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	8/10/2015-8/28/2015* FEI NUMBER 3003687986

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ronald L. Petrin , Pharmacist

FIRM NAME	STREET ADDRESS
Bedford Pharmacy Inc.	209 Route 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bedford, NH 03110-5440	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

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

Specifically,

The following deficiencies were identified related to the firm's environmental and personnel monitoring program:

A. The firm has no written procedure defining the environmental monitoring program for the aseptic processing area or for personnel monitoring of employees involved with sterile processing.
B. The ISO 5 (b) (4) is certified (b) (4) by a contract vendor. Static smoke studies are conducted during (b) (4) certifications by the vendor. No smoke studies have been performed in the ISO 5 (b) (4) under dynamic conditions to demonstrate the maintenance of unidirectional air flow during routine operations.
C. There is no routine monitoring of pressure differentials for the ISO 5 (b) (4).
D. The firm conducts personnel monitoring (fingertip plating) only at the time of (b) (4) media fills. There is no personnel monitoring following routine sterile processing, which typically is conducted (b) (4).
E. The firm conducts volumetric viable air sampling and surface sampling ((b) (4)) of the ISO 5 (b) (4) at (b) (4) There is no routine monitoring of the ISO 5 processing area during aseptic operations. In addition, there has been no surface sampling of the ISO 5 (b) (4) documented since February 2014.
F. The (b) (4) locations used for surface sampling are not documented.
G. Volumetric viable air samples are collected using both (b) (4) plates. Records reviewed for the viable air sampling since September 2013 (b) (4) occurrences) revealed that the (b) (4) plates have been incubated at (b) (4) instead of (b) (4) as recommended by the media manufacturer. There

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has been no evaluation to assess the impact (b) (4) recommended incubation temperature may have on the media and/or testing results.

OBSERVATION 2

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

Specifically,

A. Firm personnel stated that the ISO 5 (b) (4) is routinely (b) (4) (b) (4). There has been no evaluation of the impact of this practice on the ISO 5 processing area used for the preparation of sterile drug products.
B. The firm uses a (b) (4) for the sterilization and depyrogenation of reusable equipment (glassware) used in sterile processing. The depyrogenation log documented the use of variable (b) (4) ranging from (b) (4) to (b) (4). There is no data to support that the (b) (4) used are effective for endotoxin reduction as the (b) (4) have not been validated for depyrogenation. The firm uses a (b) (4) with each (b) (4) (b) (4) but has not conducted an endotoxin challenge for any (b) (4)
C. Data from the temperature logger for (b) (4) 10/30/14, documented in the depyrogenation log as a (b) (4), revealed a maximum temperature of (b) (4). The maximum temperature was maintained for less than (b) (4).
D. The firm failed to include the use of reusable glassware during the (b) (4) media fill simulations.

OBSERVATION 3

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

Specifically,

A. The firm's cleaning process (b) (4) of the ISO 5 (b) (4) on a (b) (4). There has been no evaluation of the impact of (b) (4) exposure of the ISO 5

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processing areas to the unclassified air in the room surrounding the (b) (4).

B. The firm disinfects the ISO 5 (b) (4) (b) (4) with either sterile (b) (4) or sterile (b) (4) which are (b) (4), and sterile (b) (4) and during aseptic processing. There is no sporicidal agent available for use at the firm for either routine cleaning or on an as needed basis.
C. The firm uses non-sterile low shedding wipes to clean and disinfect the (b) (4). There has been no assessment related to the use of non-sterile wipes to clean and disinfect the ISO 5 area where aseptic processing occurs.
D. The written procedures related to the cleaning and disinfecting of the ISO 5 (b) (4) are inadequate. The procedures do not include the details of the process used for cleaning and disinfecting the (b) (4) or details related to the (b) (4).
E. There is no written procedure related to the cleaning and disinfection of the ISO 5 (b) (4) prior to use for the preparation of sterile drug products (b) (4).
F. There is no written procedure describing the cleaning process for reusable equipment (including glassware) prior to sterilization and depyrogenation in the (b) (4).

OBSERVATION 4

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

Specifically,

Firm personnel stated that the firm (b) (4) conducts sterility and endotoxin testing on batches of sterile drug products consisting of (b) (4). There is no sterility or endotoxin testing required for batches of sterile drug products consisting of (b) (4).

OBSERVATION 5

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,

A. The firm does not conduct routine potency testing for prepared sterile drug products prior to release.

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B. The firm does not have written procedures related to the sterility, endotoxin, or potency testing of sterile drug products. The firm's process is to (b) (4) products (sterile or non-sterile) (b) (4) There are no established criteria for how products are selected or what testing is to be conducted.

OBSERVATION 6

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

Bimix and trimix (papaverine/phentolamine ± prostaglandin) injections and HPC (hydroxyprogesterone caproate) injections are (b) (4) (b) (4). The firm provided (b) (4) (b) (4) with a (b) (4) (b) (4). However, the firm (b) (4) to support the extended BUDs for the bimix and HPC products as well if they have a (b) (4).

***DATES OF INSPECTION**

8/10/2015(Mon),8/12/2015(Wed),8/14/2015(Fri),8/27/2015(Thu),8/28/2015(Fri)

8/28/2015

X John P Mistler

John P Mistler
Investigator
Signed by: John Mistler -S

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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."