		OF HEALTH AND HUMAN SEI AND DRUG ADMINISTRATION	RVICES	
DISTRICT ADDRESS AND PHO	NE NUMBER	DATE(S	OF INSPECTION	
One Montvale Stoneham, MA		8/1	0/2015-8/28/2015*	
	Fax: (781) 587-7556	300	3687986	
NAME AND TITLE OF INDIVIDUA		4		
FIRM NAME	trin , Pharmacist	STREET ADDRESS		
Bedford Pharm		209 Route 10		
Bedford, NH (Sterile Drug Produ	cts
observations, and do observation, or have action with the FDA	observations made by the FDA repression trepresent a final Agency determining the implemented, or plan to implement, or representative(s) during the inspection tact FDA at the phone number and according to the contract FDA at the co	nation regarding your compliand corrective action in response to a on or submit this information to l	e. If you have an objection reg n observation, you may discus	garding an ss the objection or
OBSERVATION Aseptic process Specifically,	ction of your firm we observe ON 1 ing areas are deficient regar- eficiencies were identified rel	ding the system for mon		
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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Stacey S Degarmo, Investigation P Mistler, Investigation		Stacey S Degarmo Sacey S Degarmo Investigator Speed by: Stacey S. Degarmo-S	8/28/2015
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSER		PAGE 1 OF 4 PAGES

OBSERVATION 2 Aseptic processing areas are deficient regarding systems for maintaining any equipment used to conthe 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		FOOD	AND DRUG ADMINISTRATI	ION
Ronald L. Petrin , Pharmacist PROMINGE STREET ACORESS	One Montvale Stoneham, MA	Avenue 02180		DATE(S) OF INSPECTION 8/10/2015-8/28/2015* FEI NUMBER
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DEFINITION AND DRUG ADMINISTRATION DOMESSOR REPRECION NOTURE OF ROUNDING TO WHOM REPORT ESSED RONALD L. Petrin , Pharmacist Promoder of Sterile Drug Products Bedford Pharmacy Inc. CRY, STARLE, DE CODE, COMPRE Bedford, NH 03110-5440 B. The firm disinfects the ISO 5 (b) (4) (b) (4) and during aseptic processing. C. The firm uses non-sterile low shedding wipes to clean and disinfect the ISO 5 area where aseptic processing occurs. D. The written procedures do not include the details of the process used for cleaning and disinfecting the (b) (4) are inadequate. The procedures do not include the details of the process used for cleaning and disinfecting the (b) (4) are inadequate. The procedure describing the leaning grocess for reusable equipment (including glassware) prior to sterile drug products OBSERVATION 4 Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing of (b) (4) . There is no sterile drug products consisting of (b) (4) . There is no sterile drug products consisting of (b) (4) . There is no sterile drug products consisting of (b) (4) . There is no sterile drug products consisting of (c) (d) . There is no sterile drug products consisting of (c) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterile drug products consisting of (d) (d) . There is no sterility or endotoxin testing on batches of sterile drug products consisting of (d) (d) . There is no sterility or endotoxin testing on batches of sterile drug products consisting of (d) (d) . There is no sterility or endotoxin testing required for batches	One Montvale		AID DOLLE ADMINITED AT	AN SERVICES	
(781) 587-7500 Fax: (781) 587-7556 NAME AND THILE OF PRODUCED. TOWNSHIP STREET ROUNDED. Bedford Pharmacy Inc. CITY. STATE, 2P COOR. COUNTRY Bedford, NH 03110-5440 Producer of Sterile Drug Products Producer of Sterile Drug Products B. The firm disinfects the ISO 5 (b) (4) (b) (4) with either sterile (b) (4) or sterile are (b) (4) and sterile (b) (4) and during asseptic 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 ISO 5 area where asseptic processing occurs. D. The written procedures related to the use of non-sterile wipes to clean and disinfect the ISO 5 area where asseptic procedures related to the cleaning and disinfecting of the ISO 5 (b) (4) are inadequate. The procedures related to the cleaning and disinfecting 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			ND DRUG ADMINISTRAT		
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One Montvale			8/10/2015-8/28/2 FEI NUMBER	2015*
Stoneham, MA (781)587-7500) Fax: (781) 587-7556		3003687986	
NAME AND TITLE OF INDIVIDUA	AL TO WHOM REPORT ISSUED			
	trin , Pharmacist			
FIRM NAME	Calab.	STREET ADDR		
Bedford Pharm			ute 101	
Bedford, NH (er of Sterile Drug	Products
sterile dr sterile)	testing is to be conducted.	ocess is to (b) (4)		(sterile or non-
Drug products d	lo not bear an expiration da	ate determined by	appropriate stability dat	ta to assure they
meet applicable	standards of identity, stren	igth, quality and p	urity at the time of use.	
Specifically,				
Dimir and trimir	/ (nanavarina/phantalamina	prostoplandin) is	rigations and LIDC (hyde	overne contarono
	x (papaverine/phentolamine	± prostaglandin) in	njections and HPC (hydro	
caproate) injection		(b) (4)	(b) (oxyprogesterone The
caproate) injection firm provided	ons are (b) (4) (b)	(b) (4) (4) with a (b)	(b) ((b) (4) . The
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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."