DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 8th Street, NE Atlanta,GA,30309 404-253-1161 Industry Information: www.fda.gov/oc/industry	11/17/14-11/21/14
	FEI NUMBER 3008563008

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Jonathan E. Sterling, VP of Quality, Regulatory, & Product Development

FIRM NAME	STREET ADDRESS
Exela Pharma Sciences, LLC	1325 William White Place
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Lenoir, NC, 28645	Outsourcing Facility

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:

1. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

A. Media Fills executed on site as described in procedure QA012-02, Media Fill Policy, and documented on site with respective protocols and executed batch records do not include documented evidence to:
a. justify the number and frequency of interventions simulated with regards to routine and non-routine operations conducted,
b. include routine activities such as interventions in the filling line conducted simultaneously (such as addition of stoppers while broken vials are removed and empty vials are being loaded), or
c. include full documentation of the temperature of the media prior commencing filling operations.

B. The most recent smoke study video and study completed on site to confirm the uni-directional flow of air on Grade A Sterile Area (b) (4) Filling Machine (b) (4) as described in document # 2010-PQ-123, 08/19/2010 was found inadequate in that:
a. limited smoke was used and did not completely confirm uni-directional flow inside the filling line and all of its components
b. not all operator's interventions were included such as multiple interventions conducted at the same time or line set-up activities;
c. operators were observed standing directly in front of wall air returns but video failed to follow the smoke pattern at this area;
d. operators were observed performing very slow movements while adding stoppers and opening (b) (4) doors-unlike current practice observed during routine operations at the same line on 11/17/14.

C. Procedure # OP006-02, Behavior in Manufacturing Clean Rooms, is not always followed by operators as observed during routine filling operations conducted in the Grade B area adjacent to the Grade A (b) (4) Filling Machine, media fills or smoke studies conducted on site. This filling machine is scheduled for use on site

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Noreen Muniz	Noreen Muniz, Consumer Safety Officer Brett Weed, Consumer Safety Officer	11/21/2014

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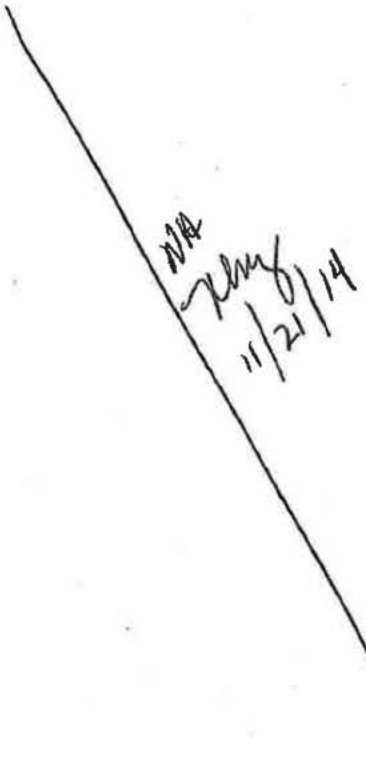
for both (b) (4) and 503B products.

a. On 11/17/14, operators exhibited non-controlled and fast movements by abruptly moving a large rack used to store sterilized vial trays, adding stoppers with fast movements, and abruptly opening enclosures at the fill line at the same time (adding stoppers and removing broken vials from opposite ends of the filler).
b. A video of the most recent media fill executed in 07/2014 showed operators moving around the filling line (Grade B) with uncontrolled movements, talking, blocking wall-air returns, and conducting interventions in the Filler Machine (Grade A) with non-controlled movements.



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