DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Los Angeles District 19701 Fairchild Irvine, CA 92612 949-608-2900 Industry Information: www.fda.gov/oc/industry	10/04/22-10/07/22
	FEI NUMBER 3011924560

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Robert T. Leark, Owner

FIRM NAME	STREET ADDRESS
Burt's Pharmacy, LLC	2333 Borchard Rd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Newbury Park, CA 91320	producer of nonsterile drugs

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:

OBSERVATION 1
Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically,
A) Your firm used (b) (4) to produce nonsterile drugs. There is no assurance the (b) (4) meets at least (b) (4), USP standards for microbiological or chemical quality. Examples of drug products produced with (b) (4) include Meperidine HCl 10 mg/ml Oral Suspension for office use, lot 09162022@(b) (4); Dyclonine 1% HCl Oral Dental Solution for office use, lot 07112022@(b) (4); and Sodium Chloride (23.4%) 4 mEq/mL Solution, lot 09272022@(b) (4).

B) Your firm used (b) (4) as a component in Dyclonine 1% HCl Oral Dental Solution for office use, lot 07112022@(b) (4). There was inadequate assurance this ingredient was suitable for use in an oral drug product. Inactive ingredients declared on the (b) (4) label include (b) (4) and (b) (4).

OBSERVATION 2
Hazardous and non-hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,
A) We observed capsule equipment designated as clean with apparent loose powder and residue in the hazardous and non-hazardous production rooms. There was no documentation available to demonstrate how long the items contained the powder and residue. Examples of finished drug capsules produced and dispensed include Progesterone 90 mg capsules, lot 08052022@(b) (4); Tadalafil 12.5 mg SR capsules, lot 07072022@(b) (4); T3 25 mcg and T4 100 mcg capsule, lot 09232022@(b) (4); Sodium Benzoate 583 mg capsule, lot 09292022@(b) (4) and

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Nicholas L. Hunt -S Digitally signed by Nicholas L. Hunt -S Date: 2022.10.07 13:44:35 -07'00'	Nicholas L. Hunt, Investigator	10/07/2022

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TO: Robert T. Leark, Owner

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Burt's Pharmacy, LLC	2333 Borchard Rd.
CITY, STATE AND ZIP CODE Newbury Park, CA 91320	TYPE OF ESTABLISHMENT INSPECTED producer of nonsterile drugs

Chloramphenicol 50 mg/Sulfacetamide 50 mg/Amphotericin B 5 mg capsules, lot 07082022@(b)(4)

B) Your firm uses (b) (4) , (b) (4) , (b) (4) dish soap, and (b) (4) to clean utensils, equipment, and work surfaces in the hazardous and non-hazardous production rooms. Your firm does not have evidence these cleaning agents can remove and deactivate hazardous compounds such as hormones, antineoplastics, and potent drugs produced in your facility. Examples of hazardous drug products include Testosterone 0.1 mg/drop sublingual suspension, lot 09212022@(b)(4) ; E2 2 mg/mL gel, lot 09232022@(b)(4) and Progesterone 90 mg capsules, lot 08052022@(b)(4) .

C) We observed the (b) (4) inside the non-hazardous production room had unknown residue on the edges of the rollers and on the inside edges of the roller housing on 10/06/22. There was no documentation of how long the residue was on the (b) (4) rollers. Technicians use the (b) (4) to (b) (4) in drug products such as (b) (4) , lot 08012022@(b)(4) for office use; Keto-Gaba-Keta-Bacl-Clon in lipoderm 5-2-5-2-0.2% cream; and Niacinamide/Biotin/Potassium Azelaoyl/Zinc clarifying base 4-0.1-10-0.1% cream for office use.

D) We observed apparent loose powder and residue on the work surface, walls, and equipment inside the (b) (4) hoods designated as clean in the hazardous and non-hazardous production rooms on 10/04/22. There was no documentation of how long the residue was inside the hoods. We observed production of Levothyroxine (T4) SR 10 mcg capsule, lot 10032022@(b)(4) inside the non-hazardous (b) (4) hood on 10/04/22.

E) We observed (b) (4) tape on capsule equipment in direct contact with bulk compounded drug being filled into capsules for Levothyroxine (T4) SR 10 mcg capsule, lot 10032022@(b)(4) on 10/04/22.

F) We observed multiple damaged spatulas with pieces missing from the edges in the hazardous and non-hazardous production rooms on 10/04/22. Technicians use the spatulas as direct product contact utensils. There was no documentation of where the missing pieces were located. The rough, damaged edges were not easily cleanable.

G) We observed damage and rough surfaces inside multiple mixing containers stored with clean utensils available for use in production on 10/04/22. The internal surfaces were not smooth and easily cleanable.

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H) We observed apparent corrosion on a brush used to clean utensils in the hazardous production room on 10/04/22.

OBSERVATION 3
Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

Specifically, your firm performs potency testing on selected products (b) (4). We observed the passing potency test result for Liothyronine (T3) 25 mcg SR capsule, lot 02142022@(b) (4), BUD 08/13/22 appeared inadequate. The measured concentration was (b) (4). The laboratory report indicates the final potency result of 90% was based on the (b) (4). (b) (4) was within the allowed (b) (4) variance from the specification for finished drug products capsules but (b) (4) was outside of the allowed (b) (4) specification for finished capsules. There was no scientific rationale to release this product after (b) (4) failed to meet the finished drug specification.

OBSERVATION 4
Vermin was observed in your production area.

Specifically, we observed a live spider crawling on the counter and sink inside the hazardous production room. There was an approximate 1-inch gap beneath the exterior door in the storage area. The production room door is located approximately (b) (4) from this exterior door with the gap at the bottom.

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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 judgement, 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."