DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderly Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	3/22/2016-3/25/2016
	FEI NUMBER 3012161781

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jessica E. Dileo , Owner, Pharmacist

FIRM NAME	STREET ADDRESS
Custom Meds, Inc.	102 E Highland Blvd
CITY, STATE, ZIP CODE, COUNTRY Inverness, FL 34452-4847	TYPE ESTABLISHMENT INSPECTED Non-sterile Compounding Pharmacy

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 OBSERVED:

OBSERVATION 1

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, you stated your firm does not test finished drug products prior to distribution. For example, documentation states since 12/22/15 to the time of this inspection your firm prepared and distributed non-sterile drug products without testing to determine conformance with potency (topical and capsule products) and microbial limit specifications (topical products). Below are some examples:

A. Creams and gels containing one or more active pharmaceutical ingredients such as testosterone, estradiol, lidocaine HCl, and pentoxifylline.

B. Capsules containing ingredients such as progesterone and liothyronine sodium (T3).

OBSERVATION 2

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 topical drug products made by your firm.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jennifer Lalama, Investigator Jennifer Lalama X Jennifer Lalama Jennifer Lalama Investigator Signed by: Jennifer Lalama-S	DATE ISSUED 3/25/2016

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OBSERVATION 3

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, your firm does not test non-sterile topical preparations for presence of objectionable microorganisms prior to distribution.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer Lalama, Investigator Jennifer Lalama X Jennifer Lalama Jennifer Lalama Investigator Signed by: Jennifer Lalama -5	3/25/2016