	DEPARTMENT OF HEAL FOOD AND DRUG	G ADMINISTRAT		
DISTRICT ADDRESS AND PHON	NE NUMBER		DATE(S) OF INSPECTION	<u></u>
550 Main Stre			6/12/2023-7/5/202 Feinumber	3*
Cincinnati, (3014391500	
(513) 322-0700	Fax: (513) 679-2772			
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
	ancia, Pharmcist-In-Charge (P	PIC)		
FIRM NAME		STREET ADDRESS	6 (5 (1)) (1) (1) (1) (1) (1) (1) (1) (1) (
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Pharmacy				
CITY, STATE, ZIP CODE, COUN LOUISVILLE, H		Producer	of Sterile and No	n-Sterile Drug
observation, or have action with the FDA questions, please con	not represent a final Agency determination rega implemented, or plan to implement, corrective a representative(s) during the inspection or subm tact FDA at the phone number and address above	action in respon it this information	se to an observation, you may	discuss the objection of
OBSERVATIO	TION OF YOUR FIRM I OBSERVED:			
	ict post-use filter-integrity testing of	n filtere uce	d to sterilize drug prod	huets
	ter post-use inter-integrity resuling 0.	n micrs use	a to stermize drug prod	nucto.
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	a min and not conduct post-use [D		tosting of the (D)	10001
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	of the sterile finished drug products.	For examp		
	of the sterile finished drug products.	For examp	les: Testosterone Cypiona	
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	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street	6/12/2023-7/5/2023*
Cincinnati, OH 45202	FEI NUMBER
(513)322-0700 Fax: (513)679-2772	3014391500
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Manuel G. Francia, Pharmcist-In-Charge (P	IC)
FIRM NAME	STREET ADDRESS
New Vitalis Pharmacy LLC dba New Vitalis	4139 Cadillac Ct Ste 201
Pharmacy	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40213-1578	Producer of Sterile and Non-Sterile Drugs

OBSERVATION 2

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

a. Your media fill program is deficient in that your media fills are not representative of batch sizes and container types. Your media fills are performed in batch sizes of (b) (4) vials however your firm routinely prepares (b) (4) batches into 2mL and 5 mL vials of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL. In addition, your firm perform sterile to sterile production of sterile eye drop filled in a 10mL plastic dropper which requires some manipulations to add the caps while assembling the sterile dropper after aseptic filling of the droppers. This process has not been simulated in your media fill.

b. Media fills do not capture the worst-case processing conditions such as the number of aseptic manipulations in the hood. For example, bulk drug product is routinely (b) (4) in the (b) (4) Hood using (b) (4) into the (b) (4) bottle part of the (b) (4) unit and stored inside the ISO 5 BSC hood pending contract testing lab results. This duration may take (b) (4) . Bulk sample taken out of the ISO 5 BSC hood, through the ISO 7 hazardous (HD) cleanroom, into the non-HD ISO 7 cleanroom and reintroduced into an ISO 5 (b) (4) laminar flow hood (LFH) for filling operations. This process was not represented in you. media fill process for operators and ^{(0)(700,10)} Your pharmacist stated that that the bulk (b) (4) step using (b) (4) in the production process for Testosterone Cypionate

180mg/mL Testosterone Propionate 20mg/mL was not included during the media fill.

OBSERVATION 3

Personnel were observed conducting aseptic manipulations where the movement of "first air" in the ISO 5 area is blocked or disrupted.

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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECT	TIONAL OBSERVATIONS	PAGE 2 of 7 PAGES

DEPARTMENT OF HEA FOOD AND DE	ALTH AND HUM RUG ADMINISTRAT		
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION 6/12/2023-7/5/2023*	
550 Main Street Cincinnati, OH 45202		6/12/2023-7/5/2023* FEI NUMBER	
(513) 322-0700 Fax: (513) 679-2772		3014391500	
n na sense sens			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
Manuel G. Francia, Pharmcist-In-Charge			
FIRM NAME New Vitalis Pharmacy LLC dba New Vitali:	STREET ADDRESS	lillac Ct Ste 201	
Pharmacy	5 4159 Cau	IIIac CL Ste 201	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHM		
Louisville, KY 40213-1578	Producer	of Sterile and Non-St	terile Drugs
Specifically, on $06/14/2023$, I observed your step to include a tray of ^(b) (4) vials, empty carton, bo with its connecting power cord in front of the HI aseptically (b) (4) and filling sterile drug produ 180mg/mL/Testosterone Propionate 20mg/mL lo the operator. Vials used during the aseptic operations on $06/1$ in the ISO 5 (b) (4) LFH closest to the opera LFH blocking First Pass air.	ttle of bulk di EPA filter in act vials of Te ot AL051120 5/2023 were	the ISO 5 (b) (4) LFH, estosterone Cypionate 23 (b) (4) between these	er(b) (4) Pump while supplies and of the vial box
OBSERVATION 4 Use of a sporicidal agent in the facility's ISO 5 ar Specifically, sporicidal agents were not used in Y Your firm's Pharmacist stated that he cleans and (b) (4) Sterile pre-saturated wipes which we (b) (4) Sterile pre-saturated wipes consists of and 06/15/2023 before and after the aseptic filling Propionate 20mg/mL lot AL05112023 (b) (4) . cleanroom was only wiped with Sterile (b) (4) These hoods have been used in the aseptic filling Testosterone Cypionate 180mg/mL Testos Papaverine/Phentolamine/Alprostadil (Tri-Mix) b	your facility's disinfects the ere (b) ng of Testost The ISO 5 I wipes that g of approxin terone Pro	s ISO 5 classified aseptic p the ISO 5 BSC's and ISO 5 (b) (4) (4) I observed this terone Cypionate 180mg/m LFH hood located in the no were also sprayed with st nately ^{(b) (4)} sterile drug proc pionate 20mg/mL, Van	LFH with only . The on 06/14/2023 L Testosterone n-hazardous IV erile (b) (4) ducts, including comycin and
OBSERVATION 5 Use of non-sterile cleaning wipes in the ISO 5 are	ea.		
SEE REVERSE OF THIS PAGE	or, Investi	gator Signed By Seator Signed By Seator Signed By Seator Date Signed CIT-05-2023 X 1305:16	date issued 7/5/2023
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE I	NSPECTIONAL (OBSERVATIONS	PAGE 3 of 7 PAGES

	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street	6/12/2023-7/5/2023*
Cincinnati, OH 45202	FEI NUMBER
(513)322-0700 Fax: (513)679-2772	3014391500
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Manuel G. Francia, Pharmcist-In-Charge (P	PIC)
FIRM NAME	STREET ADDRESS
New Vitalis Pharmacy LLC dba New Vitalis	4139 Cadillac Ct Ste 201
Pharmacy	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40213-1578	Producer of Sterile and Non-Sterile Drugs

Specifically, on 06/14/2023 and 06/15/2023, before and during filling of bulk Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) respectively, your pharmacist transferred the non-sterile wipe with the lot number of the drug product inscribed on it from BSC ISO 5 in the HD ISO 7 cleanroom to the non-HD ISO 7 cleanroom and then into the ISO 5 LFH for filling into the final drug product vials that will be distribute for patient use. Per your pharmacist this drug product bulk was prepared on 05/11/2023 and had been placed on this same non-sterile wipe since then.

OBSERVATION 6

Smoke studies were inadequately performed under dynamic conditions.

Specifically, you presented a report for smoke studies conducted by your third party (b) (4) on 1/26/2023. The smoke study reported for ISO 5 LFH located in the ISO 7 Non-Hazardous IV buffer room does not appear to have been conducted under dynamic conditions. Your pharmacist stated that he was not involved in the (b) (4) hood smoke study but only demonstrated dynamic manipulation of the (b) (4) hood which is located in the ISO 7 Hazardous chemical buffer room. This ISO 5 hood in the Non-Hazardous IV buffer room has been used in the aseptic filling of approximately ^{(b) (4)} prescriptions of your sterile products from March to May 2023, to include the following but not limited products: Vancomycin 5% eye drop and Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL

OBSERVATION 7

Use of a disinfectant in a manner insufficient to achieve adequate levels of disinfection.

Specifically, the disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate level of disinfection. You are not waiting the required (b) (4) dwell time for the disinfectants used to sanitize your ISO 5 hoods where sterile products are compounded and ISO 7 buffer rooms. Your pharmacist stated that the disinfectants direction specifies waiting (b) (4) prior to wiping down.

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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATI	IONS	PAGE 4 of 7 PAGES

	TH AND HUMAN SERVICES G ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street	6/12/2023-7/5/2023*
Cincinnati, OH 45202	FEI NUMBER
(513)322-0700 Fax:(513)679-2772	3014391500
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Manuel G. Francia, Pharmcist-In-Charge (P	IC)
FIRM NAME	STREET ADDRESS
New Vitalis Pharmacy LLC dba New Vitalis	4139 Cadillac Ct Ste 201
Pharmacy	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Louisville, KY 40213-1578	Producer of Sterile and Non-Sterile Drugs

On 06/12/2023, I observed your technician perform (b) (4) cleaning of the ISO 7 Hazard chemical buffer room and the Non-Hazardous IV buffer room along with the ISO 5 Biological safety cabinet and the ISO 5 LFH located in the buffer rooms respectively. Your technician failed to adhere to the

disinfectant times as detailed in your cleaning instruction. Disinfectant was used but immediately wiped down after application. Sterile Pre-saturated wipes (b) (4) sprayed with Sterile (b) (4) was used on the ISO 5 classified areas while (b) (4) Disinfectant was used on the floors but immediately wiped down after application. I observed that between May 19th 2023 and June 13th 2023 (b) (4) was used in the disinfection of your clean rooms which is a non-sporicidal agent.

OBSERVATION 8

Personnel infrequently sanitized gloves to prevent contamination.

Specifically, on 06/15/23, I observed operator^[9776] use his gloved hands to clean the bulk drug product spills on the ^{(b) (4)} area which is (b) (4) approximately three times using a previously used (b) (4) in the ISO 5 LFH. He immediately continued the aseptic filling of vials with Testosterone Cypionate

180mg/mL Testosterone Propionate 20mg/mL lot 05112023 (b) (4) without sanitizing his gloves.

OBSERVATION 9

HEPA filters are not sealed around the perimeter.

Specifically, the HEPA filters in the ISO 7 non-hazardous room were not properly sealed. The perimeter of the HEPA filter did not overlap to the ceiling. The HEPA filters are not adequately sealed to the ceiling and had gaps." This is a repeat observation.

The ISO 5 Laminar Air Flow Hood (LFH) used in the aseptic filling of Testosterone Cypionate 180mg/mL Testosterone Propionate 20mg/mL lot AL05112023 (b) (4) vials on 06/14/2023 and 06/15/2023 is situated in this room.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C Chudi-Nwank	wor, Investigator	Uchestuchi D Chud-Naanitaon Investigatio Signal Gy, Schestuchi C. Chus- naate Signes: 07-05-2023 13.55:16	DATE ISSUED 7/5/2023
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVAT	TONS	PAGE 5 of 7 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
district address and phone number 550 Main Street		ATE(S) OF INSPECTION		
Cincinnati, OH 45202	FE	EI NUMBER		
(513)322-0700 Fax:(513)679-2772	3	014391500		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	la			
Manuel G. Francia, Pharmcist-In-Charge (F				
FIRM NAME New Vitalis Pharmacy LLC dba New Vitalis	STREET ADDRESS 4139 Cadil	lac Ct Ste 201		
Pharmacy	Internet and the second second			
CITY. STATE, ZIP CODE, COUNTRY Louisville, KY 40213-1578	Producer o	NSPECTED of Sterile and Non-Ste	erile Drugs	
OBSERVATION 10				
The facility design was observed to allow the influ	x of lesser qua	lity air into a classified ar	rea containing	
higher quality air.				
Specifically, all material flows directly from an und	classified area	into a negative pressure I	SO 7 HD	
cleanroom in which sterile production occurs via	Contraction of the second s	Additionally, material for	NEW CONTRACTOR	
production is also brought in through this (b)				
a.On 06/14/2023 and 06/15/2023 I observed the	e operator pass	s the sterile packaged vials	s of	
Testosterone Cypionate 180mg/mL Testoste	erone Propiona	ate 20mg/mL lot		
AL05112023 (b) (4), through to the uncl				
unclassified material (b) (4) into the c			~ 옷 가 잘 잘 잘 잘 하는 것이 같아요. ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^ ^	
cleanroom where compounding of aseptical	ly manipulate	d drug products is conduc	eted.	
b. Additionally, microbial growth of 1 CFU/250	cm2 was recov	vered from this (b) (4)	in the last	
certification from January 26, 2023, Test Ro			A second s	
<i>Cladosporium species</i> which is a common f	-	1000. Wherebolar identifie	ation was	
	ungus.			
- On 06/12/2022 I sharmed the mainting and		starila Dalla Dava anhatan		
c.On 06/12/2023, I observed the weighing and a Testosterone Cypionate, Testosterone Propi				
Benzoate liquids in an unclassified area. Th		2		
unsterile components were used in manufa-				
Testosterone Propionate 20mg/mL lot 0612				
used in sterile aseptic filling of vials after la			ist will be	
ased in sterile aceptic mining of third uter to	coracory unury	, ~~~ · ·	I	
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EMPLOYEE(S) SIGNATURE			DATE ISSUED	
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OF THIS PAGE		Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi- maankwor S		
		X Date Signed: 07-05-2023 13:02:16		
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INS	SPECTIONAL OBS	FRVATIONS	PAGE 6 of 7 PAGES	
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DISTRICT ADDRESS AND PHONE NUMBER	OOD AND DRUG ADMINISTRAT	AN SERVICES		
550 Main Street Cincinnati, OH 45202 (513)322-0700 Fax: (513)679-2772		DATE(S) OF INSPECTION 6/12/2023- FEI NUMBER 3014391500	7/5/2023*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
Manuel G. Francia, Pharmcist-In-C	harge (PIC)			
New Vitalis Pharmacy LLC dba New Pharmacy	Vitalis 4139 Cad	dillac Ct Ste	e 201	
CITY. STATE, ZIP CODE, COUNTRY Louisville, KY 40213-1578	TYPE ESTABLISH Produce:	C of Sterile	and Non-St	erile Drugs
OBSERVATION 11 Use of processing aides not intended for p	pharmaceutical use in	n sterile drug pr	roduction.	
Specifically, your pharmacist stated that	(b) (4)	unit is used	in the initial
the bulk (b) (4) of Bulk Testosterone C 06122023 (b) (4) using the non-pharma addition the certificate of Quality (COQ) patient care or diagnostic procedures".	ceutical grade	(b) (4)	unit. In
*DATES OF INSPECTION				
6/12/2023(Mon), 6/13/2023(Tue), 6/14/2 7/05/2023(Wed)	023(Wed), 6/15/202:	3(Thu), 6/16/20	23(Fri), 6/26	/2023(Mon),
		gator	cheaturati C Chud-Haonikaor ungen By Lesbachi C Chud-Haonikaor ungen By Lesbachi C Chud- signer B Symer (745-2233 132:16	/2023(Mon), date issued 7/5/2023

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 judgment, 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."