

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 03/11/19, 03/12/19, 03/25/19, 03/26/19, 04/01/19 and 04/22/19 FEI NUMBER 3012223534
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Svetislav Milic, R.Ph- Pharmacist and Owner

FIRM NAME Colonia Care Pharmacy	STREET ADDRESS 515 Inman Avenue
CITY, STATE AND ZIP CODE Colonia, NJ 07067	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile and Sterile Drug Product

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:

OBSERAVTION 1

The ISO 5 classified area is located within a non-classified room (segregated production area).

Specifically, the ISO 5 classified (b) (4) located within a non-classified room which is not HEPA filter equipped. In addition, the ISO 5 classified (b) (4) is where sterile compounding operations are performed by personnel who move in and out of the unclassified room.

This is a Repeat Observation from previous inspection in 2016

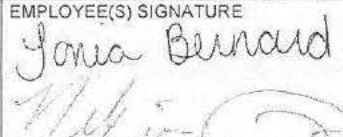
OBSERAVTION 2

Non-Pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, non-pharmaceutical grade components (b) (4) Corn Oil and (b) (4) Olive Oil were observed on the shelf with the firm's inventory barcode on the bottle. These components were used in the formulation of non-sterile veterinary drug products:

The following 1- prescription for veterinary drug was prepared using (b) (4) Corn Oil, Lot # (b) (4), Exp Date: 11/7/2019
 (b) (4) Cyclosporine 2% Ophthalmic Solution in Corn Oil (VET) 2%, Log Lot#(b) (4) , made date: 01/02/2018

The following 12- prescriptions for veterinary drugs was prepared using (b) (4) Olive Oil, Lot #: (b) (4) , Exp Date: 02/02/2018
 (b) (4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b) (4) , Lot # (b) (4) , made

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Tonia Bernard, Investigator Niketa Patel, Investigator	DATE ISSUED 04/29/19
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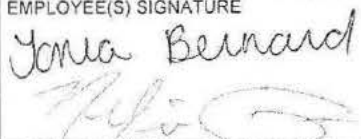

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date: 02/29/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 03/25/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 04/20/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 06/01/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 07/06/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 09/06/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 12/27/2016
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4), Lot # (b)(4), made date: 04/06/2017
 (b)(4) Atenolol Oil Suspension (Chicken Flavor) (Olive Oil) 12.5mg/ml, Log Lot# (b)(4) Lot # (b)(4), made date: 05/01/2017

OBSERVATION 3

The use of sporicidal agents in the cleanroom and/or ISO 5 area is inadequate or infrequent.

- a). The firm uses a re-sealable pouch of pre-wetted (b)(4) sterile wipes for cleaning of surfaces inside the ISO 5 classified (b)(4) which on 04/01/19, we observed that these pouches are used for more than one operation. There is no assurance that the sterile wipes remain sterile if the pouch is reused, and an expiration date after opening has not been established. A re-sealable pouch of pre-wetted wipes was observed in the ISO 5 classified (b)(4) on 04/01/19, but there was no production occurring at that time, and date of opening was not recorded on the pouch.
- b). On 04/01/19, we observed brown spots forming on the (b)(4) inside the ISO-5 classified (b)(4) used to hang

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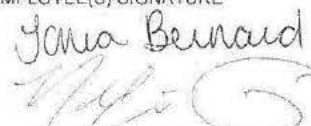

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the IV bags. According to the pharmacist these brown spots are due to the cleaning (b) (4) corroding (b) (4) over time. This ISO 5 classified (b) (4) is used for aseptic filling of sterile drug products.

c). Adequate smoke studies under dynamic conditions have not been performed to demonstrate unidirectional airflow in the ISO 5 area. On 04/01/19, it was observed that the (b) (4) (b) (4) sterile wipes, and a (b) (4) (b) (4) were stored inside the ISO 5 classified (b) (4). According to the pharmacist these items are stored in the ISO 5 classified (b) (4) and not removed because they are needed for the (b) (4) to clean the classified (b) (4). The ISO 5 classified (b) (4) air pressure is turned off when not in use. The smoke study video and report provided, dated 12/13/18, do not contain these items within the (b) (4).

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