DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center Building 20 6th Ave. and Kipling St. Denver, CO. 80225 303-236-3000 Industry Information: www.fda.gov/oc/industry	7/12/2019-7/18/2019*, 7/23/2019
	FEI NUMBER 3008476140

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Allen Jolly, Owner and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Infusion Treatment Center Inc dba ITC Compounding	651 Topeka Way Suite 600
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Castle Rock CO 80109	Producer of Non-Sterile Drugs

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

Observation 1
You produced highly potent drugs without providing adequate containment, segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.
Specifically,
Equipment, work surfaces, and utensils are used for the production of hormonal products as well as non-hormonal products. Inadequate cross-contamination precautions are established to protect drug products produced on these shared surfaces. I observed equipment and utensils that had been placed in a cleaned and ready for use designation. I observed discoloration, staining, and flaking of paint among these cleaned utensils and equipment. You have failed to deploy an approach to cleaning (dish washer as well as (b) (4) cleaning operations) that is adequate to remove cleaning agent and product residues. Non-dedicated equipment, utensils, and work surfaces include the (b) (4) , (b) (4) compounding counters adjacent to the hood, enclosed wooden drying shelves, glass stirrers, metal spatulas, metal pans, glass mortar and pestle, encapsulation machines, (b) (4) and mixing blades, (b) (4) troche molds, stir bars, and beakers.

a. On 7/12/2019 you made the following hormone containing products and non-hormone containing products with mixed use equipment, utensils, and workstations:

1. Rx (b) (6) Progesterone 100mg/ml HRT
2. Rx (b) (6) Lidocaine HCl/Prilocaine HCl/Tetracaine HCl/Phenylephrine 12.5%3%12.5%3% Gel
3. Rx (b) (6) Tretinoin/Niacinamide 0.05/4% Cream
4. Rx (b) (6) Estradiol/Progesterone/Testosterone/DHEA/Pregnenolone 0.6/175/1/10/30MG Troche HRT
5. Rx (b) (6) Naltrexone 4.5mg (b) (4)
6. Rx (b) (6) Progesterone/Niacinamide/Pyridoxine/Cyanocobalamin 200mg/500/500/500mcg Troche HRT
7. Rx (b) (6) T4/T3 SR (E) 150mcg/100mcg (b) (4)

b. You use a (b) (4) wooden shelving unit with forced airflow and fabric lined heating elements to dry (b) (4)

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	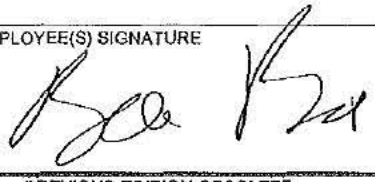	Zachary A. Bogorad, CSO	7/23/2019

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medications in open-top metal pans. This unit has fabric draped over the front and fabric lined heating blankets on every shelf. There is no documentation of any cleaning of this unit. You dry multiple products with unique active ingredients and potencies at the same time without providing adequate separation (either chronological or spatial) or protection against cross contamination. For example, Rx (b) (6) (b) (4) 20mcg (b) (4) and Rx (b) (6) (b) (4) 38mcg/9mcg (b) (4) with (b) (4) were concurrently formulated and dried in the shelving unit on 7/15/19 as detailed on your production worksheets.

Observation 2.
Non-microbial contamination was observed in your production area.
Specifically, during a walkthrough of your in-use production areas the following conditions were observed:
1. Yellow-brown discoloration was observed along the interior (b) (4) hood wall seals at the (b) (4) and (b) (4) production hoods. The scales present in these hoods had extensive yellow discoloration throughout the body and touch panel of the device. These hoods are used to produce hormone and non-hormone containing products including:
a. Rx (b) (6) Progesterone 100mg/ml HRT produced 7/12/19
b. Rx (b) (6) Lidocaine HCl/Prilocaine HCl/Tetracaine HCl/Phenylephrine 12.5%3%12.5%3% Gel produced 7/12/19
c. Rx (b) (6) Tretinoin/Niacinamide 0.05/4% Cream produced 7/12/19
2. Yellow-brown discoloration was observed along the (b) (4) hood wall seals and left most window panel at the (b) (4) hood. This hood is used to (b) (4) hormone and non-hormone containing products including:
a. Rx (b) (6) Naltrexone 4.5mg (b) (4) 7/12/19
b. Rx (b) (6) T4/T3 SR (E) 150mcg/100mcg (b) (4) 7/12/19
3. Metal pans and enameled metal pans used to hold (b) (4) drug products during drying, stored in the clean and ready for use area, had a white-silver residue along the lower interior perimeter of the pans. Enameled metal pans had extensive chips and scratches in the surface with gaps in the enamel revealing the metal beneath. These pans hold (b) (4) products including the following:
a. Rx (b) (6) (b) (4) 20mcg (b) (4) produced on 7/15/19
b. Rx (b) (6) (b) (4) 38mcg/9mcg (b) (4) produced on 7/15/19

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Additionally, on 7/12/19 during observation of your production operations I observed the use of approximately (b) (4) spatulas and spreaders with wooden handles that are porous and difficult to clean.

Observation 3

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your pharmacy makes non-sterile drug products using (b) (4) (b) (4) located in the retail area of your front office. You have never monitored the quality of (b) (4) from this (b) (4) nor have you established specifications to ensure that (b) (4) quality is suitable for pharmaceutical production operations. Examples of finished products produced with (b) (4) (b) (4) include:

a) Arbutin facial peel solution
b) Burrows .28% solution
c) Clindamycin/BPO/Niacinamide 1.2/2.5/4% MB25
d) Clindamycin/BPO/Niacinamide 1.2/2.5/4% MB50
e) Cortisol 20mg/0.6ml moisture GUA
f) Urea 40% solution

Your firm produce (b) (4) (b) (4) (b) (4) containing cream bases ((b) (4) (b) (4)) that are used as ingredients in the following finished product:

a) Clindamycin/BPO/Niacinamide 1.2/2.5/4
b) Retinoic/Niacinamide .05/4% RCH Cream
c) Clindamycin/BPO/Niacinamide 1.2/2.5/4% RCH Cream
d) Retinoic/Glycolic/Lactic .05/2/1% RCH Cream
e) Retinoic/Niacinamide .05/4% RCH Cream
f) Retinoic/Niacinamide 0.05/4% Cosmetic Light Cream
g) Retinol/Niacinamide/Lipoic acid/Peptide/Glutathione 1/4/1/10/5% RCH Cream

Observation 4.

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug product containers, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity.

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	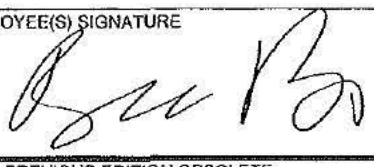	Zachary A. Bogorad, CSO	7/23/2019

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Specifically,

A. Your firm does not conduct any tests to determine identity, strength, purity, and composition for any of your unique formulations that have been produced during the last 12 months with an exception. Contract testing of your firm's products is limited to (b) (4) potency analysis of (b) (4) products produced by each pharmacy technician to demonstrate the technician's production competency. These contract potency tests are performed after products are dispensed.

B. Your firm has never performed testing on any incoming components including bulk substances, excipients, and containers and closures.

C. Your firm has failed to perform qualification of raw material suppliers. The certificates of analysis for all raw material suppliers are accepted in lieu of testing. Zero identity, strength, potency, or purity testing is performed. Your firm has failed to identify and qualify the manufacturer of any raw materials or finished dosage drug products that are purchased for use in further production.

Examples of office stock products for which these laboratory controls have not been established include:

1. Rx (b) (6) BLT (Benzocaine/Lidocaine/Tetracaine 20/8/8% Transdermal Ointment made 6/25/19, BUD 9/7/19, lot 06252019@43 made with bulk drug substance Benzocaine USP (b) (4) lot (b) (4), Lidocaine USP (b) (4) lot (b) (4), Tetracaine USP (b) (4) lot 18 (b) (4)
2. Rx (b) (6) Tetracaine/Lidocaine/Prilocaine/Phenylephrine (Spearmint) 4/10/10/2% Lipoderm Ointment made 7/10/19, BUD 1/6/20, lot 07102019@44 made with bulk drug substance Tetracaine USP (b) (4) lot (b) (4) (b) (4), Lidocaine USP (b) (4) lot (b) (4), Prilocaine (b) (4) USP lot (b) (4), Phenylephrine (b) (4) USP lot (b) (4)
3. Rx (b) (6) BLT (Benzocaine/Lidocaine/Tetracaine) 20/10/10% gel made 5/2/19, lot 05022019@16, BUD 7/31/19, made with bulk drug substance Lidocaine USP (b) (4) lot (b) (4) Tetracaine USP (b) (4) lot (b) (4) (b) (4), Benzocaine USP (b) (4) lot (b) (4)

Observation 5

Employees are not given training in current good manufacturing practices (GMP). Specifically, your firm has not performed and documented GMP training. Of the (b) (4) pharmacists and (b) (4) technicians currently working on site, none have participated in GMP training.

Examples of office stock products produced by one or more technicians and reviewed by a pharmacist include:

1. Rx (b) (6) BLT (Benzocaine/Lidocaine/Tetracaine 20/8/8% Transdermal Ointment made 6/25/19, BUD 9/7/19,

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	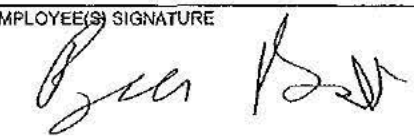	Zachary A. Bogorad, CSO	7/23/2019

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lot 06252019@43. Technician '(b) (6)' and Pharmacist (b) (6) performed the documented activities.
2. Rx (b) (6) Tetracaine/Lidocaine/Prilocaine/Phenylephrine (Spearmint) 4/10/10/2% Lipoderm Ointment made 7/10/19, BUD 1/6/20, lot 07102019@44. Technicians '(b) (6)' and '(b) (6)' and Pharmacist (b) (6) performed the documented activities.

Observation 6
The responsibilities and procedures applicable to the quality control unit are not in writing.
Specifically, your firm's procedures do not define the roles and responsibility of a quality control unit. There are no written procedures detailing the authorities of the quality control unit to include approval and rejection of procedures, release of drug products, and maintenance of specifications for ingredient and finished product identity, strength, quality and purity. Additionally, procedures do not describe responsibilities of the quality control unit as it pertains to complaint investigations, root cause analysis, and corrective/preventative actions plans.
Examples of office stock products produced by your firm include:
1. Rx (b) (6) BLT (Benzocaine/Lidocaine/Tetracaine 20/8/8% Transdermal Ointment made 6/25/19, BUD 9/7/19, lot 06252019@43
2. Rx (b) (6) Tetracaine/Lidocaine/Prilocaine/Phenylephrine (Spearmint) 4/10/10/2% Lipoderm Ointment made 7/10/19, BUD 1/6/20, lot 07102019@44

Observation 7
There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically,
A. Equipment qualifications have not been assessed for the following major manufacturing equipment used by technicians in the production of drug products: (b) (4) used for (b) (4) (b) (4) used for (b) (4) (b) (4) and (b) (4) capsule filling stations.
B. Process validation has not been performed in support of the unique formulations that you have manufactured.
Examples of office stock products produced by your firm include:
1. Rx (b) (6) BLT (Benzocaine/Lidocaine/Tetracaine 20/8/8% Transdermal Ointment made 6/25/19, BUD 9/7/19, lot 06252019@43

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