DEPARTMENT OF HEALTH AND HUMAN SERV .S
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax:(513) 679-2772 Industry Information: www.fda.gov/oc/industry	02/05/2013 - 02/07/2013
	FEI NUMBER 3009988995

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Raymond R. Carlson, RPh, Owner

FIRM NAME	STREET ADDRESS
RC Compounding Services, LLC	3030 Center Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Poland, OH 44514	sterile drug repacker

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:

Regarding your firm's repacking of vials of Avastin (bevacizumab) solution, 25 mg/ml, into syringes as listed on your Drug Report for Avastin 1.25 mg/0.05 ml from 01/01/2013 to 02/05/2013:

OBSERVATION 1

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, Assay and identity testing is not performed for each lot of repacked Avastin.

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, Sterility testing is not performed for each lot of repacked Avastin.

OBSERVATION 3

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically A process validation study has not been performed for the Avastin repacking process.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kathleen Dant Culver, Investigator Joshua S. Hunt, Investigator	02/07/2013

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OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically, A media fill has not been performed to validate the Avastin aseptic repacking process.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, There is no written stability program or stability data to support the expiry period of 4 months applied to repacked syringes of Avastin.

OBSERVATION 6

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, The Avastin Log Sheet is the record of the repacking process, but this record does not contain complete information. For example, the Avastin is repacked into insulin syringes or TB syringes, but neither the identity nor the lot number of the syringes is included in the Avastin Log Sheet.

KDC

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	Kathleen Dant Culver, Investigator Kathleen Dant Culver Joshua S. Hunt, Investigator Joshua S. Hunt	02/07/2013