 08/15/17, 08/23/17, 08/31/17
	FEI NUMBER 3013505558

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Hank Incognito, R.Ph., Owner

FIRM NAME	STREET ADDRESS
Ideal Specialty Apothecary Inc., dba Ideal Pharmacy	2333 Morris Ave, Suite B101
CITY, STATE AND ZIP CODE Union, NJ 07083-5714	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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

OBSERVATION 1

The ISO-5 (b) (4) " (b) (4) ", for aseptic filling or repackaging of sterile drug products has a negative pressure gradient to the surrounding unclassified production room (observed at -0.117" WC on 06/19/17, -0.034" WC on 08/23/17, and qualified in "Negative Mode" on 04/28/17 and 07/11/17). There is no assurance that lower-quality air does not contaminate the environment when the (b) (4) (b) (4) must be opened for cleaning, or when (b) (4) . The (b) (4) is also not tested for leaks each time the (b) (4) . For production of Medroxyprogesterone Acetate 150mg/ml Intramuscular Injection Suspension ("MPA"), the (b) (4) sterilized (b) (4) is aseptically filled into (b) (4) vials inside the ISO-5 (b) (4) . There is no assurance that sterile drug product does not become contaminated by lower quality air from the unclassified room due to the negative pressure gradient.

For example, approx. (b) (4) vials of "MPA" were produced and aseptically filled in the (b) (4) as part of Batch (b) (4) on 04/27/17 (Beyond Use Date: 04/2018); and approx. (b) (4) vials of "MPA", Batch (b) (4) were produced and aseptically filled on 05/02/17 (BUD 05/2018). The most recent performance of Environmental Viable Particulate Test on 04/28/17 isolated low levels of Bacillus, Micrococcus, "Staphylococcus Coagulase (-)", "Other Fungi", and Basidiomycetes fungi in the unclassified room (active air samples: total 7 CFU/1000 liters on (b) (4) plate; and total 3 CFU/1000 liters on (b) (4) plate), and "Staphylococcus Coagulase (-)", Basidiomycetes fungi, and Cladosporium fungi in the (b) (4) for (b) (4) (active air samples: total 1 CFU/1000 liters on (b) (4) plate; and total 4 CFU/1000 liters on (b) (4) plate).

OBSERVATION 2

Non-sterile cleaning pads are used for initial cleaning of surfaces inside the ISO-5 (b) (4) , and we observed these stored in an open package, on a shelf in the unclassified room on 06/19/17. Additionally, a resealable pouch of pre-wetted sterile wipes is used for final cleaning; but the pouch may be used for more than one operation. There is no assurance that the sterile wipes remain suitable if the pouch is reused, and an expiration date after

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Nicholas Violand, Investigator Emmanuel J. Ramos, Investigator Zakaria Ganiyu, Investigator Neda Hamandi, Consumer Safety Officer	08/31/2017

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opening has not been established. A resealable pouch of pre-wetted wipes was observed in the (b) (4) on 06/19/17, but there was no production occurring at that time, and date of opening was not recorded on the pouch.

OBSERVATION 3

There is no assurance that the ISO-5 (b) (4) is certified under dynamic conditions representative of routine operations (performed (b) (4) . The certification was done by a contract company, and the use of (b) (4) to simulate manipulations is only described during particle counts, but not during airflow smoke pattern tests. Microbiological testing (b) (4)) of the environment does not appear to be performed under dynamic conditions, during any routine operations, and was not done as part of the (b) (4) requalification, performed following HVAC construction in the production room.

OBSERVATION 4

Media fill studies are performed, but are not designed to simulate routine processing. A kit is used for the media fill, which uses (b) (4) . The media fill lot size is approx (b) (4) but a routine batch may be as many as approx. (b) (4) Equipment such as a repeater pump and (b) (4) are not used during the media fill, but may be used in routine production. Finally, the routine process for Medroxyprogesterone Acetate Injection Suspension uses (b) (4) sterilization of (b) (4) followed by aseptic filling into (b) (4) , whereas the media fill uses (b) (4) sterilization.

OBSERVATION 5

Air handling design for the unclassified production room was observed to be inadequate on 06/19/17, in that the HEPA filters supplying air to the room are located adjacent to the returns, all of which are located on the ceiling. There is no assurance that air throughout the unclassified room has been adequately circulated.

OBSERVATION 6

On 06/19/17, we observed condensation forming on two of the HEPA units on the ceiling of the production room, which was dripping on the cart containing the (b) (4) . Additionally, one of the HEPA filters in the ceiling was observed to have a small yellow mark on the filter face. No production was occurring at that time.

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