	HEALTH AND HUMAN SERVIC DRUG ADMINISTRATION	ES		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION		
Food and Drug Administration, Los Angeles District Office Address: 19701 Fairchild Irvine, CA 92612 Telephone: (949)-608-2900		03/21-24/2017, 03/27,28,30/2017		
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Attention: Steven Porter, District Director		3005144312		
Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	an the second and the second	I		
TO: Tenille D. Davis, Pharmacist In Charge	8			
FIRM NAME	STREET ADDRESS			
Civic Center Pharmacy, Inc.	7331 E. Osborn Drive	7331 E. Osborn Drive Suite 208		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT	TYPE OF ESTABLISHMENT INSPECTED		
Scottsdale, AZ 85251	Producer of Sterile an	Producer of Sterile and Non-Sterile Drug Products		
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESEN OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMIN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT C OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING TI YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUM DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:	ATION REGARDING YOUR COMPL ORRECTIVE ACTION IN RESPON HE INSPECTION OR SUBMIT THIS	IANCE. IF YOU HAVE AN OB SE TO AN OBSERVATION,	JECTION REGARDING AN YOU MAY DISCUSS THE	
ODCEDVATION 1				
OBSERVATION 1 Personnel were observed using a non-sterile tool or manually contact the inner surface of the container or closure.				
reisonnel were observed using a non-sterile tool or i	manually contact the inn	er surface of the cor	namer or closure.	
Specifically, on 03/21/2017, a Pharmacy Technician inner surface of the vial stopper that contacts the BII This is a repeat Observation from the FDA Inspectio	MIX drug product, lot m	mber 03/21/2017:02	200 million for a construction of the second s	
OBSERVATION 2 There is inadequate HEPA filter coverage or airflow	over the area to which s	terile product is exp	osed.	
Specifically, your firm's procedure for lyophilizing finished drug products includes (b) (4)				
(b) (4)				
The lyophilizer is located inside of the ISO 7 Clean Room, but it is outside of the ISO 5 environment.				
OBSERVATION 3 The final containers/closures used for drug product i pyrogenated. Specifically, your firm has no hold time studies for s stoppers that are stored in plastic bins and placed on Room. These carts are transported to the ISO 7 Clear	sterilized tools (such as (carts located in the ISO	b) (4)) and for steri	lized vials and	
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EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE	E (Print or Type)	DATE ISSUED	
REVERSE OF THIS PAGE Styld.	Stephanie A. Slater, Investig	ator	03/30/2017	
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVA	TIONS	Page 1 of 2	

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