	DEPARTMENT OF HEAL	TH AND HUMAN SERV	VICES	
DISTRICT ADDRESS AND PH			DATE(S) OF INSPECTION	
19701 Fairch		7/21 FEI NUMB	/2017-7/27/2017*	
Irvine, CA 9			670025	
(949)608-290	00 Fax:(949)608-4417	0010	0.0020	
NAME AND TITLE OF INDIVID	UAL TO WHOM REPORT ISSUED			
	io , Office Manager			
FIRM NAME		STREET ADDRESS		
	tem Cell Treatment	120 S Spaldin	g Dr, Suite 300	
Center/Cell city, state, 2P code, cou	11 Surgical Network			
Constraint and a second second second	s, CA 90212-1800	Manufacturer		
observations, and de observation, or have action with the FDA questions, please co The observations	observations made by the FDA representative(s) o not represent a final Agency determination reg implemented, or plan to implement, corrective a representative(s) during the inspection or subm ntact FDA at the phone number and address abo noted in this Form FDA-483 are not an exh a for conducting internal self-audits to identified	arding your compliance. action in response to an it this information to FE ve. austive listing of obje	If you have an objection r observation, you may disc OA at the address above. If ctionable conditions. Un	egarding an uss the objection or you have any nder the law, your
Specifically,	he identity, strength, quality, and pu failed to validate your manufacturing product at your Beverly Hills f	process for the au		
	DN 2 igned to prevent microbiological cor hed and followed.	atamination of dru	g products purportin	ng to be sterile
Specifically,				
Since July 2, 20	15, your firm has manufactured app	roximatelv(b) (4)ba	tches of autologous	Stromal
the second s	on (SVF) product. The autologous S		이 가지 않는 것 같아요. 같은 것 같아요. 이 것 같아요. 가지 않는 것 같아요. 가지 않는 것	1.1.2.00 M 2.3.4.2.00 M 2.2
vascular i racti	on (3 v1) product. The autorogous 3	vi produce is to b	e administered by it	inavenous
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darla J Christopher, Investi Michele L Forster, Investiga Biologics		Daria J Christopher Investigator Bigene By: Caria J, Civialopher -3 Dain Digned: 7/27/2017	DATE ISSUED 7/27/2017
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSI	PECTIONAL OBSERVA	TIONS	PAGE 1 OF 10 PAGES

	DEPARTMENT OF HEAL	TH AND HUM	IAN SERVICES
DISTRICT ADDRESS AND PH		G ADMINISTRAT	TION DATE(S) OF INSPECTION
19701 Fairch	nild		7/21/2017-7/27/2017*
Irvine, CA			FEI NUMBER 3013670025
(949)608-290	000 Fax:(949)608-4417		
And the second states of the second second states the	UAL TO WHOM REPORT ISSUED		1
	lio , Office Manager		
FIRM NAME	Stem Cell Treatment	STREET ADDRESS	
 Structure Succession Million Distriction - et 	Surgical Network	120 5 55	palding Dr, Suite 300
CITY, STATE, ZIP CODE, COL	NTRY	TYPE ESTABLISHM	MENT INSPECTED
Beverly Hill	s, CA 90212-1800	Manufact	turer
(mixed with SV prepared the au procedure and be administered (b) (4) (A) An aseptic product has not manufactured in i. No evidence (b) (4) provided to den temperature, hu of these produc if D) (1) preparation of t gloves. There is	F, and (b) (4) at your firm by an outologous SVF product from recovered deployed the mixed (b) (4) at your firm by an outologous SVF product from recovered deployed the mixed (b) (4) at your firm recovered deployed the mixed (b) (4) at your firm recovered for groups of intra-tumoral injurport of the solution of the set of the solution of the solut	tured at you outside affil ed adipose to produce ection. As a his manner ogous SVF sure that th gical contant facturing of rolled environmeters, suc e been estal where the au ures of (b) el are only for prepare the S	ur firm. The (b) (4) was prepared, liate under their procedures. Your firm tissue using your SVF preparation ct. The (b) (4) product is to an example, one batch of the and deployed at your firm on 7/19/17. product and (b) (4) nese products can be consistently mination. If autologous SVF product and conment. For example, no evidence was ch as pressure differentials, air flow, blished for the suite used for production itologous SVF product is prepared is (4) "used by your firm for required to wear a cap, mask, and sterile SVF product to wear an appropriate
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darla J Christopher, Investig Michele L Forster, Investigat Biologics		ITI Daris / Christopher Signed By: Daris / Christopher -S X Date Signed: 707/2017
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSP	ECTIONAL OF	BSERVATIONS PAGE 2 OF 10 PAGES

		LTH AND HUMAN SERVI	CES	
DISTRICT ADDRESS AND PH			INSPECTION	
19701 Fairch		7/21/ FEI NUMBER	2017-7/27/2017*	
Irvine, CA 9	92612-2445		70025	
(949)608-290	000 Fax:(949)608-4417			
All and a state of the state of the state of the	UAL TO WHOM REPORT ISSUED			
Judi E. Megl	io , Office Manager	STREET ADDRESS		
COMMAN PARTY	Stem Cell Treatment	120 S Spalding	Dr. Suite 300	
1. Model and a strain for a second static factor of SQL 1 and strain for the second strain strain strain strain strain.	Surgical Network	120 5 Sparding	DI, BUILE 500	
CITY, STATE, ZIP CODE, COU	NTRY	TYPE ESTABLISHMENT INSPECTED	>	
Beverly Hill	s, CA 90212-1800	Manufacturer		
stainless steel i	has failed to validate the (b) (4) steril nstruments and (b) (4) used for pro-	17		
OBSERVATI Each batch of c appropriate lab	drug product required to be free of o	bjectionable microo	rganisms is not test	ted through
Specifically,				
Vour firm has	failed to perform sterility testing on a	(b) (4)	hatches of SVE pro	duct
and a second	rom July 2, 2015 to July 20, 2017 at	Contraction of the second s	(D) (4)	product
NAME AND ADDRESS OF AD	rom December 3, 2015 to July 19, 2	And a state of the		100000
firm are admin	istered by intravenous infusion, intra	articular injection,	injection into soft	tissue, intra-
cerebroventricu	lar injection, or nebulization. The	(b) (4)	batches manufactur	red by your
firm are admini	istered by intravenous or intra-tumor	al injection.		2.2
	· · · · · ·			
OBSERVATIO		Vor 128 - 128	8. W 8.2	
Aseptic process	ing areas are deficient regarding the	system for monitor	ing environmental	conditions.
Specifically,				
No environmen the (b) (tal monitoring is performed during t	he manufacture of t	he autologous SVF	product and
				- 1
				I
SEE REVERSE	EMPLOYEE(S) SIGNATURE Darla J Christopher, Investi	ator	1	DATE ISSUED 7/27/2017
OF THIS PAGE	Michele L Forster, Investiga		Darls J Christopher	1/21/2011
	Biologics		Signed By: Carts J. Christopher -S. Date Signed: 2/27/2017	
			<u>~</u>	
FORM FDA 483 (09/05)	PREVIOUS EDITION OBSOLETE INSI	PECTIONAL OBSERVAT	IONS	PAGE 3 OF 10 PAGES

	F HEALTH AND HUM	
DISTRICT ADDRESS AND PHONE NUMBER	AND DRUG ADMINISTRAT	DATE(S) OF INSPECTION
19701 Fairchild		7/21/2017-7/27/2017*
Irvine, CA 92612-2445		FEINUMBER 3013670025
(949)608-2900 Fax:(949)608-4417		3013070023
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
Judi E. Meglio , Office Manager		
FIRM NAME	STREET ADDRESS	
California Stem Cell Treatment	120 S Sp	alding Dr, Suite 300
Center/Cell Surgical Network	TYPE ESTABLISHM	ENT INSPECTED
Beverly Hills, CA 90212-1800	Manufact	
 (B) There is no non-viable particulate monito (C) There is no active or passive air monitoring 		
OBSERVATION 5 Aseptic processing areas are deficient regardi equipment to produce aseptic conditions.	ng the system for	cleaning and disinfecting the room and
Specifically,		
(A)Your firm utilizes a checklist for cleaning (b) (4) product is prepared and or cleaning the suite that includes assignment of methods, equipment, and materials used to pe	deployed, but the responsibility an	re is no written procedure established for d a description in sufficient detail of the
(B) Your written procedure for cleaning reusa the autologous SVF product and (b) (4 methods, equipment, and materials used to pe	 product of 	loes not include sufficient detail of the
OBSERVATION 6 The identity of each component of a drug proot the identity, using specific identity tests if the		d by conducting at least one test to verify

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(B)SIGNATURE Darla J Christopher, Michele L Forster, Ir Biologics	nvestigator - Team Daris J Christoph	DATE ISSUED 7/27/2017 htt -) Challogher-5
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 4 OF 10 PAGES

		HEALTH AND HUMAN		
DISTRICT ADDRESS AND PH	ONE NUMBER	1	DATE(S) OF INSPECTION	
19701 Fairch Irvine, CA 9			7/21/2017-7/27/2017* FEI NUMBER	£
	900 Fax: (949)608-4417		3013670025	
NAME AND TITLE OF INDIVID	UAL TO WHOM REPORT ISSUED			
Judi E. Megl	io , Office Manager	STREET ADDRESS		
	Stem Cell Treatment	00557-007 -0025 -6-65	lding Dr, Suite 300	
Center/Cell	Surgical Network			
CITY, STATE, ZIP CODE, COU Beverly Hill	.s, CA 90212-1800	Manufactu:		
product manufa	logous SVF product. Since Dec	2015, your firm h	as manufactured approx	_{imately} (b) (4)
specifications, product contain identity, streng Specifically,	trols do not include the establish standards, sampling plans and te hers, closures, in-process materia th, quality and purity. failed to perform an identity test	est procedures des als and drug produ	igned to assure that com acts conform to appropria	ponents, drug ate standards of
SVF product m	anufacturing:	d)	b) (4) has manufactured approx	
the autologous the (k		(b) (4) SVF product. You	is use ar firm has failed to esta	d to calculate
specifications fo 2015, approxim	ately ^{(b) (4)} batches of autologous			Since July 2,
		SVF product wer		Since July 2,

		DEPARTMENT OF I			
DISTRICT ADDRESS AND PH	ONENUMBER	FOOD AND	DRUG ADMINISTRAT	DATE(S) OF INSPECTION	
19701 Fairch				7/21/2017-7/27/2017*	
Irvine, CA 9			FEINUMBER 3013670025		
(949)608-290	08-2900 Fax: (949)608-4417				
NAME AND TITLE OF INDIVID	UAL TO WHOM REPORT ISSUED				
Judi E. Megl	io , Office Ma	anager			
FIRM NAME			STREET ADDRESS		
	Stem Cell Treat		120 S Sp	alding Dr, Suite 300)
CENTER/CELL CITY, STATE, ZIP CODE, COU	Surgical Netwo	OIK	TYPE ESTABLISHME	ENT INSPECTED	
Beverly Hill	.s, CA 90212-18	800	Manufact	urer	
(b) (4)	product we	re manufacture	d and deployed	ce December 3, 2015, (b) to patients by your firm. batch of drug product pr	
and the second state of the second			and the second state of th	d control of each batch.	99939999999999999999999999999999999999
Specifically,					
autologous SVI	has not prepared a F product since Ju ince December 3	uly 2, 2015 and		or approximately ^{(b) (4)} ba the (b) (4)	tches of product
(B) Your firm f autologous SVI limited to: (b) (b) (4)	F product and	he specific com (b) (4)		ed in the manufacturing of the second point of	
(C) Vour firm f	ailed to identify t	he equipment u	sed in the man	ifacture of each batch of	autologous SVE
nustration for several and the second	CONTRACTOR OF A DESCRIPTION OF A DESCRIP			Manufacture of the second s	and the second provide a second se
product and	(b) (4)	The second second second second	ling, but not lin	nited to: (b) (4)	syringes, the
(b) (4)	11 5 1 45	the (b) (4)		(b) (4) and the	e (b) (4)
(b) (4)	(b) (4)				N
N258 RE	ailed to record th			(b) (4)	in the
manufacturing of	of each batch of a	utologous SVF	product and	(b) (4) produ	ct.
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darla J Chris Michele L For Biologics			M Daria J Christopher Borelighter Borelighter Data J Christopher Data Septed 7/27/2017	DATE ISSUED 7/27/2017
FORM FDA 483 (09/08)	PREVIOUS EDITION O	BSOLETE	INSPECTIONAL OI	BSERVATIONS	PAGE 6 OF 10 PAGES

		TH AND HUMAN SERVIC	CES			
DISTRICT ADDRESS AND PH	ONE NUMBER	DATE(S) OF I	DATE(5) OF INSPECTION 7/21/2017-7/27/2017*			
19701 Fairch Irvine, CA 9						
	00 Fax: (949) 608-4417		70025			
NAME AND TITLE OF INDIVID	JAL TO WHOM REPORT ISSUED					
	io , Office Manager					
FIRM NAME	0-11 m	120 S Spalding	Des Guite 200			
the second se	tem Cell Treatment Surgical Network	120 S Sparding	Dr, Suite 300			
CITY, STATE, ZIP CODE, COU	NTRY	Manufacturer				
Beverly Hill	s, CA 90212-1800	Manufacturer				
No. 1400 and the second second second		o) (4) produc	ant step in the man t, including, but no nel performing the	ot limited to the		
Written proced handling, samp Specifically,	OBSERVATION 9 Written procedures are lacking which describe in sufficient detail the receipt, identification, storage, handling, sampling, testing, approval and rejection of components. Specifically, Written procedures are limited in regards to the manufacturing process for autologous SVF product in					
that: (A) Your firm l one year for	acks written stability procedures and (b) (4)		o support the expir zen form.	ration date of		
 (B) Your firm lacks written procedures for monitoring the storage and temperatures of frozen (b) (4) in your freezer. 						
OBSERVATION 10 The responsibilities and procedures applicable to the quality control unit are not in writing. Specifically,						
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darla J Christopher, Investi Michele L Forster, Investiga Biologics	A	Data / Oxfettation averagene Book fly: Tota J, Ovisiopher & Data fly:cc. 2022017	DATE ISSUED 7/27/2017		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSI	PECTIONAL OBSERVATI	ONS	PAGE 7 OF 10 PAGES		

	DEPARTMENT OF HEAL		RVICES	
DISTRICT ADDRESS AND PH		G ADMINISTRATION	(S) OF INSPECTION	
19701 Fairch			7/21/2017-7/27/2017*	
Irvine, CA 9		12.000	JMBER 13670025	
(949)608-290	900 Fax:(949)608-4417		20010010	
NAME AND TITLE OF INDIVID	UAL TO WHOM REPORT ISSUED			
Judi E. Megl	lio , Office Manager			
FIRM NAME		STREET ADDRESS		
	Stem Cell Treatment	120 S Spaldi	ing Dr, Suite 300	
Center/Cell	Surgical Network	TYPE ESTABLISHMENT INSP	ECTED	
CONTRACTOR OF STREET, STATESTICK, STREET, STRE	s, CA 90212-1800	Manufacture		
(a) No written	procedures have been established for	the approval or	rejection of all compo	onents, in
process materia	als, and drug products.			
•	,01			
(b) No written	procedures have been established for	approving or re	ejecting all procedures	impacting on
the identity str	ength, quality, and purity of the auto	logous SVF pro	duct and (b)	(4)
discontraction of the second	Your firm uses written procedures th		ALCONTRACTOR ACCOUNTS	
		at have not been	in reviewed and approv	ed by the
quality control	unit.			
OBSERVATI				
Employees are	not given training in current good ma	anufacturing pra	actices.	
Specifically,				<u>2.</u>
No training in c	current good manufacturing practices	is provided to e	employees engaged in	the
manufacture of	the autologous SVF product and	(b) (4)	product.	
OBSERVATIO	ON 12			
Equipment used	l in the manufacture, processing, pac	king or holding	of drug products is no	ot of
	ign to facilitate operations for its inte			
appropriate and	-6-1 to 100-101 of 0-100 101 100 100			
Specifically,				
-permeany,				
1				
	EMPLOYEE(S) SIGNATURE		1	DATE ISSUED
SEE REVERSE	Darla J Christopher, Investig			7/27/2017
OF THIS PAGE	Michele L Forster, Investigat	cor - Team	Daria 3 Christophor Investigator Bigned By: Daris J. Christopher -S Date Segned: 7/27/2017	
	Biologics		X Date Signed: 7/27/2017	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSP	ECTIONAL OBSERV	14 70 1 (3 10)	PAGE 8 OF 10 PAGES

DISTRICT ADDRESS AND PH		F HEALTH AND HUM		
A NUMBER OF TAXABLE AND A DESCRIPTION OF TAXA		ND DRUG ADMINISTRAT	DATE(5) OF INSPECTION	
19701 Fairch			7/21/2017-7/27/2017	1*
Irvine, CA 9			FEI NUMBER 3013670025	
(949)608-290	00 Fax:(949)608-4417			
	UAL TO WHOM REPORT ISSUED			
Judi E. Megl	Lio , Office Manager	STREET ADDRESS		
	Stem Cell Treatment		alding Dr, Suite 300)
Center/Cell	Surgical Network			
CITY, STATE, ZIP CODE, COL	NTRY .s, CA 90212-1800	Manufact		
	not performed equipment quali			
	alification (IQ), Operational Q ng equipment used in the manu			(b) (4)
(b) (4) and	(b) (4)	(-)(-)	2	
OBSERVATI	Service of the servic			2112
	ures describing the handling of			
	etermine whether the complain			erse drug
experience whi	ch is required to be reported to	the Food and Dr	ug Administration.	
G 16 U				
Specifically,				
Your written p	rocedure for handling adverse e	events does not as	sure that events are adeq	nately evaluate
and reported to i. Patier	the FDA. The following event	s were not investi ma with the	(b) (4) product	FDA: manufactured b
and reported to i. Patier your fir	the FDA. The following event at ^{(b) (6)} was treated for astrocyto m and deployed by your firm b	s were not investi ma with the by IV drip on 12/1	(b) (4) product 1 7/15. The patient died or	FDA: manufactured b n 4/21/16.
and reported to i. Patier your fir ii. A pat	the FDA. The following event (^{b) (6)} was treated for astrocyto m and deployed by your firm b tient treated for COPD with the	s were not investi ma with the by IV drip on 12/1 c SVF product ma	(b) (4) product in 7/15. The patient died or nufactured by your firm	FDA: manufactured b n 4/21/16. experienced
and reported to i. Patier your fir ii. A pat	the FDA. The following event at ^{(b) (6)} was treated for astrocyto m and deployed by your firm b	s were not investi ma with the by IV drip on 12/1 c SVF product ma	(b) (4) product in 7/15. The patient died or nufactured by your firm	FDA: manufactured b n 4/21/16. experienced
and reported to i. Patier your fir ii. A pat hyperve	the FDA. The following event (^{b) (6)} was treated for astrocyto m and deployed by your firm b tient treated for COPD with the	s were not investi ma with the by IV drip on 12/1 c SVF product ma at procedure on 2/	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured b n 4/21/16. experienced we end of the
and reported to i. Patier your fir ii. A pat hyperve procedu	the FDA. The following event the FDA. The following event the following the astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resust	s were not investi ma with the by IV drip on 12/1 c SVF product ma at procedure on 2/	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured b n 4/21/16. experienced he end of the
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and reported to i. Patier your fir ii. A pat hyperve procedu	the FDA. The following event the FDA. The following event the following the astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resust	s were not investi ma with the by IV drip on 12/1 c SVF product ma at procedure on 2/	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured l n 4/21/16. experienced he end of the
and reported to i. Patier your fir ii. A pat hyperve procedu	the FDA. The following event the FDA. The following event the following the astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resust	s were not investi ma with the by IV drip on 12/1 c SVF product ma at procedure on 2/	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured b n 4/21/16. experienced he end of the
and reported to i. Patier your fir ii. A pat hyperve procedu	the FDA. The following event at ^{(b) (6)} was treated for astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resused tered by IV and nebulization.	s were not investi ma with the by IV drip on 12/1 c SVF product ma at procedure on 2/	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured b 1 4/21/16. experienced the end of the was
and reported to i. Patier your fir ii. A pat hyperve procedu adminis	the FDA. The following event the FDA. The following event the follow was treated for astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resuse tered by IV and nebulization.	s were not investi ma with the ny IV drip on 12/1 e SVF product ma nt procedure on 2/ citated and hospit	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the pas	FDA: manufactured b n 4/21/16. experienced the end of the was
and reported to i. Patier your fir ii. A pat hyperve procedu	the FDA. The following event at ^{(b) (6)} was treated for astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resused tered by IV and nebulization.	s were not investi ma with the ny IV drip on 12/1 e SVF product ma nt procedure on 2/ citated and hospit	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the alized. The SVF product	FDA: manufactured b a 4/21/16. experienced ae end of the was
and reported to i. Patier your fir ii. A pat hyperve procedu adminis	the FDA. The following event the FDA. The following event the follow was treated for astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deployment are and was subsequently resused tered by IV and nebulization.	s were not investi ma with the ny IV drip on 12/1 e SVF product ma nt procedure on 2/ citated and hospit	(b) (4) product in 7/15. The patient died or nufactured by your firm 6/17. He passed out at the alized. The SVF product	FDA: manufactured b a 4/21/16. experienced ae end of the was
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and reported to i. Patier your fir ii. A pat hyperve procedu adminis	the FDA. The following event at ^{(b) (6)} was treated for astrocyto m and deployed by your firm b tient treated for COPD with the entilation during the deploymen are and was subsequently resuse tered by IV and nebulization.	s were not investi ma with the ny IV drip on 12/1 e SVF product ma nt procedure on 2/ citated and hospit	(b) (4) product if 7/15. The patient died or nufactured by your firm 6/17. He passed out at th alized. The SVF product	FDA: manufactured b a 4/21/16. experienced ae end of the was

	DEPARTMENT OF HEAD	TH AND HUMAN SI	ERVICES	
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19701 Fairch			21/2017-7/27/2017*	
	vine, CA 92612-2445 049)608-2900 Fax:(949)608-4417		FEI NUMBER 3013670025	
(949)608-290				
NAME AND TITLE OF INDIVID	JAL TO WHOM REPORT ISSUED			
Judi E. Megl	io , Office Manager			
FIRM NAME		STREET ADDRESS		
California S	tem Cell Treatment	120 S Spald	ing Dr, Suite 300	
Center/Cell	Surgical Network			
CITY, STATE, ZIP CODE, COU		TYPE ESTABLISHMENT INSI		
Beverly Hill	s, CA 90212-1800	Manufacture	r	
*DATES OF I 7/21/2017(Fri), Michale L Forster Westigned P. Team X Signed By Michael L Date Signed 7/27/201	7/24/2017(Mon),7/25/2017(Tue),7/	27/2017(Thu)		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Darla J Christopher, Investi Michele L Forster, Investiga Biologics		Carls J Childropher WeerOgstor Signed By: David J. Childopher-3 Des Sonres. 707/2017	DATE ISSUED 7/27/2017
FORM FDA 483 (09/08) PAGES	PREVIOUS EDITION OBSOLETE INSI	PECTIONAL OBSER	VATIONS	PAGE 10 OF 10



Date: September 14, 2017

Judi E. Meglio California Stem Cell Treatment Center, Inc 120 S Spalding Dr Suite 300 Beverly Hills, CA 90212-1800

Subject: System Notification

Dear Judi E. Meglio,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently indvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to <u>AskORAIT@fda.hhs.gov</u>.

Sincerely,

Lisa Creason Director, Office of Information Systems Management Office of Regulatory Affairs Food and Drug Administration