HEALTH AND HUMAN SERVICES D DRUG ADMINISTRATION
DATE(S) OF INSPECTION
6/20/2016-6/29/2016*
FEINUMBER
3011752429
STREET ADDRESS
2401 S. Foothill Drive, Suite D
TYPE ESTABLISHMENT INSPECTED
503B Outsourcing Facility
1

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

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not include the conclusions and follow-up.

Specifically,

- A) Investigation into your MedWatch adverse drug event (Complaint EN-16001) did not include an evaluation of non-viable particle monitoring during the production time period associated with the product in question. During the production of triamcinolone 40mg/mL, Lot No. 12072015@10, there was a non-viable particle excursion in the <sup>(b) (4)</sup> room directly outside the <sup>(b) (4)</sup> when the product was compounded.
- B) No investigation was conducted when two finished product HCG lots failed potency specifications in April 2016. HCG lots 02081 and 03003 failed your internal potency specification of<sup>(b) (4)</sup> with results of 111.8% and 118.3%, respectively. These products were later released and distributed to customers because, according to deviation reports (DVN-16040123 and DVN-16040128), both products meet USP potency specifications of 80-125%. The potency specification and the production process remains unchanged.
- C) Investigations were inadequate to mitigate future recurrence when three lots of betamethasone acetate/betamethasone sodium phosphate 7mg/mL injection (Beta combo) failed in-process appearance specification for <sup>(b) (4)</sup> Beta combo non-conformances occurring on 2/15/16, 3/7/16, and 3/25/16 (Lot Numbers respectively: 01020, 02020, and 02070) all failed appearance specification and were discarded prior to completion of batch. The root causes identified on 2/15/16 were: <sup>(b) (4)</sup>

SEE REVERSE OF THIS PAGE			DATE 195UED 6/29/2016	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	р L. 193а -S	PAGE 1 OF 11 PAGES

	DEPARTMENT OF HEAL	TH AND HUMAN SERVIC GADMINISTRATION	ES	
	в NUMBER J St. (Р.О. Вох 25087)	DATE(S) OF IN 6/20/2	SPECTION 016-6/29/2016*	
Denver, CO 80 (303)236-3000	, CO 80225-0087 36-3000 Fax: (303)236-3100			
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED			
Mr. William C	). Richardson , CEO			10000
(1997) 1979 (1998) - 1	macy Solutions, LLC	STREET ADDRESS 2401 S. Foothil TYPE ESTABLISHMENT INSPECTED	1 Drive, Suite	Ð
anana kana manaka manakan	y, UT 84109-1479	503B Outsourcin	g Facility	
3/7/16 ar (b) (4) a. (C r if b. (C s s D) No invest methylpic custome "clumpin both bate prescribe investiga a. (C t i b. (C s s s custome "clumpin both bate prescribe investiga a. (C t i d. (C) (d) (d) (d) (d) (d) (d) (d) (d	No corrective and preventative act and 3/25/16. Later in May 2016, two issues occurred in doctor's offices is Complaint EN-160002, 5/6/16, Beta eported that he thought there were ( njectable. Complaint EN-160004, 5/18/16, Beta ticky note attached to the record the ize too big? Vials caps breaking offices stigations were conducted to mitigat rednisolone/lidocaine (MP40) 40/10 r complaints commenced on May 11 ng issues" and "sticking to the vial." ches had been sterilized using a <sup>(b) (4)</sup> ation, include: Complaint EN-160005, 5/23/16, (MI o fully mix the vial. The vial/products s still clumpy. Unable to draw up in Complaint EN-160006, 5/23/16, MP eceived two lots of MP40 where the he vial." Complaint EN-16007, (no date docu 'Lot #3045 10 vials * cloudy/clump Complaint EN-16008, (no date docu 'D (4), Lot No. 03045 – "10 vials of I as mentioned by other offices."	complaints concern in Florida and New Combo (no lot num b) (4) in the combo (no lot rep combo (no lot rep combo (no lot rep combo (no lot rep combo (no lot rep complaints was not complaints revie P40 lot number was ct is stuck to the bot complaints revie P40 lot number was ct is stuck to the bot complaints revie P40, Lot Numbers: 0 complaints a not m complaint was not m	hing the same Beta York. ber documented): the betamethasone c corted or document d: "Complaint for ection." when six Lot Numbers 0304 ffice concerns inclu- batch records disc wed from custome not recorded) – "the tom. After shaking 3045, 03046 – "the ixing and stuck to the ixing off when shaking off when shaking coming off when shaking off when	combo <sup>(b) (4)</sup> A doctor ombo ed): on a Beta molecule 5 and 03046) aded: overed that when the rs, with no hey are unable g vigorously it e office the bottom of 0. 03045 – naking." g/mL, Part No.
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Zachery L Miller, Investigat Jamie L Dion, Investigator	tor	KZBKOR X Zachery L Miller Zachery KRis Instant Dignel by Zachery L Niler 4	DATE ISSUED 6/29/2016
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL OBSERVAT	IONS	PAGE 2 OF 11 PAGES

		TH AND HUMAN SERVICES	
DISTRICT ADDRESS AND PH		DATE(S) OF INSPECTE	∾ -6/29/2016*
Denver, CO 8		FEI NUMBER 301175242	
	WAL TO WHOM REPORT ISSUED		
	0. Richardson , CEO		
FIRM NAME		STREET ADDRESS	
Isomeric Pha	armacy Solutions, LLC	2401 S. Foothill D	Drive, Suite D
	ity, UT 84109-1479	503B Outsourcing F	acility
e.	Complaint EN-16009 (no date docur "clumping issues Lot #03045."	nented), MP40, Part No	b. <sup>(b) (4)</sup> Lot No. 03045,
f.	Complaint EN-160003, 5/19/16, Mer and liquid are not mixed wellthey	shook the vial but it has	
	Clinic wants all 20 vails replaced AS	SAP."	
E) Negati	ve environmental monitoring trends a	re not appropriately inv	vestigated.
a.	For example, Monitoring Event Form environmental surface sample collec		
			ggered the firm's "Action
	Status" for this area. Per SOP 607-0		7.7.
	(b) (4)	- (	
			. There is no root cause or
	corrective action identified (form is	plank) and the investiga	
	day it was opened.		
h	In MEE 16050017 5/06/16 a tanha	aion was found with (	b) (1) grouth (Basillus
υ.	In MEF 16050017, 5/26/16, a techni flexus) after working within the ISO	NUMBER OF STREET, STRE	
	technician was found again with pos		
	(Penicillium sp.). Per SOP 607-02, '	1280 87	on 🖏 (b) (4) (b) (4)
	(rememum sp.). rei 30r 007-02,	(	(0) (4)
	Root ca	use in both instances wa	as determined to be: "Most
	Probable Root Cause is Personnel Tr		ALL STILL MADE SALARD
	product and/or process was not ident	and an even that we a management that the	
с.	In CAPA-16004, dated 4/14/16, a no	on-conformance identifi	ied six "microbial and fungal
	grow outs in clean classified areas th	at exceeded action limi	its" (3 incidents found in (b)
	(b) (4) , 2 incidents for	und in $(0)$ (4)	and 2 incidents within
	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE OF THIS PAGE			•247816 6/29/2016
OF THIS PAGE	Damie i Dion, investigator	22 5	K Zachesy L Müller octory L Micr meligidar
FORM FDA 483 (09/08)		PECTIONAL OBSERVATIONS	S PAGE 3 OF 11 PAGES
· 0701 / 07 403 (09/08)	PREVIOUS EDITION OBSOLETE INS	A DOLLOUGH ODDER TATION	TAUE 3 OF 11 FAUE 3

	DEPARTMENT OF HEAL FOOD AND DRUG			
DISTRICT ADDRESS AND PHONE	NUMBER		DATE(S) OF INSPECTION	
6th & Kipling Denver, CO 802	St. (P.O. Box 25087)		6/20/2016-6/29/2016*	
	-3000 Fax: (303)236-3100		3011752429	
	2			1211 IZ311 IZ
NAME AND TITLE OF INDIVIDUAL				
	. Richardson , CEO			
FIRM NAME		STREET ADDRESS		<b>D</b>
CITY, STATE, ZIP CODE, COUNTR	macy Solutions, LLC	Z4UL S. TYPE ESTABLISHM	Foothill Drive, Suite	<u> </u>
	y, UT 84109-1479	503B Out	sourcing Facility	
dd cc re (I of An adequate num expiration date. Specifically, A) Your firm stability p did not fo a. C ba tr	ocumented as "Serious environmer prrective actions were implemented emains open and verification of act Deviation – OOS), which governs r therwise, corrective actions and inv	tal contami t; however, ion items ha non-conforr vestigations estigations based upon of cetate 40 mp	after two months the invest as not occurred. Per SOP 1 nances, "unless justification should be completed within ested to determine an approp completed stability studies. ' The following reviewed s g/mL injection is 124 days. from only <sup>(b) (4)</sup>	identified and ligation .020 is provided n <sup>(b) (4)</sup> priate Per drug tability studies This value is of
di b	Current BUD for betamethasone acc ays. This value is based upon <sup>(b) (4)</sup> etamethasone submitted for the sta o not support your 128 day timefra	) bility study	from <sup>(b) (4)</sup>	of
SEE REVERSE OF THIS PAGE	EMPLOYFE(S)SIGNATURE Zachery L Miller, Investiga Jamie L Dion, Investigator	tor	eperson X Zachery L Miller Zeckert I Var Breisphr Styne by: Zachwy L Minr -S	DATE ISSUED 6/29/2016
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL	OBSERVATIONS	PAGE 4 OF 11 PAGES

<ul> <li>(b) (4) lots of oxytocin submitted for the stability study. The preservative and stern parameters do not support your 62 day timeframe.</li> <li>d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup> preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.</li> <li>B) In addition, the ability to retain sterile conditions, a function of the container/closure system not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protocome.</li> </ul>	6th & Kipling St. (P.O. Box 25087)       6/20/2016-6/29/2016*         Denver, CO 80225-0087       3011752429         (303)236-3000 Fax: (303)236-3100       3011752429         NME X00INE OF WORK INFORMATION       2401 S. Foothill Drive, Suite D         MWE X00INE OF Commercial/Sterile)       978857000488         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)       for (b) (4)         (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steril parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         obs of product submitted for the stability study. The (b) (4)       submitted (b) (4) fa preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, (b) (4)         (b) (4)       Hence, drug product (b) (4)       (b) (4) <th></th> <th>FOOD AN</th> <th>YHEALTH AND HUM</th> <th>ION</th> <th></th>		FOOD AN	YHEALTH AND HUM	ION	
Denver, CO 80225-0087 (303)236-3000 Fax; (303)236-3100       FEINAMEER 3011752429         MME AND TITLE OF HIGHDOLD TO WHOM REPORT ESSED       STREET ADDRESS         Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D TYPE ESTABLIANCE TO THE SUPPORT         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> (b) <sup>(4)</sup> from <sup>(b) (4)</sup> (b) <sup>(4)</sup> d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> (b) <sup>(4)</sup> d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> (b) <sup>(4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> (b) <sup>(4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> (b) <sup>(4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> (b) <sup>(4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain s	Deriver, CO 80225-0087 (303)236-3000 Fax: (303)236-3100       FERIOMER 3011752429         NAME ADD THE OF MEMORIAL TO MENUMEROW TEACHED Mr. William O. Richardson, CEO       FERIOMER 2401 S. Foothill Drive, Suite D         TSOMETIC Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CIVE STANDARD TO MENUMEROW TEACHED TRANSME       PREE TANDRESS         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup> (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.         d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> obs52015@114 = 69.10%). The 180 day (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, <sup>(b) (4)</sup> <sup>(b) (4)</sup> (b) (4)       (b) (4)       during each study, not (b) (4)					016*
(303)236-3000 Fax: (303)236-3100       3011752429         Mr. William O. Richardson , CEO       9778EETADDRESS         Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CITY.STAR.ZPCODE.COUNTY       9778EETADDRESS         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup> (b) (4)       lots of oxytocin submitted for the stability study. The preservative and ster parameters do not support your 62 day timeframe.       for <sup>(b) (4)</sup> d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. To value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> <	(303)236-3000       Fax: (303)236-3100       3011/52429         MXE AND THE 3FMEMALUL TO WHAN RESION TEXTED       MY.       WILLIAM         MY.       William O. Richardson , CEO       2401 S. Foothill Drive, Suite D         FRMUNNE       2401 S. Foothill Drive, Suite D       MY.         Salt Lake City, UT 84109-1479       503B Outsourcing Facility       From (b)(4)         c.       Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b)(4)       from (b)(4)         (b)(4)       Iots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.       d, Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. The value is based upon (b)(4)         ots of product submitted for the stability study. The (b)(4)       for (b)(4)         lots of product submitted for the stability study. The (b)(4)       for (b)(4)         ots of product submitted for the stability study. The (b)(4)       submitted (b)(4) for (b)(4)         of the set stability lots.       B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, (b)(4)       (b)(4)         (b) (4)       (b) (4)       (b) (4)       (b) (4)				FEINUMBER	V 1.W.C
Mr. William O. Richardson , CEO         FIRMADME         Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CITY. STATE, 2P CODE, COUNTRY       TYPE ESTABUSAMENT PREPROTED         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)       from (b) (4)         (b) (4)       lots of oxytocin submitted for the stability study. The preservative and stern parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The only pres	Mr. William O. Richardson , CEO         FREE MODEL         Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         (nr, SMR.2 root.coum       WretsMauseum Mascons         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)       from (b) (4)         (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon (b) (4)         lots of product submitted for the stability study. The (b) (4)       for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) fa preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content to point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, (b) (4)         (b) (4)       Hence, drug product (b) (4)       during each study, not (b) (4)         (b) (4)       Hence, drug product (b) (4)       during each study, not (b) (4)				3011752429	
FIRMINAME       STREET ADDRESS         I someric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CITY, STARE, 29 CODE, COMITAY       YTHE ESTABLISAMENT INSPECTED         Salt Lake City, UT 84109–1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup> (b) (4)       lots of oxytocin submitted for the stability study. The preservative and ster parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protocome acetach product. Furthermore, per your stability protocome acetach product. Furthermore, per your stability protocome acetach product.	FREET ADDRESS         Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CMY, STARE 20 CODE, COURTINY       WYE ESTANDAMENT MERCETED         Salt Lake City, UT 84109–1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)       from (b) (4)         (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) for (b) (4)         not been estabilished for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc         BUD-16001 and BUD-16007, (b) (4)       (b) (4)       during each study, not (b) (4)         (b) (4)       Hence, drug product (b) (4)       during each study, not (b) (4)       during each study, not (b) (4)	NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED	. <del>He</del> nds in this states	N	
Isomeric Pharmacy Solutions, LLC2401 S. Foothill Drive, Suite DCITY, STATE, ZP CODE, COUNTRYYTTE ESTABULIANCENT INSPECTEDSalt Lake City, UT 84109-1479503B Outsourcing Facilityc. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)from (b) (4)(b) (4)lots of oxytocin submitted for the stability study. The preservative and stern parameters do not support your 62 day timeframe.d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Tvalue is based upon (b) (4)for (b) (4)for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The submitted (b) (4) for (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The submitted (b) (4) for (b) (4)submitted (b) (4) for (b) (4)lots of product submitted for the stability study. The submitted (b) (4) for these stability lots.submitted (b) (4) for (b) (4)B) In addition, the ability to retain sterile conditions, a function of the container/closure system not bee	Isomeric Pharmacy Solutions, LLC       2401 S. Foothill Drive, Suite D         CMY, STARE, 20-000E, COURTAY       MREESTABULGAUENT MEDPECTED         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon (b) (4)       from (b) (4)         (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.         d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon (b) (4)       for (b) (4)         lots of product submitted for the stability study. The (b) (4)       submitted (b) (4) fa preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, (b) (4)         (b) (4)       (b) (4)         (b) (4)       Mence, drug product (b) (4)         (b) (4)       Mence, drug product (b) (4)	Mr. William C	. Richardson , CEO			
CITY, STATE, ZP CODE, COUNTRY       TYPE ESTABLISHMENT INSPECTED         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup> [b) (4) [ots of oxytocin submitted for the stability study. The preservative and ster parameters do not support your 62 day timeframe.         d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots of product submitted for the stability study. The <sup>(b) (4)</sup> [ots 06252015@114 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protocome and period for each product. Furthermore, per your stability protocome and period for each product. Furthermore, per your stability protocome and period for each product.	CITY, STARE_2P GODE_COURTY       Implementation         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         Salt Lake City, UT 84109-1479       503B Outsourcing Facility         c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup> for (b) (4)       from <sup>(b) (4)</sup> from <sup>(b) (4)</sup> from <sup>(b) (4)</sup> (b) (4)       lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.       d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup> necervative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No.       08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.         B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoc BUD-16001 and BUD-16007, <sup>(b) (4)</sup> (b) (4)         (b) (4)       Hence, drug product <sup>(b) (4)</sup> during each study, not <sup>(b) (4)</sup>					
<ul> <li>Salt Lake City, UT 84109-1479</li> <li>c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup> lots of oxytocin submitted for the stability study. The preservative and ster parameters do not support your 62 day timeframe.</li> <li>d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(</sup></li></ul>	<ul> <li>Salt Lake City, UT 84109-1479 503B Outsourcing Facility</li> <li>c. Current BUD for oxytocin 30 units per 500 mL bag solution (commercial/sterile to commercial/sterile) is 62 days. This value is based upon <sup>(b)(4)</sup> from <sup>(b)(4)</sup></li> <li>(b)(4) lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.</li> <li>d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. The value is based upon <sup>(b)(4)</sup> lots of product submitted for the stability study. The <sup>(b)(4)</sup> submitted <sup>(b)(4)</sup> lots of product submitted for the stability study. The <sup>(b)(4)</sup> submitted <sup>(b)(4)</sup> for <sup>(b)(4)</sup> lots of product submitted for the stability study. The <sup>(b)(4)</sup> submitted <sup>(b)(4)</sup> fa preservative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content to point for these stability lots.</li> <li>B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoce BUD-16001 and BUD-16007, <sup>(b)(4)</sup> (b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> <li>(b)(4)</li> </ul>					uite D
<ul> <li>commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup> lots of oxytocin submitted for the stability study. The preservative and stern parameters do not support your 62 day timeframe.</li> <li>d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. T value is based upon <sup>(b) (4)</sup> for <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup> lots of product submitted for the stability study. The <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup> for <sup>(b) (4)</sup> submitted <sup>(b) (4)</sup>. The 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.</li> <li>B) In addition, the ability to retain sterile conditions, a function of the container/closure system not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protocome.</li> </ul>	<ul> <li>commercial/sterile) is 62 days. This value is based upon <sup>(b) (4)</sup> from <sup>(b) (4)</sup></li> <li>(b) (4) lots of oxytocin submitted for the stability study. The preservative and steri parameters do not support your 62 day timeframe.</li> <li>d. Current BUD for methylprednisolone acetate/lidocaine 40/10 mg/mL is 180 days. Th value is based upon <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup> for <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup></li> <li>submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup></li> <li>submitted <sup>(b) (4)</sup></li> <li>lots of product submitted for the stability study. The <sup>(b) (4)</sup></li> <li>submitted <sup>(b) (4)</sup></li> <li>generative content at 180 days (Lot No. 06252015@19 = 70.6%; Lot No. 08052015@14 = 69.10%). The 180 day test point was the only preservative content point for these stability lots.</li> <li>B) In addition, the ability to retain sterile conditions, a function of the container/closure system, not been established for any product. Sterility analysis has not been conducted at the end of expiration/beyond use dating period for each product. Furthermore, per your stability protoe BUD-16001 and BUD-16007, <sup>(b) (4)</sup></li> <li>(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> <li>(b) (4)</li> </ul>					
(b) (4) Hence, drug product (b) (4) during each study, not	OBSERVATION 3	d. C v le p 0 p B) In additi	Current BUD for methylpredni alue is based upon <sup>(b) (4)</sup> ots of product submitted for the reservative content at 180 day 8052015@14 = 69.10%). The oint for these stability lots.	solone acetate/li ne stability study ys (Lot No. 0625 e 180 day test po	docaine 40/10 mg/mL . The <sup>(b) (4)</sup> s 2015@19 = 70.6%; L sint was the only prese	for <sup>(b) (4)</sup> ubmitted <sup>(b) (4)</sup> fai ot No. ervative content t
Time limits are not established when appropriate for the completion of each production phase to as		expiration BUD-16 (b) (4) (b) (4) OBSERVATION Time limits are	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup>	Sterility analysis or each product.	has not been conduct Furthermore, per you (b) (4) during	ed at the end of r stability protoc each study, not t
the quality of the drug product.	the quanty of the drug product.	expiration BUD-16 (b) (4) (b) (4) OBSERVATION Time limits are	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup>	Sterility analysis or each product.	has not been conduct Furthermore, per you (b) (4) during	ed at the end of a r stability protoco each study, not t
the quality of the drug product.		expiration BUD-16 (b) (4) (b) (4) OBSERVATION Time limits are the quality of th	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup>	Sterility analysis or each product.	has not been conduct Furthermore, per you (b) (4) during	ed at the end of a r stability protoco each study, not t
		expiration BUD-16 (b) (4) (b) (4) OBSERVATION Time limits are the quality of th	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup>	Sterility analysis or each product.	has not been conduct Furthermore, per you (b) (4) during	ed at the end of a r stability protoco each study, not t
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close	Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill	on/beyond use dating period fo 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close	Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoc each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	Specifically, Your Media Fill <sup>(b) (4)</sup> simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>N 3</b> not established when appropri- e drug product.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup>	Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup>	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic	on/beyond use dating period for 001 and BUD-16007, <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> Hence, drug product <sup>(b) (4)</sup> <b>ON 3</b> not established when approprise drug product. (b) (4) compounding, to include working to your firm's most compounding.	Sterility analysis or each product. iate for the comp Process rst-case activities	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup>	Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup>	expiration BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of the Specifically, Your Media Fill simulate aseptic provide a challe	<ul> <li>(b) (4)</li> <li>(b) (4)</li> <li>(c) (4)</li> &lt;</ul>	Sterility analysis or each product. iate for the comp Process rst-case activities lex production p	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and	ed at the end of or r stability protoco each study, not t each study, not t ction phase to ass 017) fails to close conditions that
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup>	Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup> SEE REVERSE Zachery L Miller, Investigator 6/29/20	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic provide a challe	<ul> <li>(b) (4)</li> <li>(b) (4)</li> <li>(c) (4)</li></ul>	Sterility analysis or each product. iate for the comp Process rst-case activities lex production p	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and process: (b) (4)	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close t conditions that
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup> SEE REVERSE OF THIS PAGE Dion, Investigator American Americ	Specifically,       Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to close simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup> SEE REVERSE OF THIS PAGE       EMPLOYEE(9) SIGNATURE       DATE ISSUED         Jamie L Dion, Investigator       X Zathery L Miler       6/29/20	expiratio BUD-16 (b) (4) (b) (4) <b>OBSERVATIO</b> Time limits are the quality of th Specifically, Your Media Fill simulate aseptic provide a challe	<ul> <li>(b) (4)</li> <li>(b) (4)</li> <li>(c) (4)</li></ul>	Sterility analysis or each product. iate for the comp Process rst-case activities lex production p	has not been conduct Furthermore, per you (b) (4) during pletion of each produc Qualification (VPQ-0 s (E.g. hold times) and process: (b) (4)	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close t conditions that
the quality of the drug product. Specifically, Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup> SEE REVERSE OF THIS PAGE Second Miller, Investigator Jamie L Dion, I	Specifically,         Your Media Fill <sup>(b) (4)</sup> Process Qualification (VPQ-017) fails to closs simulate aseptic compounding, to include worst-case activities (E.g. hold times) and conditions that provide a challenge to your firm's most complex production process: <sup>(b) (4)</sup> SEE REVERSE OF THIS PAGE       EMPLOYEE(S) SIGNATURE         Zachery L Miller, Investigator       X Zachery L Miller         Jamie L Dion, Investigator       X Zachery L Miler         Vertex UNE       Kenture	expiratio BUD-16 (b) (4) (b) (4) (b) (4) OBSERVATIO Time limits are the quality of th Specifically, Your Media Fill simulate aseptic provide a challe	<ul> <li>(b) (4)</li> <li>(b) (4)</li> <li>(c) (4)</li></ul>	Sterility analysis or each product. iate for the comp Process rst-case activities lex production p	has not been conduct Furthermore, per you (b) (4) during pletion of each produce Qualification (VPQ-0 s (E.g. hold times) and process: (b) (4)	ed at the end of or r stability protoco each study, not t each study, not t etion phase to ass 017) fails to close t conditions that

		EALTH AND HUM DRUG ADMINISTRAT		
	NUMBER St. (P.O. Box 25087)		DATE(S) OF INSPECTION 6/20/2016-6/29/201	.6*
Denver, CO 802 (303)236-3000	225-0087 Fax: (303)236-3100		FETNUMBER 3011752429	
NAME AND TITLE OF INDIVIDUAL				
	. Richardson , CEO			
FIRM NAME		STREET ADDRESS		
Isomeric Pharm	macy Solutions, LLC	2401 S. TYPE ESTABLISHM	Foothill Drive, Sui	te D
- en a la company de la company de la com	 y, ut 84109-1479	a series and the series of the	sourcing Facility	
the <sup>(b) (4)</sup> only <sup>(b) (4)</sup> on 3/16/1	<ul> <li>6) was held for<sup>(b) (4)</sup></li> <li>of your batch record a <sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup></li> <li><sup>(b) (4)</sup></li> </ul>	fills conducted process occurs (batch record ls conducted of product (Lot 1	l on $^{(b)}$ (4) were held ( <sup>b</sup> product (Lot No. $^{(b)}$ s, $^{(b)}$ (4) d calls for a $^{(b)}$ (4) n $^{(b)}$ (4) were only $^{(b)}$ (4) No. $^{(b)}$ (4) , QA released ne media was $^{(b)}$ (4) , wherea	(4) QA release
	processing time of your media og time for Lot No. <sup>(b) (4)</sup> was		) (4) whereas	s the total
Deviations from Specifically, A) Your just sterilizati Accordin of an obje	g time for Lot No. <sup>(b) (4)</sup> was	almost <sup>(b) (4)</sup> s control proced 0/15; DVN-160 nd Depyrogena	dures are not justified. were not used during <sup>(b) (</sup> )3073, 2/29/16) was inac ation, "Validation of <sup>(b) (</sup>	<ul> <li>(4)</li> <li>dequate.</li> <li>(4) sterilizati</li> <li>Currently you:</li> <li>DATE ISSUED</li> </ul>
Deviations from Specifically, A) Your just sterilizati Accordin of an obje	ng time for Lot No. <sup>(b) (4)</sup> was N 4 written production and process tification as to why <sup>(b) (4)</sup> on <sup>(b) (4)</sup> (DEV16010001, 12/30 og to SOP 8.010, Sterilization a ect depends <sup>(b) (4)</sup>	almost <sup>(b) (4)</sup> s control proced 0/15; DVN-160 nd Depyrogena	dures are not justified. were not used during <sup>(b) (</sup> )3073, 2/29/16) was inac ation, "Validation of <sup>(b) (</sup>	<ul> <li>(4)</li> <li>dequate.</li> <li>(4) sterilization</li> <li>Currently your</li> <li>DATE ISSUED</li> </ul>

	1. 1997 - 19			
58	DEPARTMENT OF HEAL FOOD AND DRUG	TH AND HUMA ADMINISTRATIO		
OISTRICT ADDRESS AND PHON	E NUMBER		DATE(S) OF INSPECTION	
Denver, CO 80	) St. (P.O. Box 25087) 0225-0087		6/20/2016-6/29/2016* Feinumber	24 sp.
	Fax: (303)236-3100		3011752429	
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED			
Mr. William (	). Richardson , CEO			
FIRM NAME	2 1	STREET ADDRESS		
Isomeric Phan CITY, STATE, ZIP CODE, COUNT	macy Solutions, LLC	2401 S. F	oothill Drive, Suite	D
a lan he had	y, UT 84109-1479	CONTRACTOR STORES - STORES - LA	ourcing Facility	
(b) (4)	has not been perform	ance qualifi	ed (PQ) as evidenced by d	lraft PO
	, VPQ-007.	anov quuin		
	For example in DEV16010001, the j	ustification	for disposition of sterilized	d material
N N	vithout the use of a (b) because they	were <sup>(b) (4)</sup>	was <sup>(b) (4)</sup> has bee	
N	validated and end products <sup>(b) (4)</sup>		undergo end	
	esting." In addition, the deviation d			
	ctual product or glassware, and no			
192	ecurrence. This is evidenced by the	recurrence	of the same issue in DVN-	-1603073 on
	2/29/16; n DVN-1603073, <sup>(b) (4)</sup>	Ware not	included in the sterilization	on (b) because
		Id not wait "	included in the sterilization On 2/11/16, Lot #021120	16/2 was
r	we were $^{(b)}(4)$ couproduced without a $^{(b)}_{(4)}$ and approved was $^{(b)}(4)$ which was sent	for release	because <sup>(b) (4)</sup> is validate	and product
	was $^{(b)}(4)$ which was sent	for testing a	ind passed." No investiga	tion or
	corrective action was required per de			
	leviation as it was prepared on 2/29			
·				<u>11 </u>
OBSERVATIO			£	o to ha ataulla
	gned to prevent microbiological convolution of the sterilization process		or arug products purportin	ig to be sterile
ao not include v	validation of the sterilization process			
Specifically,				
		1 (12) V	15 855 16 10 10	5
CONTRACTOR - CONFERENCE - CONTRACTOR	m's in situ air pattern analysis (smo	신비 같은 이 이 가지가 한 것이 있는 것이 같아. 이 가		250
1. <del>- 1</del> 1 1 1 1 1 1 1.	on (i.e. compounding equipment in	The second se	perations ongoing). Dynan	nic smoke
studies f	ilmed on <sup>(b) (4)</sup> do not reflect the <sup>(b)</sup>	) (4)		
<b>F</b>	(b)		- Janias and in the 100 F	un du attau
		e air sample	r device used in the ISO 5	production
area wei	e not observed in the videos.			
				DATE ISSUED
SEE REVERSE	EMPLOYEE(S)SIGNATURE Zachery L Miller, Investiga	tor	W24203	L. Martin Martin Street and Street
OF THIS PAGE	Jamie L Dion, Investigator		X Zachery L Miller	
			Zachery L Hiller Swissiga tor Signed by Zachery L. Hiller -G	]
	areas.	1998 - 944 		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	SPECTIONAL O	BSERVATIONS	PAGE 7 OF 11 PAGES

	DEPARTMENT OF HEAL FOOD AND DRU	TH AND HUMAN		
DISTRICT ADDRESS AND PHONE	ENUMBER		ATE(S) OF INSPECTION	
Denver, CO 80	St. (P.O. Box 25087) 225-0087		5/20/2016-6/29/2016* EINUMBER	
	3000 Fax: (303) 236-3100		3011752429	
NAME AND TITLE OF INDIVIDUAL				
- 0.5 C	, Richardson , CEO			
FIRM NAME	, Richardson , CEO	STREET ADDRESS		art at
Isomeric Phar	macy Solutions, LLC	2401 S. FO	oothill Drive, Suite E	)
Salt Lake Cit	y, UT 84109-1479	503B Outso	ourcing Facility	
performe	the third party <sup>(b) (4)</sup> I ISO cented under <sup>(b) (4)</sup> conditions. repeat observation from the pre	tification con vious FDA ir		
B) The <sup>(b) (4)</sup>	e	terilization (b)	<sup>(4)</sup> for product glassware	has not been
and a second second	ہ I, nor has the Performance Qualific			
12515357495259655495495	ducts undergo <sup>(b) (4)</sup> sterilization <sup>(b)</sup>		) in <sup>(b) (4)</sup>	ng minaned
arug pro	ducts undergo com stermization con		)	
(k	) (4	)		
including	the Tuttenaeur Autoclave sterilizat 3: <sup>(b) (4)</sup> idated, nor has Performance Qualif	of a	ctive air sampler, and <sup>(b) (4)</sup>	n production) has not
OBSERVATION 6 Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically,				
			1	
SEE REVERSE	EMPLOYEE(S)SIGNATURE Zachery L Miller, Investiga	tor	6/26/2018	DATE ISSUED 6/29/2016
OF THIS PAGE	Jamie L Dion, Investigator	.01	X Zachery L Miller Zachery L Miler Persityski Signed 7, Izekory L reter -5	V/29/2VI0
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE IN	SPECTIONAL OB	SERVATIONS	PAGE 8 OF 11 PAGES

	DEPARTMENT OF HEAL FOOD AND DRUG	LE AND HUMAN S ADMINISTRATION	ERVICES			
DISTRICT ADDRESS AND PHON		35233				
Denver, CO 80	J St. (P.O. Box 25087) 1225-0087		20/2016-6/29/2016* NUMBER			
	3000 Fax: (303)236-3100		011752429			
NAME AND TITLE OF INDIVIDUA						
	). Richardson , CEO					
FIRM NAME		STREET ADDRESS				
	macy Solutions, LLC		othill Drive, Suite	D		
CITY, STATE, ZIP CODE, COUNT Salt Lake Cit		TYPE ESTABLISHMENT INS				
A) On 6/20/ burnt, br prior to (	Salt Lake City, UT 84109-1479       503B Outsourcing Facility         A) On 6/20/16, sterilized glassware stored on shelving in the <sup>(b) (4)</sup> Room was found with burnt, brown carbon-like staining/spotting. The glassware is used for processing testosterone prior to <sup>(b) (4)</sup> sterilization.					
CALIFORNY STOCKASTIC STOCKASTICS	<ul> <li>(16, a chemical-type, white staining</li> <li>HEPA filters)</li> <li>(b) (4)</li> <li>(c) (4)</li> <li>(c)</li></ul>			ates (directly in Rooms.		
Iront of J	HEPA Inters) or the ISO 51	ammar now no	Jods in the	Kooms.		
OBSERVATION 7 Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.						
Specifically,						
On 6/20/16, a <sup>(b) (4)</sup> cart was observed transporting processing components (e.g. <sup>(b) (4)</sup> between unclassified areas and the classified ISO 8 Prep Room. The cart was not cleaned and disinfected prior to entering the ISO 8 area. Additionally, this cart including wheels, are not incorporated in your environmental monitoring program (SOP 607-02), nor in your cleaning procedure (SOP 301-01).						
OBSERVATION 8 Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices and written procedures required by current good manufacturing practice regulations.						
Specifically,						
	ning matrix or curriculum establishe uding pharmacists and cleanroom o					
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Zachery L Miller, Investiga Jamie L Dion, Investigator	tor	S259000 X Zachery L Miller Zeskyr Hann Innetjylar Signet fyr Zeskory L Mar i S	DATE ISSUED 6/29/2016		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	PECTIONAL OBS	ERVATIONS	PAGE 9 OF 11 PAGES		

	HEALTH AND HUMAN SERVICES D DRUG ADMINISTRATION
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087)	6/20/2016-6/29/2016*
Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	FETNUMBER 3011752429
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	12 10 10 10 10 10 10 10 10 10 10 10 10 10
Mr. William O. Richardson , CEO	
FIRM NAME	STREET ADDRESS
Isomeric Pharmacy Solutions, LLC	2401 S. Foothill Drive, Suite D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Salt Lake City, UT 84109-1479	503B Outsourcing Facility

(b) (4) ; however, they have not performed process qualifications (I.e. media fills) for any of the sterile products compounded.

## **OBSERVATION 9**

The labels of your outsourcing facility's drug products are deficient.

Specifically,

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

• The statement "Not for Resale."

Examples of drug product labels that do not contain this information:

- o Triamcinolone Acetonide/Lidocaine HCl 40/10 mg/mL Injectable Suspension
- o Triamcinolone Diacetate 40 mg/mL Injectable Suspension
- o Methylprednisolone Acetate/Lidocaine HCl 80/10 mg/mL Injectable Suspension
- Betamethasone Acetate/Betamethasone Sodium Phosphate 7 mg/mL Injectable Suspension
- o Phenylephrine HCl/Tropicamide 2.5%/1% Ophthalmic Solution
- o Testosterone Cypionate/Testosterone Propionate 200/20 mg/mL Injection
- Cyanocobalamin/Methionine/Inositol/Choline Chloride 1/25/50/50 mg/mL Injection
- Dexamethasone Sodium Phosphate/Lidocaine HCl 10/10 mg/mL Injectable Solution
- o Methylprednisolone Acetate/Lidocaine HCl 40/10 mg/mL Injectable Suspension

SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SKGNATURE Zachery L Miller, Inv Jamie L Dion, Investi	같은 것이 있는 것이 있는 것이 있는 것이 있는 것이 있다. 이 가지 않는 것이 있는 것이 없는 것이 있는 것이 있는 것이 있는 것이 있는 것이 있는 것이 있는 것이 없는 것이 있는 것이 있 같이 있는 것이 있 같이 있는 것이 있다. 것이 있는 것이 있	1/29/2916	DATE ISSUED 6/29/2016
FORM FDA 483 (09/08) PACES	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS		PAGE 10 OF 11

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF				<u> </u>	
	h & Kipling St. (P.O. Box 25087) enver, CO 80225-0087		/20/2016-6/29/2016*	<u>1-21</u>	
(303)236-3000 Fax: (303)236-3100			011752429		
NAME AND TITLE OF INDIVIDUA	L TO WHOM REPORT ISSUED				
Mr. William O. Richardson , CEO					
FIRM NAME STREET ADDRESS					
			Foothill Drive, Suite D		
CHY, STATE, ZIP CODE, COUNT Salt Lake Cit			wemected urcing Facility		
<ul> <li>A list of inactive ingredients, identified by established name and the quantity or proportion of each ingredient.</li> <li>Examples of drug product labels that do not contain this information:         <ul> <li>Oxytocin 30 Units added to 500 mL 0.9% Sodium Chloride for Injection USP</li> </ul> </li> <li>*DATES OF INSPECTION 6/20/2016(Mon),6/21/2016(Tue),6/22/2016(Wed),6/23/2016(Thu),6/24/2016(Fri),6/27/2016(Mon),6/28/2016(Tue),6/29/2016(Wed)</li> </ul>					
SEE REVERSE OF THIS PAGE	EMPLOYEE(S)SIGNATURE Zachery L Miller, Investiga Jamie L Dion, Investigator	tor	scerce ++ X Zachery L Miller Zackey i Nor Instants Store (r, Extery L Miler - S	date issued 6/29/2016	
FORM FDA 483 (09/08) PREVIOUS EDITION ORSOLETE INSPECTIONAL OBSERVATIONS PAGES				PAGE 11 OF 11	