DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	08/26/2014 - 09/12/2014* FEI NUMBER 3004714346

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Marcos T. Contreras, Interim Head, Compounding & Research Support Pharmacy

FIRM NAME	STREET ADDRESS
UCSF Home Therapy Services	3333 California St Ste.216 E & Annex 40
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Francisco, CA 94118-1981	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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically,

a) There are no airflow pattern evaluations (smoke studies), under static or dynamic conditions, performed in the ISO 5 hoods or the surrounding ISO 7 cleanroom.

b) The operating (b) (4) of the (b) (4) are set at (b) (4) at (b) for (b) (4) to (b) sterilize glassware such as beakers, flasks and graduated cylinders; utensils such as measuring spoons; and weigh boats used during compounding of your sterile drug products. This (b) (4) has not been qualified and the (b) sterilized components are not depyrogenated.

i. There is no documentation of validation of the (b) (4).
ii. There are no records of the (b) (4) (b) due to (b) (4) (b) (4) malfunction.
iii. There is no assurance that these (b) (4) are adequate for the intended use.
iv. In addition, (b) (4) is periodically placed (b) (4) during sterilization (b)(b) (4) (b) (4). The (b) (4) can only (b) the maximum (b) (4).

c) Production components such as beakers, flasks and graduated cylinders; utensils such as measuring spoons; and weigh boats are not depyrogenated.

OBSERVATION 2

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer H. Rhyu, Investigator Alicia K. Mckinsey, Microbiologist	09/12/2014

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a) The batch record worksheet: "(b) (4) " states to "(b) (4) ". USP < 71> Sterility Tests states that each lot of product is to be tested for growth promotion of aerobes, anaerobes, and fungi in the same manner the sterility testing is conducted. According to the Pharmacist in Charge, there has been only one suitability test conducted on Dakin's Solution/Lot#11216 in 2011 by a contract lab.

b) Policy Number: 11.6, "Sterility Testing - (b) (4) Procedures", effective 07/14, which states that (b) (4) is not followed. The (b) (4) are the only products tested for sterility and endotoxin when applicable. These products are for (b) (4)

OBSERVATION 3

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

Specifically,

a) The firm does not perform personnel monitoring during daily operations. Gloved fingertip sampling is the only personnel monitoring performed. It is conducted (b) (4) Personnel monitoring is not conducted after a media fill or after (b) filling operations for drug products such as Glycerol-2-^{13}C 8g/30mL injection, Ethanol 95% injection, or L-leucine-5,5,5-d_3 2g/120mL in SWFI injection.

b) The firm does not perform environmental monitoring during daily operations. Policy Number: 5.8, "Environmental Monitoring", effective 07/14, states that (b) (4) . According to the Pharmacist in Charge and your environmental monitoring records, (b) (4) air and surface monitoring is performed (b) (4) of the cleanroom, ISO 5 hoods, and HEPA filters, under static conditions.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer H. Rhyu, Investigator
Alicia K. Mckinsey, Microbiologist

DATE ISSUED
09/12/2014

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Policy Number: 5.4, "Clean Room Cleaning", effective 07/14, states that (b) (4) [redacted] You do not follow the manufacturer's directions for use which requires that treated surfaces should (b) (4) [redacted]. In addition, you wipe down the ISO 5 hoods with (b) (4) [redacted] after cleaning with the above cleaning agents but you have not performed any cleaning validation or evaluated their cleaning effectiveness.

OBSERVATION 5

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, your Policies and Procedures are inadequate including but not limited to the following:

a) You have not established a written procedure for (b) (4) [redacted] testing, which requires (b) (4) [redacted] for method suitability. Policy Number: 11.6, "Sterility Testing - (b) (4) [redacted]", effective 07/14, states (b) (4) [redacted].

b) You have not established written procedures for Environmental Monitoring to recover yeast and mold. Policy Number: 5.8 "Environmental Monitoring" effective 07/14 does not address mold and yeast as potential contaminants. The policy states that all plates should be incubated at (b) (4) [redacted] This temperature range does not support the growth of yeast and mold.

c) You have not established procedures for personnel monitoring. Policy Number: 5.8 "Environmental Monitoring" effective 07/14, identifies personnel gloves and gowns as potential routes of contamination but does not include personnel monitoring as part of the Environmental Monitoring program.

*** DATES OF INSPECTION:**
08/26/2014(Tue), 09/02/2014(Tue), 09/03/2014(Wed), 09/04/2014(Thu), 09/08/2014(Mon), 09/12/2014(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer H. Rhyu, Investigator Alicia K. Mckinsey, Microbiologist	09/12/2014

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."