FOOD AND DR	LUG ADMINISTRATION DATE(S) OF INSPECTION	
6751 Steger Drive	08/24/2015 - 09/21/2015*	
Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772	FEIMUMBER 3011509553	
Industry Information: www.fda.gov/oc/ind	ustry	
TO: Edward J. Zatta, Managing Partner,	Owner	
FIRM NAME	STREET ADDRESS	
RXQ Compounding LLC	340 W State St Unit 9	
City, State, Zip Code, Country	TYPE ESTABLISHMENT INSPECTED	
Athens, OH 45701-1564	503B Facility	
This document lists observations made by the FDA representative observations, and do not represent a final Agency determination re observation, or have implemented, or plan to implement, corrective action with the FDA representative(s) during the inspection or sub- questions, please contact FDA at the phone number and address ab	garding your compliance. If you have an objection regarding an e action in response to an observation, you may discuss the objection or mit this information to FDA at the address above. If you have any	

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Facilities and Equipment system

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

On^{(D)(4)} I (CTM), observed a third party contractor perform a smoke study of the clean room (ISO 7) and ISO 5 hood. During the smoke study, it appeared that the smoke^{(b)(4)} Management and a representative from the third

party contractor performing the smoke study confirmed. Two purportedly sterile products have been processed in the ISO 5 hood since the last certification: IC-Green 6.25mg/ml Ophthalmic Solution lot#08132015@1, processed on 8/13/15 (released and distributed) and Acetaminophen 10mg/ml Injectable lot#08212015@7, processed on 08/21/15 (on sterility test hold at time of inspection).

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to monitor differential pressure readings frequently during aseptic production.

Production system

	ENPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Christopher T. Middendorf, Investigator Joshua P. Wireman, Investigator	09/21/2015
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS	PAGE 1 OF 5 PAGES

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Cinclinacii, OH 45237-3037 PREMARE (513) 679-2700 Fast:(513) 679-2772 3011509553 Industry Information: www.fda.gov/oc/industry 301509553 TO: Edward J. Zatta, Managing Partner, Ornez Pressure RXQ Compounding LLC 340 W State St Onit 9 Treat Device Cover Metrocover Athens, OK 45701-1564 5033 Facility OBSERVATION 3 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process. Specifically, 1. Your firm ourneally performs ^{(b)(4)} and (a)(0)(4) wate antipations. For example, you have not performed a medial fill using the (b)(4) was used to biopsci 10 more than paniputations. For example, you have not performed a medial fill using the (b)(4) was used to b(0)(4) (wead for farmaceutical use. During the inspection, we reviewed the label of a (b)(4) (4) (4) (4) was used to b(0)(4) (wead for distribution). 2. (b)(4) used by your firm is not intended for pharmaceutical use. During the inspection, we reviewed the label of a (b)(4) was used to b(0)(4) (wead for distribution). 3. The validation of the deprogenation (b)(4) (used to depyrogenate finished product vials) and(b)(4) (used for and/or represent actual production, you difficus. For example: a. The validation of the deprogenation (B)(1) (within any vial during your validation of the deprogenatin	DISTRICT ADDRESS AND PHOM		O ADMINISTRATION	DATE(S) OF INSPECTION		
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Industry Information: www, fda.gov/oc/industry TO: Edward J. Zatta, Managing Partner, Owner RNG Compounding LLC 340 W State St Unit 9 RNG Compounding LLC 340 W State St Unit 9 RNG Compounding LLC 140 W State St Unit 9 RNG Compounding LLC 140 W State St Unit 9 RNG Compounding LLC 140 W State St Unit 9 RNG Compounding LLC 140 W State St Unit 9 OBSERVATION 3 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process. Specifically. and 1. Your fire.currently performs (b(4) Wess of aseptic processing: (b)(4) and (b)(4) Wess of aseptic processing: (b)(4) and (b)(4) Wess of aseptic processing: (b)(4) was used to istribution, intended for pharmaceutical use. During the inspection, we reviewed the label of a (b)(4) was used to (b)(4) was the label read in pair. "For escannels, so the value on the productice on the object of a introbution). 2. (b)(4) used by your firm is not intended for pharmaceutical use. During the inspection, we reviewed the label of a (b)(4) was used to (b)(4) was used to (b)(4) was used to (b)(4) was used to (b)(4). 3. The validation of the deprogenation(b)(4) (was used to reliation of stopper, tools and other glassware) did not include(b)(4) (miss the of and/or represent actual production, you (b)(4) was used (b)(4) was used (b)(4) was used (b)(4) was used (b)(4) was usere (b)(4) was used (b)(4). a. Y						
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			ator	CTM	09/21/2015	
	FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSP		VATIONS	PAGE 2 OF 5 PAGES	

	DEPARTMENT OF H	DRUG ADMINISTRATION	MATTEES	
DISTRICT ADDRESS AND PHONE	MAJBER		DATE(S) OF INSPECTION	
6751 Steger D: Cincinnati, Ol			08/24/2015 - 09/21	/2015*
(513) 679-270	0 Fax:(513) 679-2772		3011509553	
Industry Info:	rmation: www.fda.gov/oc/is	ndustry		
	. Zatta, Managing Partner	, Owner		
RXQ Compoundin	ng LLC	340 W State		
		TYPE ESTABLISHMENT IN		
Athens, OH 4	5701-1564	503B Facili	ty	
OBSERVATION 5	5			
Batch production an of drug product prod	nd control records do not include a des duced.	scription of drug prod	uct containers and closures us	sed for each bat
Specifically, you do	o not include lot numbers of containers	s or stoppers in produ	ct batch records.	
Laboratory system		•••••	10 JU	
OBSERVATION	3			
Test procedures rela	ative to appropriate laboratory testing	for sterility are not fo	llowed.	
(b)(4) (b)(4 sterility testing of A SOP #016, entitled,	 a)(4) used to perform finished product sterility finished product sterility funing the inspection I (CTM), obstruction in the inspection I (CTM), obstruction in the inspection of the inspec	served apparent (b)(4) 15@7 in the same incu aration Testing", secti	(b)(4) for the finishe bator - the temperature was - on 9.1.5 reads in part, "Steril	ed product ~ 35°C, Your
OBSERVATION 7	7			
Each batch of drug	product purporting to be sterile is not	laboratory tested to de	etermine conformance to such	requirements
Specifically, you di lot#08132015@1.	d not perform sterility testing before of Although the product is stored frozen.	listributing IC-Green		in requirements.
	duct manufactured was $(b)(4)$ iption for a single patient.	. the BUD is 45 or less (b)(4) units pr	s days from the date of manuf oduced), you did not compou	ion facture, and the
	duct manufactured was $(b)(4)$. the BUD is 45 or less ^{(b)(4)} units pr	s days from the date of manuf oduced), you did not compou	ion facture, and the
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pursuant to a prescr	duct manufactured was(b)(4) iption for a single patient,	. the BUD is 45 or less	s days from the date of manul oduced), you did not compou	ion facture, and the
pursuant to a prescr Quality system OBSERVATION 6	duct manufactured was(b)(4) iption for a single patient,	^{(b)(4)} units pr	oduced), you did not compou	ion facture, and the and this lot
pursuant to a preser Quality system OBSERVATION & There is a failure to Specifically, you di Product Refrigerato	duct manufactured was(b)(4) iption for a single patient. 8 thoroughly review any unexplained d d not open an investigation per your S or and Freezer" when the refrigerator u perature range of the refrigerator is 2-	^{(b)(4)} units pr liscrepancy whether o SOP 008 entitled, "Uso ised to store drug proc	oduced), you did not compou r not the batch has been alrea e, Calibration and Maintenand lucts was out of established h	ion facture, and the and this lot dy distributed. ce of the Drug imits. Accordi ed temperature
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADORESS AND PHONE NUWBER	DATE(S) OF INSPECTION		
6751 Steger Drive	08/24/2015 - 09/21/2015*		
Cincinnati, OH 45237-3097	FEINIWBER		
(513) 679-2700 Fax: (513) 679-2772	3011509553		
Industry Information: www.fda.gov/oc/indu	istry		
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED			
TO: Edward J. Zatta, Managing Partner, ()wner		
FIRM NAME	STREET ADDRESS		
RXQ Compounding LLC	340 W State St Unit 9		
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED		
Athens, OH 45701-1564	503B Facility		
the drug product refrigerator or freezer does not fall within th	e designated range drug products must be removed immediately		

the drug product refrigerator or freezer does not fall within the designated range, drug products must be removed immediately and placed in an alternate, properly calibrated drug product refrigerator or freezer. QA/QC shall be notified and if necessary, an OOS incident shall be issued." A review of the temperature log for the refrigerator revealed the refrigerator was operating out of established limits on the following days:

- 6/5/15, operating temperature was -4C
- 6/8/15, operating temperature was -1C
- 6/29/15, operating temperature was 20C

Packaging and Labeling system

OBSERVATION 9

The batch production and control records are deficient in that they do not include copy of labeling.

Specifically, you did not retain a sample of all labels used for the following products:

a. IC-Green 6.25mg/ml Ophthalmic Solution, lot#08132015@1 batch record does not include a sample of the unit label or the container label

b. Acetaminophen 10mg/ml Injectable, lot# 08212015@7 batch record does not include a sample of the unit label

Additionally. vou did not follow vour OSD #16, entitled, "Product Label Information per Current USP", which requires, (b)(4)

OBSERVATION 10

The labels and containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B).

Specifically,

The following information is not found on some of your drug product labels:

- 1. The established name of the drug.
- 2. The statement of quantity or volume, as appropriate.
- 3. The storage and handling instructions.
- 4. The inactive ingredients, identified by established name and the quantity or proportion of each ingredient.
- Furthermore, the following information is not found on or in the containers for some drug products you produce:
- Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch and 1800FDA1088

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

- Acetaminophen 10 MG/ML Injectable
- IC-Green 6.25 MG/ML OPH SOLN

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SEE REVERSE OF THIS PAGE	Christopher T. Midde Joshua P. Wireman, I	endorf, Investigator Investigator ゴーム	0-	09/21/2015
	EMPLOYEE(S) SIGNATURE			DATE ISSUED

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097		DATE(S) OF INSPECTION 08/24/2015 - 09/21/	2015*		
		FEINUMBER	2013		
(513) 679-270 Industry Info	679-2700 Fax: (513) 679-2772 try Information: www.fda.gov/oc/industry		3011509553		
NAME AND THE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: Edward J. Zatta, Managing Partner, Owner					
FIRM NAME		STREET ADDRESS	St Upit 0		
RXQ Compoundi City, state, 219 code, count		TYPE ESTABLISHMENT INSI	PECTED		
Athens, OH 4	OH 45701-1564 503B Facility				
Lidocaine/Prilo	caine 2.5%, Gabapentin 6%, Meloxicam 0	.2%			
* DATES OF INSPI 08/24/2015(Mon), 08	ECTION: /25/2015(Tue), 08/26/2015(Wed), 08/27/2015((Thu), 09/21/2015(M	lon)		
	EMPLOYEE(S) SIGNATURE		MIL-MAIN	DATE ISSUED	
SEE REVERSE OF THIS PAGE	Christopher T. Middendorf, Joshua P. Wireman, Investig	Investigator ator	Chatyph J. Mr. Idu	09/21/2015	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPI	/ ECTIONAL OBSERV	ATIONS	PAGE 5 OF 5 PAGES	

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."