DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/11/2015-5/28/2015* FEI NUMBER 3004611372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Diane M. Bernardi , Co-Owner, Pharmacist

FIRM NAME	STREET ADDRESS
Merissa Corp. DBA Johnson Compounding and Wellness	577 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waltham, MA 02452-5527	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 systems for maintaining any equipment used to control the aseptic conditions.

Specifically, your firm's dynamic air flow pattern evaluations of the ISO 5 classified [redacted] (b) (4) and the ISO 5 classified [redacted] (b) (4) Laminar Airflow (LAF) hood, both used to produce sterile preparations, do not demonstrate unidirectional airflow at critical sites under expected worst case conditions with all of the equipment and components typically present during production as follows:

a) Video of your [redacted] (b) (4) dynamic airflow pattern test (smoke study), performed as part of certification on 01/21/2015, shows assessment of [redacted] (b) (4) Your dynamic smoke study did not evaluate all equipment and component configurations including expected worst case conditions such as when a repeater pump and associated equipment and drug components are placed within the enclosure.

b) Video of your LAF dynamic airflow pattern test (smoke study), performed as part of certification on 01/21/2015, shows assessment of [redacted] (b) (4) Your dynamic smoke study did not evaluate all equipment and component configurations including expected worst case conditions such as when [redacted] (b) (4) within the enclosure and process equipment and drug components are placed within the enclosure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edmund F Mrak, Investigator X	DATE ISSUED 5/28/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/11/2015-5/28/2015* FEI NUMBER 3004611372
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Diane M. Bernardi , Co-Owner, Pharmacist	
FIRM NAME	STREET ADDRESS
Merissa Corp. DBA Johnson Compounding and Wellness	577 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waltham, MA 02452-5527	Producer of Sterile Drugs

OBSERVATION 2

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

Specifically, your aseptic simulation (media fill) program is inadequate in that not all aseptic manipulations routinely performed in the preparation of sterile drugs are simulated in a media fill challenge. Additionally, the most challenging or stressful conditions involved producing sterile preparations are not evaluated in aseptic simulations. For example:

a) Your process for producing (b) (4) Alprostadil (b) (4) , including the (b) (4) (b) (4) (b) (4) (b) (4) (b) (4); and finally vial filling are not simulated in your media fills.

b) Aseptic filling of open vials, such as Papaverine 30mg/ml Phentolamine 1mg/ml Injectable Solution, filling is not simulated in a media fill.

OBSERVATION 3

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

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/11/2015-5/28/2015* FEI NUMBER 3004611372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Diane M. Bernardi , Co-Owner, Pharmacist	
FIRM NAME Merissa Corp. DBA Johnson Compounding and Wellness	STREET ADDRESS 577 Main St
CITY, STATE, ZIP CODE, COUNTRY Waltham, MA 02452-5527	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

Specifically, your firm's environmental and personnel monitoring frequency are inadequate to support aseptic operations and effective trending to determine whether the areas are maintained within a state of control as follows:

a) Sampling for viable monitoring at surface sites in the ISO 5 classified critical zones [redacted] (b) (4) and Laminar Airflow Hood) and ISO 7 classified support areas is performed only every [redacted] (b) (4) and not all meaningful sites are sampled. For example, frequently contacted sites such as [redacted] (b) (4) squeeze bottles and spray bottles and door handles to pass-throughs are not sampled.

b) Viable air monitoring within ISO 5 classified critical zones [redacted] (b) (4) Laminar Airflow Hood) is only performed [redacted] (b) (4)

c) Personnel monitoring (finger contact plates) are only performed [redacted] (b) (following aseptic operations and on a [redacted] (b) (4) interval as part of gowning re-qualification. Personnel sites in close proximity to aseptic operations such as forearms and chest are not sampled.

d) Total Particulate monitoring within ISO 5 classified critical zones [redacted] (b) (4) [redacted] (b) (4) and Laminar Airflow Hood (LAF)) is performed only every [redacted] (b) (4) during clean room, LAF and [redacted] (b) (4) recertification.

OBSERVATION 4

Each lot of a drug product container and closure that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Edmund F Mrak, Investigator	X	DATE ISSUED 5/28/2015

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/11/2015-5/28/2015* FEI NUMBER 3004611372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Diane M. Bernardi , Co-Owner, Pharmacist

FIRM NAME	STREET ADDRESS
Merissa Corp. DBA Johnson Compounding and Wellness	577 Main St
CITY, STATE, ZIP CODE, COUNTRY Waltham, MA 02452-5527	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

Specifically, Your firm does not perform testing to verify that commercially prepared sterilized and depyrogenated primary containers including vial/closures (vial, stopper, seal) are sterile and free of objectionable pyrogens before use in the preparation of sterile drugs.

OBSERVATION 5

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

Specifically, sterile wipes used to sanitize surfaces including those within the ISO 5 classified (b) (4) (b) (4) and LAF (Laminar Airflow Hood) are opened in the respective ISO 7 classified buffer rooms and stored in a manner that does not guarantee that they remain sterile before use.

OBSERVATION 6

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

Specifically, disposable sterile gowns, donned by personnel engaged in aseptic operations for the preparation of sterile drugs within the ISO 5 classified (b) (4) and Laminar Airflow Hood (LAF), are reused over the period of a working shift and are not maintained sterile. Also, the upper portion of the face from the bridge of the nose to the upper forehead of personnel engaged in aseptic operations for the preparation of sterile drugs within the (b) (4) and LAF is uncovered. Additionally, the dust mask worn over the nose and lower face of personnel engaged in aseptic operations is not sterile before use.

*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator	X	5/28/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556	5/11/2015-5/28/2015* FEI NUMBER 3004611372

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Diane M. Bernardi , Co-Owner, Pharmacist

FIRM NAME	STREET ADDRESS
Merissa Corp. DBA Johnson Compounding and Wellness	577 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Waltham, MA 02452-5527	Producer of Sterile Drugs

5/11/2015(Mon),5/12/2015(Tue),5/13/2015(Wed),5/14/2015(Thu),5/28/2015(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edmund F Mrak, Investigator	X	5/28/2015

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 judgment, 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."