DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New York District 158-15 Liberty Avenue Jamaica, New York 11433 (718) 340-7000 Industry Information: www.fda.gov/oc/industry	August 07/08/11/14/22, 2014
	FEI NUMBER To be assigned.

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin C. Ellsworth, Chief Financial Officer

FIRM NAME	STREET ADDRESS
Sina LLC, dba OncoMed (Onco360)	225 Community Drive, Suite 100
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Great Neck, New York, 11021	Producer of Sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A) Smoke studies, conducted in the ISO-5 biological safety cabinets (BSC) and laminar flow hoods (LAFW) were not performed under dynamic conditions to verify that operators, processing equipment or activities do not obstruct or alter the unidirectional flow of HEPA-filtered air where aseptic operations are performed.

B) A ductless air conditioning unit was observed mounted to a wall inside the ISO-7 cleanroom, directly adjacent to an ISO-5 BSC. The quality of air supplied by this unit cannot be assured; creating a contamination risk in this critical area.

C) The wall mounted room air-pressure monitors (Magnehelic Pressure Gauges) used to monitor differential air pressures of the (b) (4) ISO-7 clean rooms and ISO-7 ante room are not monitored continuously during production. Pressure differentials are recorded only (b) (4) . There is no mechanism to prevent or identify excursions (i.e., no alarms and/or central monitoring).

D) An automated tablet/capsule counter was observed on a rolling cart directly adjacent to (b) (4) of the ISO-5 BSCs. This tablet counter, when used, potentially creates and disperses dust, from potentially cytotoxic and/or mutagenic drug products.

E) We observed an operator use a wall mounted hand air-dryer (i.e., "blow-dryer") inside the ISO-7 ante room to dry his hands after washing. When on, this dryer propels high velocity air throughout the ISO-7 ante room,

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		Robert C. Steyert, Investigator Helen B. Ricalde, Investigator	08/22/2014

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creating a contamination risk.

OBSERVATION 2

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

An operator was observed preparing sterile drug products wearing a non-sterile gown, non-sterile facial mask, and non-sterile hair bonnet.

OBSERVATION 3

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

Specifically,

A) Environmental monitoring for viable air counts in the ISO-5 hoods is not performed at least (b) (4) during sterile drug processing operations.

B) The work surfaces inside the ISO-5 hoods are not sampled and tested for microbial contamination at least (b) (4) during sterile drug processing operations and at the end of operations.

C) Operators' gloves are not tested for microbial contamination at least (b) (4). Gloved fingertip sampling/testing (for contamination) is performed only as part of their operator qualification program and generally performed only (b) (4) for each operator.

D) Environmental monitoring for non-viable particulates in the ISO-5 hoods is not performed under dynamic conditions. This was last performed in April 2014.

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OBSERVATION 4

Drug products purporting to be sterile and pyrogen-free are not laboratory tested to determine conformance to such requirements.

Specifically,

Your firm has not conducted sterility testing or bacterial endotoxin testing for any sterile products dispensed for patient administration.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed.

Specifically,

A) An operator was observed putting on shoe-covers in a non-classified area (i.e., outside the ante room), where he stepped on an unclean floor, then entered the ante room and continued into the clean room; potentially transporting contaminants to the sterile drug processing area.

B) There are no written procedures describing the frequency or methods for performing media fills/process simulations. Media Fills/Process Simulations do not simulate actual sterile drug processing activities.

OBSERVATION 6

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

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Cleaning and disinfection of the ISO-7 cleanroom and ISO-5 hoods are deficient as there are no studies to support the effectiveness of the cleaning agents (i.e., frequency and rotation) and methods employed.

Specifically,

A) While observing an operator performing daily cleaning of the cleanroom, we witnessed the mop, used to clean the ceiling, floors, and walls, drip onto a wire rack containing sterile components, including syringes and IV bags, which are used in the processing of sterile drug products.

B) The firm does not use sporicidal agents to disinfect the ISO-5 surfaces.

C) Bottles of (b) (4) used to clean ISO-5 hoods and other cleanroom surfaces, are used for an undetermined period of time; however, their sterility cannot be assured once the bottles are removed from their packaging (i.e., overwrap).

D) Non-sterile wipes are used in an attempt to disinfect the interior surfaces of the ISO-5 hoods.

OBSERVATION 7

There is a lack of written procedures describing in sufficient detail the methods, equipment and materials to be used for cleaning and maintenance operations.

Specifically,

A) SOP 3.020 "Cleaning and Maintenance of the Clean Room Facility," which is referenced in SOP 4.06, "Compounding Equipment," and SOP 4.02, "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer," does not exist.

B) Cleaning instructions followed by operators are inadequate in that neither the instructions, nor any of their

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current standard operating procedures, identifies the actual cleaning agents used, or provides instructions for cleaning solution preparation.

OBSERVATION 8

Laboratory controls do not include a determination of conformance to appropriate specifications for drug products.

Specifically,

There are no written procedures requiring the performance of visual checks of all sterile drugs for clarity, discoloration or particulates. Furthermore, there is no documentation to support this practice is actually being performed.

OBSERVATION 9

Records are not always kept for the cleaning of equipment.

Specifically,

There is no documentation that cleaning of the cleanroom and hoods was performed on the following days in which sterile drug products were processed:

- 5/1/14: sterile processing of (b) (4)
- 6/5/14: sterile processing of
- 6/6/14: sterile processing of (b) (4)
- 6/9/14: sterile processing of (b) (4)
- 6/27/14: sterile processing o

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