DISTRICT ADDRESS AND PHON	FOOD AND	DRUG ADMINISTRAT	ION	
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19701 Fairch:	rchild A 92612-2445 2900 Fax:(949)608-4417		9/8/2020-9/23/2020* FEINUMBER 3013436443	
(242) 000 2000				
NAME AND TITLE OF INDIVIDU				
Ryan D. Oiter FIRM NAME	bro, Principal and CEO	STREET ADDRESS		
STREET STREET	& Associates, Inc. dba		lison St # 702	
	Compounding Pharmacy		WENT INSPECTED	
Seattle, WA S			r of Sterile and Non-Sterile Drug s	
observations, and do observation, or have action with the FDA	observations made by the FDA representati not represent a final Agency determination implemented, or plan to implement, correc representative(s) during the inspection or s nact FDA at the phone number and address	n regarding your con tive action in respor submit this information	npliance. If you have an objection regard use to an observation, you may discuss the	ling an ne objection or
OBSERVATIO				
Materials or sup	oplies were not disinfected prior	to entering the	aseptic processing areas.	
Specifically,				
•	absorved the storils production s	of three lots of l	Eninenhrine/Ketorolac/Bonivio	caine
On 09/09/20, 1 o	observed the sterile production c			
On 09/09/20, 1 0 0.0006%/0.03%	6/0.2%, during which the rubber	stoppers on sir	gle use vials of Epinephrine, k	
On 09/09/20, 1 o 0.0006%/0.03% Ropivicaine, an	6/0.2%, during which the rubber d Sodium Chloride were swabbe	stoppers on sir ed with non-ste	gle use vials of Epinephrine, H rile (b) (4)	Ketorolac,
On 09/09/20, I o 0.0006%/0.03% Ropivicaine, an (b) (4) prio	6/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4)	stoppers on sir ed with non-ste in the	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class	Ketorolac,
On 09/09/20, I o 0.0006%/0.03% Ropivicaine, an (b) (4) prio	6/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring	stoppers on sir ed with non-ste in the ge was then (b)	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4)	Ketorolac, sified
On 09/09/20, 1 o 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood).	6/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring	stoppers on sir ed with non-ste in the ge was then (b)	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class	Ketorolac, sified
On 09/09/20, 1 o 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4)	6/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4) on step prior to delivery to pat	Ketorolac, sified tients.
On 09/09/20, 1 c 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril	b/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no full le (b) (4) wipes were observed	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4) on step prior to delivery to pat	Ketorolac, sified tients.
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On 09/09/20, I of 0.0006%/0.03% Ropivicaine, an (b) (4) prior Laminar Hood). (b) (4) These non-steril of Epinephrine/	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no ful le (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006%	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4) on step prior to delivery to pat	Ketorolac, sified tients.
On 09/09/20, 1 o 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no full (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006%	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th 0.03%/0.2%.	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4) on step prior to delivery to pat ne production of lots 6373, 636	Ketorolac, sified tients.
On 09/09/20, 1 o 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no ful le (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006%	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th 0.03%/0.2%.	ngle use vials of Epinephrine, F rile (b) (4) Biosafety Cabinet (ISO 5 class (4) on step prior to delivery to pat ne production of lots 6373, 636	Ketorolac, sified tients.
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On 09/09/20, 1 c 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/ OBSERVATIO Your facility de Specifically, a) The most re 7 Gowning	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no full (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006%	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th 0.03%/0.2%. quality air into your firm to de	a higher classified area. monstrate the flow of air betw on 07/10/19, showed a stagnar	Ketorolac, sified tients. 58, and 636 7een the ISC nt
On 09/09/20, 1 c 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/ OBSERVATIO Your facility de Specifically, a) The most re 7 Gowning	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no fulle (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006% DN 2 esign allowed the influx of poor ecent smoke study conducted by Room into the ISO 7 Hazard Ro	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th 0.03%/0.2%. quality air into your firm to de	a higher classified area. monstrate the flow of air betw on 07/10/19, showed a stagnar	Ketorolac, sified tients. 58, and 636 reen the ISC nt
On 09/09/20, 1 c 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/ OBSERVATIO Your facility de Specifically, a) The most re 7 Gowning	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no fulle (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006% DN 2 esign allowed the influx of poor ecent smoke study conducted by Room into the ISO 7 Hazard Ro	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th 0.03%/0.2%. quality air into your firm to de	a higher classified area. monostrate the flow of air betw on 07/10/19, showed a stagnar	Ketorolac, sified tients. 58, and 636 99 90 90 90 90 90 90 90 90 90 90 90 90
On 09/09/20, 1 c 0.0006%/0.03% Ropivicaine, an (b) (4) prio Laminar Hood). (b) (4) These non-steril of Epinephrine/ OBSERVATIO Your facility de Specifically, a) The most re 7 Gowning	5/0.2%, during which the rubber d Sodium Chloride were swabbe or to (b) (4) . The material inside each syring with no fulle (b) (4) wipes were observed Ketorolac/Ropivicaine 0.0006% DN 2 esign allowed the influx of poor ecent smoke study conducted by Room into the ISO 7 Hazard Ro	stoppers on sir ed with non-ste in the ge was then (b) urther sterilizati in use during th //0.03%/0.2%. quality air into your firm to de oom, conducted f the Hazard Ro	a higher classified area. monstrate the flow of air betw on 07/10/19, showed a stagnar between the area in front of the l	Ketorolac, sified tients. 58, and 636 ween the ISC nt

FOOD AND	EALTH AND HUMAN SERVICES DRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445	9/8/2020-9/23/2020*
(949)608-2900 Fax: (949)608-4417	3013436443
(313) 300 1300 Iur. (343) 600 441/	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ryan D. Oftebro, Principal and CEO	
FIRM NAME	STREET ADDRESS
Kelley-Ross & Associates, Inc. dba	805 Madison St # 702
Kelley-Ross Compounding Pharmacy CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle, WA 98104-1172	Producer of Sterile and Non-Sterile Drug
Beattle, WA 90104-1172	Products
flowing from the ISO 7 Hazard Room into the OBSERVATION 3	rd Room, conducted on 06/12/18, showed smoke he Biosafety Cabinet.
OBSERVATION 3 The ISO 5 classified aseptic processing areas ha surface.	
OBSERVATION 3 The ISO 5 classified aseptic processing areas ha	he Biosafety Cabinet.
OBSERVATION 3 The ISO 5 classified aseptic processing areas ha surface. Specifically, The Biosafety Cabinet (ISO 5 classified Lamina	he Biosafety Cabinet. d difficult to clean and visibly dirty equipment or ar Hood) used to perform production of sterile drug om, which is adjacent to the ISO 7 Gowning Room. On
 OBSERVATION 3 The ISO 5 classified aseptic processing areas has surface. Specifically, The Biosafety Cabinet (ISO 5 classified Lamina products is located inside the ISO 7 Hazard Roo 09/11/20, I observed difficult to clean and visible) a) A white residue on the Hazard Room side of Gowning Room, located along the bottom expression. 	he Biosafety Cabinet. d difficult to clean and visibly dirty equipment or r Hood) used to perform production of sterile drug om, which is adjacent to the ISO 7 Gowning Room. On y dirty surfaces in the following areas: f the (b) (4) separating the Hazard Room from the
 OBSERVATION 3 The ISO 5 classified aseptic processing areas has surface. Specifically, The Biosafety Cabinet (ISO 5 classified Lamina products is located inside the ISO 7 Hazard Roo 09/11/20, I observed difficult to clean and visible a) A white residue on the Hazard Room side of Gowning Room, located along the bottom exproses.	he Biosafety Cabinet. d difficult to clean and visibly dirty equipment or ar Hood) used to perform production of sterile drug om, which is adjacent to the ISO 7 Gowning Room. On by dirty surfaces in the following areas: f the (b) (4) separating the Hazard Room from the dge of the (b) (4) containing (b) (4) between the
 OBSERVATION 3 The ISO 5 classified aseptic processing areas has surface. Specifically, The Biosafety Cabinet (ISO 5 classified Lamina products is located inside the ISO 7 Hazard Roo 09/11/20, I observed difficult to clean and visiblea) A white residue on the Hazard Room side of Gowning Room, located along the bottom exproms. b) A white residue on the Hazard Room side of Comparison.	he Biosafety Cabinet. d difficult to clean and visibly dirty equipment or r Hood) used to perform production of sterile drug on, which is adjacent to the ISO 7 Gowning Room. On by dirty surfaces in the following areas: f the (b) (4) separating the Hazard Room from the dge of the (b) (4) containing (b) (4) between the f the (b) (4) separating the Hazard Room from the
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 OBSERVATION 3 The ISO 5 classified aseptic processing areas has surface. Specifically, The Biosafety Cabinet (ISO 5 classified Lamina products is located inside the ISO 7 Hazard Roo 09/11/20, I observed difficult to clean and visiblea) A white residue on the Hazard Room side of Gowning Room, located along the bottom exproms. b) A white residue on the Hazard Room side of Gowning Room, located along the bottom exproms. b) A white residue on the Hazard Room side of Gowning Room, located along the bottom exproms. c) A white residue on the Hazard Room side of Gowning Room, located along the bottom expression. c) A white residue on the Hazard Room side of Gowning Room, located along the bottom expression. c) A white residue on the Hazard Room side of Gowning Room, located along the bottom expression.	he Biosafety Cabinet. d difficult to clean and visibly dirty equipment or r Hood) used to perform production of sterile drug om, which is adjacent to the ISO 7 Gowning Room. On by dirty surfaces in the following areas: f the (b) (4) separating the Hazard Room from the dge of the (b) (4) containing (b) (4) between the f the (b) (4) separating the Hazard Room from the dge of the (b) (4) next to the left side of the Biosafety

- d) A white residue on the Hazard Room side of the door between the Hazard Room and the Gowning Room, located just above the door handle.
- e) A buildup of dust on the(b) (4) installed in the wall between the Hazard Room and the

SEE REVERSE	EMPLOYEE(S)SIGNATURE	Investigator	DATE ISSUED
OF THIS PAGE	Christopher R Czajka,		9/23/2020
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 2 of 4 PAGES

	HEALTH AND HUMAN SERVICES	
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION	
19701 Fairchild	9/8/2020-9/23/2020*	
Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	FEINUMBER 3013436443	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Ryan D. Oftebro, Principal and CEO		
FIRM NAME	STREET ADDRESS	
Kelley-Ross & Associates, Inc. dba Kelley-Ross Compounding Pharmacy	805 Madison St # 702	
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED	
Seattle, WA 98104-1172	Producer of Sterile and Non-Sterile Drug Products	

Gowning Room that allows air to flow into the Hazard Room.

f) A temperature and humidity meter taped to the Hazard Room side of the (b) (4) between the Hazard Room and the ISO 8 Prep Room, with the battery compartment cover missing and the batteries exposed.

OBSERVATION 4

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

On 09/09/20, I observed an employee put on disposable sterile gloves just prior to performing sterile production of Epinephrine/Ketorolac/Ropivicaine 0.0006%/0.03%/0.2% by using the sterile side of one glove to hold onto the non-sterile side of the opposite glove. This practice was observed prior to the production of lots 6373, 6368, and 6366 of Epinephrine/Ketorolac/Ropivicaine 0.0006%/0.03%/0.2%.

OBSERVATION 5

You produced hazardous drugs without providing adequate cleaning of utensils to prevent crosscontamination.

Specifically,

Your firm performs non-sterile production of the following cyt	otoxic drugs using non-product dedicated(b) (4)
(b) (4) without ensuring that the method used to clean (b) (4)	between production operations effectively
removes all cytotoxic material:	

- a) Anastrazole/Clomiphene/DHEA 2mg/25mg/50mg capsules
- b) Chlorambucil (vet) Fixed Oil 1.9mg/ml suspension
- c) Fluorouracil (5-Fu)/Salicylic Acid 5%/20% DMSO topical suspension

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OF THIS PAGE	Christopher R Czajka,		9/23/2020
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	HEALTH AND HUMAN SERVICES
PISTRICT ADDRESS AND PHONE NUMBER	D DRUG ADMINISTRATION
19701 Fairchild	9/8/2020-9/23/2020*
Irvine, CA 92612-2445	FEINUMBER
949)608-2900 Fax:(949)608-4417	3013436443
IAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Ryan D. Oftebro, Principal and CEO	
IRM NAME	STREET ADDRESS
Kelley-Ross & Associates, Inc. dba Kelley-Ross Compounding Pharmacy	805 Madison St # 702
ATTY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle, WA 98104-1172	Producer of Sterile and Non-Sterile Drug Products
	luction of which compounded drug lots.
	Thu), 9/11/2020(Fri), 9/14/2020(Mon), 9/15/2020(Tue),
[27] 27] 27] 27] 27] 27] 27] 27] 27] 27]	

FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIO	NS	PAGE 4 of 4 PAGES
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Christopher R Czajka,	Investigator	Chraboher R GLaski Invergator South Constantive R Grand South Constantive R Grand South Constantive R Grand South Constantive R Grand South Constantive R Glaski South Constanti South	DATE ISSUED 9/23/2020