

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax: (781) 587-7556 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 09/08/2014 - 09/17/2014*
	<small>FEI NUMBER</small> 1270482

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John G. Kelly, CNO/COO

<small>FIRM NAME</small> Marlborough Hospital	<small>STREET ADDRESS</small> 157 Union Street
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Marlborough, MA 01752	<small>TYPE ESTABLISHMENT INSPECTED</small> Producer of 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 OBSERVED:

OBSERVATION 1

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

Specifically,

A. Environmental monitoring of the ISO 5 area and BSC hood is performed (b) (4). Sterile drug products are aseptically manipulated in these hoods as part of daily operations. However, environmental monitoring is conducted by pharmacy staff and results are read by pharmacy staff members that have not received adequate training on microbiology and reading of petri dishes.

B. Personnel Monitoring of pharmacy staff is conducted (b) (4).

OBSERVATION 2

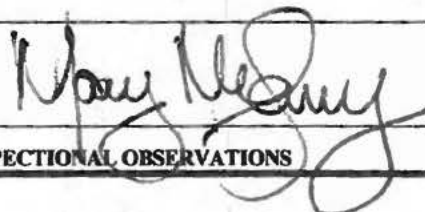
Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically, the firm has not performed air flow pattern studies in their ISO 5 hoods, ISO 7 and ISO8 rooms under dynamic conditions that are used for the production of sterile drug products.

OBSERVATION 3

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


Specifically, the firm's cleaning procedure lacks the use of a sporicidal.

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Mary McGarry, Investigator		<small>DATE ISSUED</small> 09/17/2014

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* DATES OF INSPECTION:
09/08/2014(Mon), 09/09/2014(Tue), 09/17/2014(Wed)

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	Mary McGarry, Investigator 	09/17/2014

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."