DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA 4040 North Central Expressway #300 Dallas, TX 75204 (214) 253-5200 Industry Information: www.fda.gov/oc/industry	3/23-27; 30-31; 4/1-2;6-8;13-17; 5/5/2015
	FEI NUMBER 3009815000

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: William L. Swail, R.Ph., Managing Partner

FIRM NAME	STREET ADDRESS
Specialty Compounding, LLC	211 South Bell Blvd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Cedar Park, TX 78613	Producer of Drugs

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 (I) (WE) OBSERVED

OBSERVATION #1

Your firm has failed to establish adequate procedures for conducting appropriate media fill simulations.

Specifically,

Your most recent media fills dated 4/30/2014 and 10/1/2014 for each of the operators that work in the ISO 5 LAF hoods do not closely simulate planned production. For example, the (b) (4) [redacted].

OBSERVATION #2

Your firm has not ensured that your facility is suitably designed with respect to the flow of personnel, in-process materials, and finished sterile drugs; the need for room segregation and process separation; and the impact from heating ventilation and air conditioning (HVAC), air pressurization, and unidirectional airflow, to prevent contamination and other hazards to sterile drugs.

Specifically,

A. The smoke studies performed by your vendor in 9/2014 for ISO 5 LAF Hood # 1 indicated the presence of non-unidirectional airflow in the ISO 5 LAF Hood # 1, and specifically air backflow into the ISO-5. There was no evaluation of this finding.

B. The "Sterile Processing Room" has a window used as a pass through for dirty glassware from the ISO 7 area to an unclassified area. Your firm has not determined whether there is an influx of air from the unclassified area into the ISO 7 when the window is opened.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Steph D Brown	Stephen D. Brown, Investigator	5/5/2015

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OBSERVATION #3

Your firm has failed to establish and implement adequate operational procedures designed to prevent microbiological contamination of drugs purporting to be sterile.

Specifically,

Your (b) (4) used for the depyrogenation of glassware used in aseptic processing was qualified on 3/24/2015 using the (b) (4) ((b) (4)). The directions for use for the test indicate that the (b) (4) (b) (4). To date, your firm has not determined where the (b) (4) (b) (4).

OBSERVATION #4

Your firm has not established adequate written Standard Operating Procedures to ensure proper maintenance of aseptic processing areas and equipment used in those areas.

Specifically,

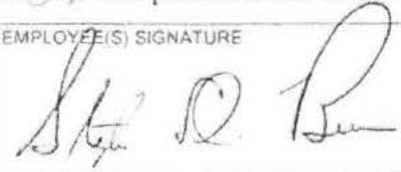
Your firm has not established written procedures that describe the cleaning of glassware used in the production of sterile drug products.

OBSERVATION #5

Your firm failed to ensure the accuracy of the labels used in the finished preparation.

Specifically,

The product, Methylcobalamin/RG3 (90%)/Cyclodextrin/Nicotinamide 2mg/2mg/60mg/50mg/ml Nasal Spray, (lot #12222014@6), was produced on 12/22/2014. According to compounding records, the BUD for the product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Stephen D. Brown, Investigator	5/5/2015

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Methylcobalamin/RG3 (90%)/Cyclodextrin/Nicotinamide 2mg/2mg/60mg/50mg/ml Nasal Spray, (lot #12222014@6, Production Date: 12/22/2014), was 2/5/2015. However, the label on the distributed product had a different BUD of 2/14/2015. The product was dispensed on 1/12/2015.

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	Stephen D. Brown	Stephen D. Brown, Investigator	5/5/2015