E.**		FOOD AND	HEALTH AND HUMAN SERVICES DRUG ADMINISTRATION		
DISTRICT O New Engla	FFICE ADDRESS AND PHONE NUMBER nd District Office 1 Montvale Ave, 5	Stoneham, MA 021	80	DATE(S) OF INSPEC 10/1-2, 10/4-5, 10/9,	CTION 10/15, and 10/26/12
Tel: (781) 5	187-7500 Industry Information: V TITLE OF INDIVIDUAL TO WHOM REPORT	www.fda.gov/oc/ind	dustry	FEI NUMBER 3003623877	
	rry J. Cadden, Owner	AT IS ISSUED			
FIRM NAME			4	OTDEET HOODE	
New En	gland Compounding Pharmacy I	nc., d/b/a New E	ngland Compounding Center	STREET ADDRESS 697 Waverly Str	
CITY, STATE	AND ZIP CODE				SHMENT INSPECTED
	ham, MA 01702			Compounding	harmoou
IMPLEMENT, CO OR SUBMIT TH	DRRECTIVE ACTION IN RESPONSE TO AN OBS S INFORMATION TO FDA AT THE ADDRESS AB	ERVATION, YOU MAY DI OVE. IF YOU HAVE ANY	RING THE INSPECTION OF YOUR FACILITY. THEY YOU HAVE AN OBJECTION REGARDING AN OBSE ISCUSS THE OBJECTION OR ACTION WITH THE FU Y QUESTIONS, PLEASE CONTACT FDA AT THE PHO	ARE INSPECTIONAL OBSE RVATION, OR HAVE IMPLE DA REPRESENTATIVE(S) DU DNE NUMBER AND ADDRES	RVATIONS, AND DO NOT MENTED, OR PLAN TO JRING THE INSPECTION IS ABOVE.
distribution from the s	on data), a sterile injectable drug	to contain what	e (83) vials out of a bin containing @51 (shipped to customers betwee appeared to be greenish black fore tive free) 80mg/mL were observed	n 8/17/12 - 9/25/1	2 per firm
analysis o Lot #0810	f FDA Sample #693965, consist	ing of methylpre	al vial of bulk formulated methylpr o analysis started 8/14/12 and repord dnisolone acetate (preservative free presence of viable microbial grow eatures.	ted 8/28/12). How	vever, the FDA
injectable inspection. were steril of methylp to sterilize 3. The firm Room 1 an	assuspensions including but not lin , we observed that the labeling for e. Samples were collected for a rednisolone acetate. The firm p suspensions formulated using n a's environmental monitoring pro- d Clean Room 2, used for the pro-	nited to preserva or the methylpre- nalysis of the nor rovided no docu- on-sterile API ar	are sterile, the Pharmacy Director s, with the exception of sterile wate ative free methylprednisolone aceta dnisolone API and additional raw n-sterile API and 3 additional raw mentation or evidence to support th ad raw materials is effective.	er for injection, to f ate and triamcinolo materials did not in materials used in th hat the steam autoc	ormulate ne. During the dicate that they he formulation lave cycle used
	Table #1	: Surface Sample	es from ISO 6 (Class 1,000) Rooms	S	
	Location	Alert: 3 CFU Result	Action: 5+ CFU Result	Dete	BLACK LINE
		Bacteria	Mold	Date	ON
	Main Clean Room				ORIGINAL -
	CRBin1 (polymyxin under station 1)	0	1	2/16/12	NOT A REDACTION
	4 FLR (near hood 5)	10*	2*	2/23/12	
	2 FLR (near hood 3)	3	1	3/8/12	
SEE REVERSE	EMPLOYEE(S) SIGNATURE	r.V.	EMPLOYEE(S) NAME AND TITLE	(Print or Type)	DATE ISSUED
OF THIS PAGE	Theman W. Nemery, I marting of	myarix	Stacey S. Degarmo, Investigato Philip Kreiter, Investigator Almaris N. Alonso, Microbiologi	or	10/24/13
	Debra n 2000	POLISALC HA	 Thomas W. Nerney, Investigato Debra M. Emerson, Investigator 	r r	= #]
FORM FDA 4	83 (9/08) PREVIOUS EDITION OBS	OLETE	INSPECTIONAL OBSERVA		age 1 of 8

	D		ALTH AND HUMAN SERVICES		
	ICE ADDRESS AND PHONE NUMBER District Office 1 Montvale Ave,			DATE(S) OF INSPEC	TION
rion England		Stonenam, WA 02100		10/1-2, 10/4-5, 10/9, FEI NUMBER	10/15, and 10/26/12
Tel: (781) 587	-7500 Industry Information:	www.fda.gov/oc/indus	try	3003623877	
	LE OF INDIVIDUAL TO WHOM REPO	RT IS ISSUED			
TO: Barry	J. Cadden, Owner				
FIRM NAME				STREET ADDRESS	1
New Engla	and Compounding Pharmacy	Inc., d/b/a New Eng	land Compounding Center	697 Waverly St	reet
CITY, STATE A	ND ZIP CODE		······································		SHMENT INSPECTED
Framingha	im, MA 01702			Compounding F	harmacy
IMPLEMENT, COR OR SUBMIT THIS I	RECTIVE ACTION IN RESPONSE TO AN OB	SERVATION. YOU MAY DISC	G THE INSPECTION OF YOUR FACILITY. TH DU HAVE AN OBJECTION REGARDING AN OE USS THE OBJECTION OR ACTION WITH THE JESTIONS, PLEASE CONTACT FDA AT THE F	SERVATION, OR HAVE IMPLE	MENTED, OR PLAN TO
	Location	Result Bacteria	Result Mold	Date	
	4 FLR (near hood 5)	2	2	3/15/12	-
	Table 2	0	1 mold (34 of plate)*	3/29/12	-
				07100000-071000-0700	

Table 2	0	1 mold (34 of plate)*	3/29/12
1 FLR (near hood 1)	One h	air with growth around it	3/29/12
4 FLR (near hood 5)	OG*	0	4/5/12
CRBin1(inside big uline bin with omnipaque 240)	1	1	6/13/12
3 FLR (near horiz hoods)	OG*	0	6/13/12
3 FLR (near horiz hoods)	1	2	6/28/12
CRBin2 (front of tetracaine Hcl powder container)	0	OG mold*	7/5/12
Pass thru	0	l small mold	7/26/12

Note: (*) indicates result over action level; OG indicates over growth

1.1

		5 CFU	Action: 7+ CFU		BLACK LINE
	Location	Result Bacteria	Result Mold	Date	
	Gown Room (Clean Room 1)		1		ORIGINAL -
	8 FLR (GR/near hooks)	23*	0	2/16/12	NOT A REDACTIO
	GRmisc2 (vent arms)	13*	1*	2/16/12	-
	GRmisc2 (empty plastic bag in empty bin)	19*	0	2/23/12	
	GRmisc1 (vent arms behind hand washer)	27*	0	2/23/12	
	7 FLR (gown room/entrance)	2*	11*	2/23/12	-
	8 FLR (gown room/near hooks)	11*	4*	2/23/12	-
	7 FLR (gown room/entrance)	0	1	3/1/12	-
	WallGR2 (windowsill side to MR)	18*	0	3/1/12	1
	8 FLR (gown room/near hooks)	12*	0	3/1/12	7
	GRmisc2 (vent grids)	16*	2*	3/1/12	-
	7 FLR (gown room/entrance)	3	2	3/8/12	1
	8 FLR (gown room/near hooks)	3	2	3/8/12	
	7 FLR (gown room/entrance)	3	3	3/15/12	7
	8 FLR (gown room/near hooks)	0	2	3/15/12	1
	8 FLR (gown room/near hooks)	16*	0	3/29/12	1
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	in_	EMPLOYEE(S) NAME AND TITLE Stacey S. Degarmo, Investigat Philip Kreiter, Investigator Almaris N. Alonso, Microbiolog Themas W. Alexandrea	or	
ORM FDA 4	183 (9/08) PREVIOUS EDITION OBSOLETE		Thomas W. Nerney, Investigat Debra M. Emerson, Investigato INSPECTIONAL OBSERVA	<u>or</u>	Page 2 of 8

Table #2: Surface Samples of ISO 7 (Class 10,000) Rooms

d District Office 1 Montvale Ave, Stoner 7-7500 Industry Information: www.fc TLE OF INDIVIDUAL TO WHOM REPORT IS IS y J. Cadden, Owner land Compounding Pharmacy Inc., d	a couloo/industry		10/1-2, 10/4-5, 10/9,	10/15, and 10/26/12
TLE OF INDIVIDUAL TO WHOM REPORT IS IS y J. Cadden, Owner land Compounding Pharmacy Inc., d	la.gov/oc/industry SSUED		FEI NUMBER	
y J. Cadden, Owner land Compounding Pharmacy Inc., d	SSUED		3003623877	
land Compounding Pharmacy Inc., d				
	In a New Franks I O		STREET ADDRESS	50 ···
	/b/a New England C	ompounding Center	697 Waverly St	
am, MA 01702			and the second second second second	SHMENT INSPECTED
			Compounding F	Pharmacy
RECTIVE ACTION IN RESPONSE TO AN OBSERVATION FOR ACTION TO FOR AT THE ADDRESS ABOVE. IF	ON YOU MAY DISCUSS THE	AN OBJECTION REGARDING AN OBS	ERVATION, OR HAVE IMPLE	MENTED, OR PLAN TO
Location	Result	Result	Date	7
	Bacteria	Mold	Date	
	11*	0	3/29/12	1
	10*	0	4/5/10	_
7 FLR (gown room/entrance)	0	1		
			1.5112	
GRmisc1 (rubber flap over wheel of rack)	9*	0	4/12/12	
middle room)		0	4/12/12]
bouffants)		0		
	And the second se	1		_
		the second se	and the second state of th	-
7 FLR (GR entrance)	3	3		-
	3/4 of plate OG*	1*	7/26/12	-
		0	7/26/12	
				_
GRmisc2 (loose bootie bin)	0	-		-
Middle Room			0/25/12	
				BLACK
		1		LINES ON
	Constant of the second s			
MRmisc1 (dh20 gallon)	1			NOT A
Gown Room				REDACTIC
(Clean Room 2)				
	OG*	0	1/26/12	
		1	3/1/12	
	9*	0	8/9/12	
(Clean Room 2)				
Prep Room Flr	1	1	2/2/12	
Misc #2 PR (top of radio)	0	1	2/7/12	
		1	4/4/12 6/13/12	
Mise #2 PR (top of radio) Mise: PR (Calcium chloride bin) Prep Room Flr	1			_
R	RECTIVE ACTION IN RESPONSE TO AN OBSERVATION TO FDA AT THE ADDRESS ABOVE. IF INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF ECTION OF YOUR FIRM WE OBSERVED: INFORMATION TO FDA AT THE ADDRESS ABOVE. IF INFORMATION TO FOAD AT THE ADDRESS ABOVE. IF INTERCENT AND	Reference 0	Interpretation of the constraint constraint of the constraint of the constraint of the constrai	Location Result Bacteria Result Mold Date GRmisc2 (floor under barrel against wall) 11* 0 3/29/12 8 FLR (gown room/near hooks) 10* 0 4/5/12 7 FLR (gown room/near hooks) 10* 0 4/5/12 GRmisc1 (rubber flap over wheel of rack) 9* 0 4/12/12 GRmisc1 (rubber flap over wheel of rack) 9* 0 4/12/12 GRmisc1 (rubber flap over wheel of rack) 9* 0 4/12/12 GRmisc1 (rubber flap over wheel of rack) 9* 0 4/12/12 GRmisc1 (rubp of rack with bouffants) 12* 0 5/10/12 Bacteria 9* 0 5/31/12 8 FLR (GR/near hooks) 19* 0 5/31/12 8 FLR (GR/near hooks) 0 13* 6/28/12 GRmisc1 (bottom of bootie bin) ½ of plate OG* 1* 7/26/12 GRmisc2 (toot of rack with) plate ¼ overgrown* 0 7/26/12 GRmisc2 (toot of rack) 9* 0 7/26/12 GRmisc2 (toot of rack ot

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DISTRICT OFFI New England	CE ADDRESS AND PHONE NUMBER District Office 1 Montvale Ave, Stone	eham, MA 02180		and the second se	ECTION 9, 10/15, and 10/26/12
Tel: (781) 587	-7500 Industry Information: www.	fda.gov/oc/industry		FEI NUMBER 3003623877	
	LE OF INDIVIDUAL TO WHOM REPORT IS	ISSUED		000023077	
	J. Cadden, Owner				
FIRM NAME				STREET ADDRE	SS
New Engla	and Compounding Pharmacy Inc.,	d/b/a New England	Compounding Center	697 Waverly	
CITY, STATE AN	ND ZIP CODE				LISHMENT INSPECTED
	m, MA 01702			Compounding	Pharmacy
IMPLEMENT, CORF	ISTS OBSERVATIONS MADE BY THE FDA REPRE: AL AGENCY DETERMINATION REGARDING YOUR RECTIVE ACTION IN RESPONSE TO AN OBSERVAT VFORMATION TO FDA AT THE ADDRESS ABOVE. CTION OF YOUR FIRM WE OBSERVED: Table #3: S	TION, YOU MAY DISCUSS TH	AN OBJECTION REGARDING AN C	HEY ARE INSPECTIONAL OF DBSERVATION, OR HAVE IMP IE FDA REPRESENTATIVE(S) PHONE NUMBER AND ADD	SERVATIONS, AND DO NOT PLEMENTED, OR PLAN TO
	Aler	rt: 8 CFU	Action: 10+ CFU	ooms	
	Location	Result	Result	Date	BLACK LINE
		Bacteria		Date	ON
	Prep Room (Clean Room 1)				ORIGINAL -
	Misc. Prep room samples	0	OG with m	old* 1/6/12	NOT A
	(shopping cart handle)	0		1/0/12	REDACTION
	Misc. Prep room samples (metal cart)	1	1	1/26/12	REDACTION
	PR (carriage w/blue handle w/scratch marks)	3	1	2/2/12	
	PR (carriage w/blue handle w/x)	4	1	2/2/12	
	PR (outside of barrel)	16*	2*	3/1/12	
	9 FLR (PR) (near entrance) PR (blue tamper evident caps,	1	7	3/8/12	
	bin)	4	3	3/15/12	
	PRmisc2 (inside plastic cover to clear plastic bags)	OG*	0	4/5/12	
	9 FLR prep room (near entrance)	3/4 plate OC	j* 0	4/5/12	
	10 FLR (PR) (under 2 nd rack)	3		4/12/12	
	PR MISC 2 (top of lid of white container under rack)	1	1	5/24/12	
	10 FLR (PR) (back of room area)	OG*	0	5/24/12	
	10 FLR (PR) (back of room area) 9 FLR (PR) (entrance area)	0	3	5/31/12	
	10 FLR (PR) (back of room area)	OG* 	0	6/15/12	
	10 FLR (PR) (back of room area)	12*	0	6/15/12	
[9 FLR (PR) entrance area	4*	15*	6/28/12	-
	Note: (*) indicates result over ac Table #4: Location		0 6 (Class 1,000) Room t Resul	lt Date	
		Datter	IVI0IO		BLACK LINE ON
	Middle Room (Clean Room 2)				ORIGINAL -
	Middle room	0	l big m	old 5/29/12	NOT A
SEE E	MPLOYEE(S) SIGNATURE		EMPLOYEE (S) MAKE AND T	TIE (Drint as T	DATE
OF THIS	Hours Manue Enerstrator	5	EMPLOYEE(S) NAME AND TI Stacey S. Degarmo, Invest	igator	DATE ISSUED
PAGE 1	Lynn Wind, Investigator	, inc	Philip Kreiter, Investigator Almaris N. Alonso, Microbio Thomas W. Nerney, Invest	ologist	10/26/12-
5004 55 1	Joben D. Faire	Low white they -t	Debra M. Emerson, Investi	gator	
FORM FDA 48	3 (9/08) PREVIOUS EDITION OBSOLE	TE I	NSPECTIONAL OBSER	RVATIONS	Page 4 of 8

			T OF HEALTH AND AND DRUG ADMI	HUMAN SERVICES		
	ADDRESS AND PHONE NUM strict Office 1 Montvale A		IA 02180	1997 - 01.3 - 19 77 - 5 Mare - 198	DATE(S) OF INSPE 10/1-2, 10/4-5, 10/9 FEI NUMBER	ECTION 0, 10/15, and 10/26/12
Tel: (781) 587-75	500 Industry Informatic OF INDIVIDUAL TO WHOM RI	n: www.fda.gov	/oc/industry		3003623877	
	Cadden, Owner	PORT IS ISSUED				
FIRM NAME	Cadden, Owner				STREET ADDRES	
	d Compounding Pharma	cv Inc., d/b/a N	lew England Com	pounding Center	697 Waverly S	
CITY, STATE AND						LISHMENT INSPECTED
Framingham,	, MA 01702				Compounding	420.50
IMPLEMENT, CORREC OR SUBMIT THIS INFO	TS OBSERVATIONS MADE BY THE AGENCY DETERMINATION REGAR DTIVE ACTION IN RESPONSE TO AN DRMATION TO FDA AT THE ADDRE ION OF YOUR FIRM WE OBSERVED	DING YOUR COMPLIA I OBSERVATION, YOU SS ABOVE. IF YOU H	NCE. IF YOU HAVE AN C	BJECTION REGARDING AN	OBSERVATION, OR HAVE IMP	LEMENTED, OR PLAN TO
		able #5: Air S		(Class 10,000) Roo	oms	
	Location	Alert: 5 C		Action: 8+ CFU Result	Date	- I
			teria	Mold	Date	
	Gown Room					
	(Clean Room 1) Gown room	29)*	 *	5/31/12	BLACK
	Gown room	1	the second se	1*	6/28/12	LINES ON
	Middle Room (Clean Room 1)					ORIGINAL -
	Crimp Station		3		2/23/12	NOT A
	Prep Room				2/20/12	REDACTION
	(Clean Room 2) Prep room			1	5/2/12	
	Gown Room		,	1	5/2/12	
	(Clean Room 2)	Ē				
	Gown room Note: (*) indicates res		*	3*	8/9/12	
	note. () indicates les		level			
	Table #6.	Surface and A	in Compliant of IC	0.5 (Class 100) Cl	D 2	
				O 5 (Class 100) Cle n for ISO 5 (Class 1		
	Location	Sample	Result	Result	Date	-
	Table 1 (and the last	Туре	Bacteria	Mold		
	Table 1 (near Horiz L & R hoods)	Surface	0	3	1/26/12	
	Table 1 (near Horiz L & R hoods)	Surface	1	1	5/2/12	
	Between Horiz L & Horiz R	Air	1	1	7/25/12	
	HONZ K	, L.				
There was no	investigation conducted	by the firm wl	nen levels exceed	ed their action limit	ts and there was no i	dentification of the
isolates. No d	ocumented corrective a	ctions were tak	en to remove the	microbial contamir	nation (bacteria and i	mold) from the
facility.						57
SEE EN	PLOYEE(S) SIGNATURE		EM	PLOYEE(S) NAME AND	TITLE (Print or Tuno)	DATE ISSUED
REVERSE	guy Dagenes, Tru	ship av	Sta	cey S. Degarmo, Inve	stigator	DATE ISSUED
PAGE T	how W. Verr, Im	shoch .	7 Alm	ip Kreiter, Investigato aris N. Alonso, Microl	r biologist	1/12/12
			lind	mas W. Nerney, Inve	stigator	. 1 . 1 .
FORM FDA 483		NOBSOLETE		PECTIONAL OBSE		
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FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER New England District Office 1 Montvale Ave, Stoneham, MA 02180	DATE(S) OF INSPECTION 10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12
Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	FEI NUMBER 3003623877
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Barry J. Cadden, Owner	
FIRM NAME New England Compounding Pharmacy Inc., d/b/a New England Compounding Center	STREET ADDRESS 697 Waverly Street
CITY, STATE AND ZIP CODE Framingham, MA 01702	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. TH REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OB	

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 FOA 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:

4. The environmental monitoring procedure requires sampling via personnel touch plates taken upon completion of sterile compounding and prior to cleaning. Records from January thru September 2012 for Clean Room 1 and Clean Room 2 showed the following results inside production hoods:

Denne Land Classe Den

Date	Isolates	Location	Product
1/3/12	OG with bacteria	Horizontal 1 (Clean Room 1)	Avastin
4/12/12	OG with bacteria	IT/Hood 3 (Clean Room 1)	Product not documented
6/15/12	l bacteria, i mold	Horizontal 2A (Clean Room 1)	Ropiv/Ketor/Epi
6/21/12	2 bacteria	Horizontal R (Clean Room 2)	Product not documented
7/2/12	½ plate OG with bacteria	Horizontal L (Clean Room 2)	Product not documented
7/19/12	I bacteria, 2 molds	Horizontal 2C (Clean Room 1)	Mafenide Acetate
7/31/12	2 bacteria	Horizontal 2A (Clean Room 1)	KCI/Lido/DSW
8/16/12	2 bacteria	Hood 3 (glovebox) (Clean Room 1)	Ace 20%, Ped Atropine

Note: OG indicates over growth

These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products.

5. The conditions listed below were identified during the inspection in areas used for the preparation, filling, and/or storage of sterile drugs products.

• On 10/04/2012, we observed condensation and what appeared to be tarnished discoloration on the interior surfaces (e.g. chamber) of the '(b) (4) mautoclave'', located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions, including preservative free formulations of methylprednisolone and triamcinolone, which are intended for injection. Of note, this is the final sterilization step in the process for these products.

FORM FDA 463 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	Page 6 of 8
SEE REVERSE OF THIS PAGE PAGE EMPLOYEE(S) SIGNATURE Intervention for the former former New New The Former former Intervention for the former former Intervention for the former former Intervention for the former former Intervention for the former former former Intervention for the former for	EMPLOYEE(S) NAME AND TITLE (Print or Type) Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nerney, Investigator Debra M. Emerson, Investigator	DATE ISSUED 小力し

DEPARTMENT OF HEALTH FOOD AND DRUG A	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER New England District Office 1 Montvale Ave, Stoneham, MA 02160	DATE(S) OF INSPECTION 10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12 FEI NUMBER
Tel: (781) 587-7500 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	3003623877
TO: Barry J. Cadden, Owner	
FIRM NAME	STREET ADDRESS
New England Compounding Pharmacy Inc., d/b/a New England CITY, STATE AND ZIP CODE	Compounding Center 697 Waverly Street TYPE OF ESTABLISHMENT INSPECTED
Framingham, MA 01702	Compounding Pharmacy
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS TH OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIO	NSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO E OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION
DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:	the second s
"Inside" autoclave, located in the firm's Middle Room (I	on lining the interior surface of the viewing lens within the SO 7). This is one of two tabletop autoclaves used for steam vials of multiple sizes, stoppers, and spin bars) used in the
trays) of the "Outside" autoclave located in the firm's M along the interior surfaces of the "Outside" autoclave to	ted discoloration on the interior surfaces (e.g. chamber and iddle Room (ISO 7). Moreover, condensation was observed collect in a pool at the base of the chamber. This is one of two s components and equipment (e.g. vials of multiple sizes, e drug products.
mattresses and plastics. On 10/02/2012, the area was ob	area by a recycling facility that handles such materials as served to include large equipment (e.g. excavators and freight top units serving the firm's HVAC system were estimated to sility.
louvers of an HVAC return located behind the ' (b)	articulate and white, filamentous substances covering the autoclave", located in the firm's Middle Room (ISO 7). Wated bulk drug suspensions, including preservative free which are intended for injection.
	idue lining the rear return of Weigh Station 2 Hood and 3 Hood, both located in the firm's ISO 6 Clean Room. The nts and other raw materials utilized in the formulation of sterile
	the surface of the (b) (4) ceiling, exposed to the (b) (4) firm's ISO 6 Clean Room. The firm uses Weigh Station als utilized in the formulation of sterile drug preparations.
	hed discoloration on the interior surfaces (e.g. chamber and from (ISO 8). This (b) (4) is used to sterilize equipment ion of sterile drug products.
	EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED
SEE REVERSE OF THIS PAGE DE TURN W. New, Tomeliging Law W. New, Tomeliging Law Mary, Tomeliging	EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED Stacey S. Degarmo, Investigator Philip Kreiter, Investigator Almaris N. Alonso, Microbiologist Thomas W. Nemey, Investigator
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS Page 7 of 8

SEE REVERSE OF THIS PAGE EMPLOYEE(S) SIGNATURE Townson The Townson Tow	EMPLOYEE(S) NAME AND TITL Stacey S. Degarmo, Investiga Philip Kreiter, Investigator Almaris N. Alonso, Microbiolo Thomas W. Nemey, Investiga – Debra M. Emerson, Investiga	ator Distator
 On 10/04/2012, we observed what appeared to be of the bottom edge of the closed pass through installed ISO 6 Clean Room to formulate and fill sterile prep 	d within the wall of the ISO 6 Cla	ean Room. The firm utilizes the
 On 10/04/2012, we observed cloudy discoloration of metal surfaces within the "Pass Thru," installed with within the ISO 6 Clean Room, was observed to com ISO 6 Clean Room to formulate and fill sterile prepared 	thin the wall of the ISO 6 Clean F tain reddish-brown and cloudy st	Room. Moreover, the metal ledge, ubstances. The firm utilizes the
 On 10/02/2012, the tacky mat located within the enwas observed to be brown and soiled. This room is (b) (4) 		
 On 10/04/2012, a boiler installed within approxima to be leaking water into puddles. Moreover, wet flo debris and thick black, granular material. Gaps wer the Prep Room (ISO 8) and the warehouse, despite equipment and includes the the flow (b) (4) 	oor surfaces around the boiler appression of the surfaces around the boiler appression of the surfaces around the surfaces aro	beared to be soiled with thick white s, located at the transition between
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Framingham, MA 01702		Compounding Pharmacy
TY, STATE AND ZIP CODE	and compounding center	TYPE OF ESTABLISHMENT INSPECTE
NAME New England Compounding Pharmacy Inc., d/b/a New Eng	land Compounding Center	STREET ADDRESS 697 Waverly Street
		OTOSET ADDREAD
AME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED D: Barry J. Cadden, Owner	try	FEI NUMBER 3003623877
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AME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED O: Barry J. Cadden, Owner		DATE(S) OF INSPECTION 10/1-2, 10/4-5, 10/9, 10/15, and 10/26/12

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