DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	11/18/2014 - 12/02/2014* FEI NUMBER 3007200605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Troy A. Albright, President

FIRM NAME	STREET ADDRESS
Zions Rx Formulations Services LLC dba Rx Formuations Serv.	5949 E University Dr·
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mesa, AZ 85205-7435	Producer of Sterile Drug Products

Note: This observation was previously cited on FDA-483 dated 01/09/14.

OBSERVATION 2

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

There is no provision for protection of exposed skin such as the areas of the face around the eyes and area around the neck within the cleanroom environment. Gowning components used by the firm include: low particulate gowns, hair covers, face maskes, and powder-free gloves. Gowning components are donned in the unclassified area of the facility. It was explained that operators involved in aseptic processing of drug products use sterile gloves, however, there is no use of sterile over sleeves by personnel working in the ISO Class 5 Hood environments.

Note: This obsevation was previously cited on FDA-483 dated 01/09/14.

OBSERVATION 3

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

Specifically,

Beyond use dates and/or Expiration dates on drug products by the firm are not supported by stability studies of actual products.

For example, B-12 for injection is labeled by the firm with an expiration date of 30 days from the date of compounding. There is no stability study data to support this time period. It was explained that the 30 day time period was established based on literature references.

Note: This observation was previously cited on FDA-483 dated 01/09/14.

*** DATES OF INSPECTION:**
11/18/2014(Tue), 11/19/2014(Wed), 11/20/2014(Thu), 12/02/2014(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Joey V. Quitania, Investigator Paul A. Bonneau, Interdisciplinary Scientist 12/02/14	12/02/2014

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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

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

Specifically,
Monitoring of the firm's ISO Class 5 Hood environments and ISO Class 7 Cleanroom Enviornment used to produce sterile drug products is not necessarily done during actual production, for example:

a) Lack of viable particulate air monitoring (ISO Class 5). There is no monitoring of the viable air particulates during aseptic processing of drug products in the ISO Class 5 environments. Air sampling is only conducted by an outside contractor during (b) (4) certification of the cleanroom suite.

b) Lack of viable particulate air monitoring (ISO Class 7). There is no routine monitoring of the viable particulates during aseptic processing of drug products in the ISO Class 7 cleanroom. Viable air sampling is conducted in the ISO Class 7 cleanroom (b) (4) by the firm, however not necessarily during production of aseptically processed drug products.

c) Lack of non-viable particulate air monitoring (ISO Class 5 and ISO Class 7). There is no routine monitroing of the non-viable particulates during aseptic processing of drug products. Non-viable particulate air monitoring is performed only by an outside contractor during s(b) (4) certification of the cleanroom suite.

d) Lack of routine personnel monitoring for operators conducting aseptic processing of drug products. Sampling of personnel gloves, arms or chest is not conducted after every lot of aseptically processed drug products in the ISO Class 5 environment. Sampling of personnel gloves is conducted (b) (4) for the purpose of gowning qualification of the firm's operators.

e) Environmental monitoring surface samples are taken every (b) (4) in the ISO Class 5 and ISO Class 7 environments, however not necessarily after aseptic processing of drug products.

f) Pressure differential measurements (ISO Class 5 and ISO Class 7) are read and recorded (b) (4).

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