DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	08/04/2014 - 08/28/2014* FEI NUMBER 3009855773

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Paul R. Wheeler, President / Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Custom Compounding Centers, LLC	10525 Humbolt Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Los Alamitos, CA 90720	Producer of Sterile Drug Products

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

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,
Environmental Monitoring of the firm's ISO 5 and ISO 7 Cleanroom Environments used to produce sterile drug products does not represent actual production, for example:

a) Lack of active monitoring of differential pressures. There is no monitoring of the cleanroom pressure differentials during aseptic process of drug products. Within the firm's sole cleanroom, the ISO 5 area is separated from the ISO 7 area only by flexible plastic curtain strips. There is no manner in which to measure pressure differentials for these areas. Further, there is no system to detect loss of air supply to HEPA filters during processing.

b) Lack of active non-viable particulate air monitoring - ISO 5 and ISO 7. There is no active monitoring of the non-viable air particulates during aseptic processing of drug products in the ISO 5 or ISO 7 areas of the cleanroom. There is only semi-annual non-viable particulate monitoring conducted by an outside contractor.

OBSERVATION 2

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

Specifically,
There is no release testing performed to assess the presence of bacterial endotoxin in finished drug products aseptically processed and not terminally sterilized. Drug products are produced from non-sterile API by the firm; sterilization is by 0.22µ filtration, aseptically processed. The firm does not conduct an endotoxin analysis on each aseptically processed drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joey V. Quitania, Investigator JQuitania 08/28/14	08/28/2014

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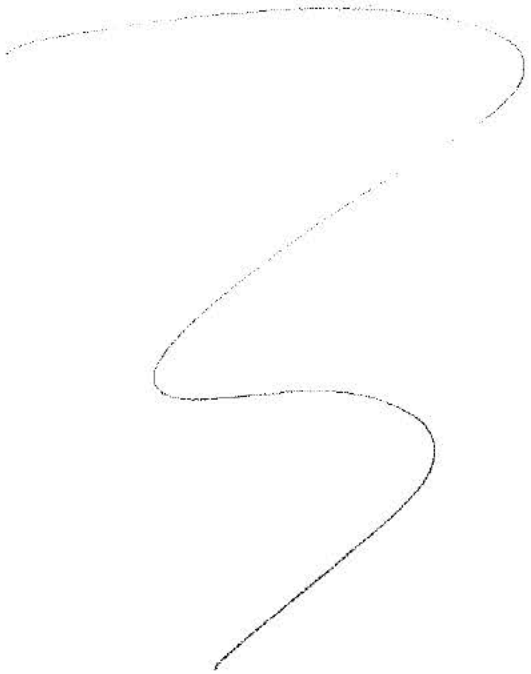
OBSERVATION 3

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

Specifically,
There is no release testing performed to assure the potency of each active ingredient for each batch. The firm does not conduct potency testing on aseptically processed drug products. Furthermore, there is no second verification on the weighing out of the active ingredient raw materials during formulation.

*** DATES OF INSPECTION:**
08/04/2014(Mon), 08/05/2014(Tue), 08/06/2014(Wed), 08/07/2014(Thu), 08/08/2014(Fri), 08/28/2014(Thu)



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