DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Kansas City District Office 8050 Marshall Drive Suite 205 Lenexa, KS 66214 913-495-5100 Industry Information: www.fda.gov/oc/industry	09 OCT- 24 OCT 2012
	FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Andrew F. Knudten, Vice President, Operations, Plant Manager - McPherson

FIRM NAME	STREET ADDRESS
Hospira, Inc.	1776 Centennial Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
McPherson, KS 67460-1247	Human and Veterinary Drug Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, the design of the personnel entryways, personnel and material traffic flows and gowning practices, particularly with regard to dedicated plant uniforms, captive plant shoes and shoe covers, is deficient. The current practice promotes the propagation of microbial contamination. The following was observed during the inspection 09 OCT- 24 OCT 2012 and has been the current practice for approximately one (1) year. This is applicable to all drug products, over approximately two hundred drug product combinations of strengths and dosage configurations.

Aseptic filling personnel were observed to frequent common public areas such as administrative offices, restrooms, the warehouse, and the cafeteria without being required to change out of dedicated plant shoes which are then worn back into aseptic fill rooms under their aseptic gowning. Employees and visitors wearing shoes which are worn outside the facility, must don shoe covers in manufacturing corridors and hallways. However, employees in dedicated plant shoes were seen coming from the warehouses, and in the cafeteria, commingling with personnel wearing outside shoes then returning to the plant manufacturing areas for work. There is no distinction in these practices other than a (b) (4) sanitization step required (b) (4) of all employees in dedicated shoes. This sanitization is negated as soon as employees return to common hallways and public areas of the plant.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Tara L Beckenridge	Tara L. Beckenridge, Investigator	10/24/2012

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This is a failure to mitigate the ingress of dirt, debris and microorganisms.

For June, July and August of 2011 and 2012 there was an increase over action limit trending guidelines used within the firm, for the presence of microorganisms in environmental monitoring data which represents a seasonal increase in the recovery of vegetative organisms.

OBSERVATION 2

Investigations of an unexplained discrepancy did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

1. Since March 2012 your firm has discovered 2 lots ((b) (4) and (b) (4)) of Fentanyl Citrate for injection which failed HPLC stability time point analysis for total impurities. Subsequent investigation of the failures revealed the impurities were due to extractables from the rubber plunger. In addition, under study (b) (4) your firm tested (b) (4) lots of Fentanyl Citrate from retain samples and determined one additional lot ((b) (4)) failed for total impurities and 2 others were at the USP limit.

There are (b) (4) lots of Fentanyl Citrate currently distributed and unexpired; your investigation was not expanded to comprehensively determine the number of lots which fail USP specifications.

2. There were 2 incidents within the past 2 months of city water leaking from sprinkler heads located in your aseptic areas; these sprinkler heads and piping had been replaced by your contractor during a recent shutdown.

• Incident PR ID: 95301 occurred 17Aug2012 near lyophilizer (b) (4) (room 335, 335B) during the unloading of (b) (4) drug product. The root cause of the leak was attributed to the tapering of the threading between the piping and the reducer; the pipes did not fit each other correctly.

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• Incident PR ID: 95564 occurred 20Aug2012 in the SPA corridor near the entrance door to the (b) (4) filling suite during filling of Diphenhydramine. The root cause was attributed to the pipe fitting seal on the sprinkler system plumbing.

Although in each case the event was contained, and drug product was not affected, neither investigation extended to other wet sprinkler heads throughout the facility to adequately evaluate if they had been properly installed, or could be leaking.

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