DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food & Drug Administration New England District One Montvale Avenue, 4th Floor Stoneham, MA, 02180 Phone: 781-587-7500 Industry Information: www.fda.gov/oc/industry	10/12-14/2016, 10/18/2016
	FEI NUMBER 3005823862

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Annik S. Chamberlain, Pharmacist, Owner

FIRM NAME	STREET ADDRESS
DCA, Inc., dba Beacon Prescriptions	609 North Main Street
CITY, STATE AND ZIP CODE Southington, CT 06489	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile 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

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

1. Your firm lacks cleaning validation data to support (b) (4) and (b) (4) are appropriate cleaning agents for drug production equipment used to manufacture hormones, teratogenic materials, antibiotics and controlled substances.

2. Your firm cleans with (b) (4) and does not use purified water as a final rinse after cleaning drug production equipment.

OBSERVATION 2

The flow of components, drug product containers, in process material and drug product through the building is not designed to prevent contamination.

Specifically, you handle potent drug substances including hormones, teratogenic materials, antibiotics and controlled substances without providing adequate containment, segregation, and cleaning of work surfaces, equipment, and personnel to prevent cross-contamination. The following objectionable conditions were observed relating to control and containment of hormone drug substances and prevention of cross contamination of non-hormone drugs produced in the general pharmacy (including shared hoods, (b) (4)):

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Nealie C. Newberger, Investigator John P. Mistler, Investigator Chris (NMI) Janik, Investigator	10/25/2016

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OBSERVATION 2 CONT:

1. Your firm produced a teratogenic drug product (e.g. Allopurinol/Colchicine, (b) (6)) in the same hood and with the same equipment used for the production of other drug products (i.e. Prednisolone Liquid, (b) (6) , both produced on 14OCT2016). No cleaning validation data was provided to demonstrate the cleaning performed is adequate for these materials.

OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed.

A. Your firm's complaint investigations are inadequate in that investigations are not always completed.

1. A complaint related to (b) (6) , Estriol 0.5mg/mL Vag, a female patient complained of burning, no investigation was documented and an explanation of why an investigation was not performed was not documented.
2. A complaint related to (b) (6) , Progesterone 300mg, a female patient reported that she believed "there was a mistake in filling," because she developed abnormal bleeding and lumps in her breasts was not further investigated.
3. A complaint related to (b) (6) , DMSO 50% Cream/Stearic Acid, patient reported a burning sensation upon application of the medication produced by your firm. The patient was told to contact her physician – no further investigation was performed.

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OBSERVATION 4

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically, there are no established specifications for microbial limits for the non-sterile drug products prepared by your firm for distribution as "Office Stock." For example, during the last 3 months your firm prepared non-sterile drug products, such as Epinephrine 0.05/Lidocaine 4/Tetracaine 0.5% in amber syringes (topical numbing agent for human use) and Ampotericin B 100mg/mL (vetrinary use), and distributed without testing for the presence of objectionable microorganisms.

OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, your firm does not test each batch of "Office Stock", finished drug product, for identity or potency - prior to distribution. For example, during the last 3 months your firm prepared non-sterile drug products, such as Epinephrine 0.05/Lidocaine 4/Tetracaine 0.5% in amber syringes (topical numbing agent for human use) and Ampotericin B 100 mg/mL (veterinary use), and distributed them without testing to determine conformance with identity or potency.

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OBSERVATION 6

The calibration of instruments is not done at suitable intervals in accordance with an established written program and with provisions for remedial action in the event accuracy and/or precision limits are not met.

A. Your firm has failed to calibrate your (b) (4) analytical balances used to weigh active pharmaceutical ingredients and components for your drug products. No daily external weight check is performed on each balance. Additionally, there are no written procedures describing the requirements for the calibration of the balances and calibrations weights.

B. Your firm is not currently using calibrated thermometers or hygrometers for temperature and/or humidity sensitive drug component storage.

OBSERVATION 7

Employees engaged in the manufacture, processing and packaging of drug product lack the training required to perform their job functions.

Specifically, (b) (4) out of the (b) (4) employees that perform non-sterile drug production at your firm lack the appropriate training documentation specific to their job function.

Dates of Inspection: 10/12/2016(Wed), 10/13/2016(Thu), 10/14/2016(Fri), 10/18/2016(Tue), 10/25/2016(Tue)

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