DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHON	E NUMBER	AT ADMINISTRATION.	DATE(S) OF INSPECTION	
	55 Winderley Place, Suite 200		12/01/2010 - 12/16/	2010*
	0 Fax: (407) 475-4768		3008522961	
Industry Info	rmation: www.fda.gov/oc/indu	ıstry	<u> </u>	
TO: Carol L.	Roberts, MD, Principal Inve	estigator		
Carol Roberts		1209 Lakeside Drive		
		Wellness Works		
टान तामह शास्त्रहर रेज्यार Brandon, FL	33510-4109	Clinical Investigator		
				· · · · · · · · · · · · · · · · · · ·
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 INSPEC	TION OF YOUR FIRM WE OBSERVED:			
OBSERVATION	1			
An investigation wa	as not conducted in accordance with the s	igned statement of	investigator and investigation	nal plan.
Specifically,				
a. Commitment to t	follow the protocol.			
1. Subject(b)(6) met exclusion criterion #16 "Inability to tolerate the weekly fluid load (500cc of fluids)" due to underlying lung disease that left the subject "very sensitive to even slight fluid overload" according to a physician that assessed him two months prior to the subject enrolling into the study.				
2. Subjects (b) (6) required by the pr		eceived their infus	sions of study drug in less that	the three hours
3. Subjects (b) (6) , and (b) (6) had laboratory values that required delay of subsequent infusions and increased laboratory follow-up per the protocol that did not occur.				equent infusions
4. Subject (b) (6)	received an infusion that was meant for	or another subject.		
5. Subject (b) (6)	5. Subject(b) (6) received an infusion that was prepared outside of the ⁽⁶⁾ hour window specified by the protocol.			
b. Obtaining inform	ned consent			
1 Subjects (b) (6)	were not re-c	onsented with vers	sion 3 of the ICF as required b	y the IRB.
2. Subjects (b) (6) were not reconsented with version 4 of the ICF as required by the IRB.				
AMENDMENT 1				
SEE REVERSE OF THIS PAGE	Gene R. Gunn, Investigator Gennifer A. Robinson, Inves	N) tigator		12/16/2010
				I

INSPECTIONAL OBSERVATIONS

FORM FDA 483 (09/08)

PREVIOUS PHOTON OBSOLETE

PAGE FOR 4 PAGES

DEPARTM	ENT OF HEALTH AND HUMAN FOOD AND DRUG ADMINISTRATION	SERVICES		
DISTRICT ADDRESS AND PHONE NUMBER	TOOD AND DREST MARKET MARKET	DATELS) OF INSPECTION		
555 Winderley Place, Suite 200	55 Winderley Place, Suite 200		2010*	
Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-47	<i>c</i> a	3008522961		
Industry Information: www.fda.go	v/oc/industrv	3000322303		
MADE AND LITES OF REDVIOUAL TO WHOM REPORT ISSUED				
TO: Carol L. Roberts, MD, Princ	ipal Investigator			
Carol Roberts	took talanda Buine			
Calor Roberts	Wellness W			
CITY, STATE, Z:P CODE, COUNTRY	TYPE ESTABLISHMENT			
Brandon, FL 33510-4109	Clinical l	investigator		
3. Subjects (b) (6)	were not re-consented with ve	ersion 5 of the ICF as required by	y the IRB.	
3. Subjects (b) (b)				
c. Informing subjects of investigational status of	`drug			
THE RESERVE OF THE STREET OF T	DAL COMPENS states the fe	Hanging		
a. The last paragraph on the PATIENT GENE	KAL CONSENT states the to	mowing:		
"I understand that some of the treatments sugg	ested for me are as of yet unp	roven and experimental, howe	ever, I have been	
informed of this, and I am willing to accept the	e risks on the basis of the info	rmation provided to me. I will I	have the	
opportunity to ask questions and to research a	ry treatment suggested before	I agree to do it. I understand the	at the doctors	
have done their research as well, including (in	most cases) having taken the	se treatments themselves."		
L On 11/02/00 Subject/b/(s) galand via nk	one message if the IV is FI)A	approved. The reponse on the	nhone message	
b. On 11/02/09 Subject(b)(6) asked via plis "Yes!". The study drug, edetate disodium, v	vas not approved for any indi	cation at this time as the NDAs	and ANDAs	
were withdrawn on 05/15/08 as was published	in the Federal Register. E	detate disodium was never appro	oved for the	
indication being studied and was being evalua	ted under an IND.	••		
-				
OBSERVATION 2				
Failure to report promptly to the IRB all unantic	ipated problems involving ris	sk to human subjects or others.		
Specifically,				
a. Subject(b)(6) -was-hospitalized-from(b)(4)	Loratrial-fibril	lation-and-angina. This event-wa	as-not-renorted	
by the site as an SAE to the IRB.	101 4114111111111			
5) . 5 45 4				
b. Subject (b) (6) was hospitalized from (b) (4)	· · · · · · · · · · · · · · · · · · ·	chest pain, and transient ischemi	c attack. These	
events were not reported by the site as SAEs to the IRB.				
- Subjective died on (b) (c) This SA	P was capacted to the site on i	06/02/05. It was reported to the	IRR on	
c. Subjec(b)(6) died on(b)(4) This SA 05/23/08.	E was reported to the site on	06/02/03. It was reported to the	IND OII	
VIII ZII VIII.				
d. Subject (b) (6) died or (b) (4) . This SAE was reported to the site on 11/18/05. It was reported to the IRB on				
05/23/08.				
	AMENDMENT 1			
EMPLOYEC(S) SIGNATURE DATE ISSUED				
SEE REVERSE Gene R. Gunn, Inve			12/16/2010	
Lastua Base (Jennilei A. Robins	om, investigator		1 22/20/20/0	

INSPECTIONAL OBSERVATIONS

PAGS 2 OF 4 PAGES

OF THIS PAGE

FORM FDA 483 (09/98)

PREVIOUS CRITION OBSOLETE

*************	OF HEALTH AND HUMA AND DRUG ADMINISTRATI		
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
555 Winderley Place, Suite 200		12/01/2010 - 12/16/2010*	
Maitland, FL 32751		FEINGRIER	
(407) 475-4700 Fax: (407) 475-4768		3008522961	
Industry Information: www.fda.gov/oc/industry			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
TO: Carol L. Roberts, MD, Principal	l Investigator		
FIRM NAME	STREET ADORESS		
Carol Roberts 1209 Lakes		ide Drive	
	Wellness Works		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHME	TYPE ESTABLISHMENT INSPECTED	
Brandon, FL 33510-4109	FL 33510-4109 Clinical Investigator		

OBSERVATION 3

Failure to obtain informed consent in accordance with 21 CFR Part 50 from each human subject prior to conducting study-related tests.

Specifically,

Subject (b) (6) was screened for the trial on 09/13/05 and had study related laboratory tests done on 09/06/05. The subject did not sign the Informed Consent Form until 09/16/05.

OBSERVATION 4

Failure to assure that an IRB complying with applicable regulatory requirements was responsible for the initial and continuing review and approval of a clinical study.

Specifically,

Continuing review of the study was approved for 12 months by the IRB on 02/07/08. It was approved again 16 months later on 06/04/09, four months past the IRB imposed deadline.

OBSERVATION 5

Failure to prepare or maintain adequate case histories with respect to observations and data pertinent to the investigation and informed consent.

Specifically,

Subject (b) (6)

's original source documentation and consent forms were not available for review.

* DATES OF INSPECTION:

12/01/2010(Wed), 12/02/2010(Thu), 12/06/2010(Mon), 12/07/2010(Tue), 12/08/2010(Wed), 12/09/2010(Thu), 12/16/2010(Thu)

AMENDMENT 1			
SEE DEVEDSE	Gene R. Gunn, Investigator	DATE ISSUED	
OF THIS PAGE	Gene R. Gunn, Investigator Jennifer A. Robinson, Investigator	12/16/2010	

FORM FDA 483 (09/08) PREVIOUS FOLLON ORSOLETE INSPECTIONAL OBSERVATIONS PAGE 3 OF 4 PAGES

	DEPARTMENT OF HEAD		SERVICES		
DISTRICT ADDRESS AND PHON	FOOD AND DRUG ADMINISTRATION PHONE NUMBER DATE(S) OF INSPECTION				
	y Place, Suite 200		12/01/2010 - 12/16/2010*		
Maitland, FL			FEI NUMBER		
(407) 475-470	0 Fax: (407) 475-4768		3008522961		
Industry Info	rmation: www.fda.gov/oc/indu	stry	<u></u>		
TO: Carol L.	Roberts, MD, Principal Inve	STREET ADDRESS			
	Carol Roberts 1209 Lakeside Drive Wellness Works City, STATE, ZIP CODE, COUNTRY Type establishment inspected				
caror nozerce					
CITY, STATE, ZIP CODE, COUNT	RY				
Brandon, FL	33510-4109	Clinical In	vestigator		
ì					
ļ					
ł					
Į.					
Ì					
				•	
j					
(
1					
1					
AMENDMENT 1					
 	EMPLOYEEISI SIGNATURE			DATE ISSUED	
SEE DEVEDOR	Gene R. Gunn, Investigator Jennifer A. Robinson, Inves	NICADIA	<u>~</u>		
SEE REVERSE OF THIS PAGE	Jennifer A. Robinson, Inves	tigator V		12/16/2010	
OF ITIS PAGE				l	

INSPECTIONAL OBSERVATIONS

PAGE 4 OF 4 PAGES

FORM FDA 483 (09/08)

PREVIOUS BUILTON OBSOLETE