DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	May 16-21,23-27/16 & 6/8/16
	FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan J. Rushford, Site Head/Vice President Operations	
FIRM NAME Hospira Inc. A Pfizer Company	STREET ADDRESS 1776 Centennial Dr.
CITY, STATE, ZIP CODE, COUNTRY McPherson, KS 67460	TYPE ESTABLISHMENT INSPECTED Human Drug/Device Manufacturer

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:

Drugs – Quality System:

OBSERVATION 1

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

Specifically,

A) Despite performing an investigation with a root cause implicating an entire product line and finding widespread impact across the line during numerous retention sample reviews, you did not expand your investigation beyond individual lots to the whole line:

On 2/12/15, you received a complaint of multiple label defects (missing label, double labels, and pealing label) for Diltiazem ADD-Vantage Vial lot 39105DD, and you determined the primary root cause of the defects was the use of label adhesive that was optimal for glass vial adhesion but not for plastic vials. This label adhesive was used for your six ADD-Vantage products, all of which use plastic vials:

- Diltiazem HCl 100mg/vial;
- Erythrocin Lactobionate-I.V. 500 mg/vial;

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- Sterile Vancomycin HCl, USP 750 mg/vial;
- Vancomycin HCl for Injection, USP 500mg/vial;
- Vancomycin HCl for Injection 1g/vial; and
- Azithromycin for Injection, USP 500 mg/vial.

You did not consider and evaluate the impact on these other ADD-Vantage products and, at the time the investigation was closed on 4/22/15, approximately (b) (4) still-unexpired lots were on the market.

You received additional complaints and conducted a review of retention samples as follows:

- Azithromycin USP lot 49335DD exam on 4/20/15 (148 labels defective out of (b) (4))
- Vancomycin 1g/vial lot 46240DD exam on 4/20/15 (51 labels defective out of (b) (4))
- Vancomycin 1g/vial lot 49170DD exam on 4/20/15 (55 labels defective out of (b) (4))
- Vancomycin 1g/vial lot 49245DD exam on 4/20/15 (80 labels defective out of (b) (4)
- Diltiazem lot 47385DD exam on 4/20/15 (30 labels defective out of (b) (4)
- Diltiazem lot 48045DD exam on 4/20/15 (81 labels defective out of (b) (4)
- Diltiazem lot 50075DD exam on 5/18/15 (120 labels defective out of (b) (4)
- Diltiazem lot 51305DD exam on 6/25/15 (10 labels defective out of (b) (4))

Despite multiple complaints and the high defect rates repeatedly discovered during retention sample review, the investigation was still not expanded to cover all ADD-Vantage products. You did not examine and investigate all ADD-Vantage products to determine the full extent of the problem.

During the FDA inspection we examined approximately (b) (4) unexpired retain samples including Vancomycin lots 44170DD, 49325DD and 50235DD; Diltiazem lots 41160DD, 47385DD and 51305DD; and Azithromycin lot 49335DD. Of those units, approximately 96% were defective and

60% had a complete gap between the bottle and label for the entire vertical length of at least one side of the label.

Repeat Observation from 4/03/2015

OBSERVATION 2

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration. Specifically,

Your reserve sample selection criteria, as well as your sample inspection procedures and practices are inadequate as demonstrated by their inability to detect the pervasive label degradation in the ADD-Vantage line of products discussed above in Observation 1. In 2015, approximately (b) (4) lots of ADD-Vantage products were selected for annual visual review to represent all ADD-Vantage products, but you did not discover or document any degradation:

A) Your firm does not inspect reserve samples on a yearly basis for all types of degradation, such as visible label adhesive degradation and particulates caused by degradation. Per SOP QC0801.30, you only examine reserve samples for: 1) (b) (4) deterioration, 2) appearance for (b) (4), and 3) (b) (4). Your SOP (standard operating procedure) is inadequate because it does not require employees to look for all types of degradation.

B) You do not use acceptable statistical procedures to select units for yearly examination which resulted in significant under-examination of reserve samples. Per SOP QC0801.30, you perform annual examination on approximately (b) (4) batches for each product code.

However, of the batches selected for examination, you do not examine all units in the reserve sample for that batch, and you only inspect up to a maximum of (b)(4) units total. You arrived at this number by improperly applying ANSI-ASQ Z1.4-2003/MIL-STD-105E by basing the calculation on the (b) (4). As a result, you inspect (b) (4) units in a batch as large as (b) (4) units (which itself is intended to be representative of approximately (b)(4) total batches, the other (b)(4) of which are not examined.) Therefore, for your high volume products, this means you examine (b)(4) units to represent approximately (b) (4) units on the market.

In 2015, the reserve criteria/procedures/practices discussed above were used for all of the approximately (b) (4) batches / (b)(4) million units you manufactured.

OBSERVATION 3

An FDA Field Alert was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

A. You received complaints and performed retention sample evaluations between 4/20/15 and 6/25/15 showing at least (b)(4) different lots of different products had significant label deterioration. Approximately (b) (4) lots were impacted by the root cause of the issue. You did not file a field alert notifying the district.

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B. Your Field Alert practices and SOPs for quality defects reported, did not include reporting requirements to FDA for products distributed outside of the United States (i.e. internationally).

C. A complaint for Ketoralac Tromethamine Injection 30 mg/mL Vials, lot no. 46205DD was received reporting particulates observed in vials. Complaint no. 3018231, registration date 9/22/15, documents this complaint was received by Regulatory Affairs Operations Specialist GCM on 9/16/15. This complaint investigation also documents GCM received another notification of the complaint from FDA with MSB # 2015-06906 on 9/21/15. On 9/22/15, during the investigation and evaluation of their retention samples, you found (b) (4) units out of the (b) (4) also contained particulate matter (PM). You did not file the Initial Field Alert until 9/24/15.

D. You received four complaints on Dobutamine Inj. USP, 12.5 mg/mL, 20 mL in 20 mL vials, lot no. 52175DD, which reported the product was "discolored". These complaints were received on 1/12/15, 2/25/15, 3/08/15 and 3/09/15 before you initiated a Field Alert on 3/10/16, as follows:

1. Complaint no. 3139049 was received on 1/12/16 for a discolored solution described as a "dingy champagne color".
2. Complaint no. 3189961 was received 2/25/16 for "4 vials that are discolored".
3. Complaint no. 3205537 was received 3/08/15 for product reported to be a "peachy color and have not seen it that way". This complaint also reported the vial contained "Chucks of floating in there little flakes, like eraser dust."
4. Complaint no. 3207686 was received on 3/09/15 reported eight vials "rapidly changed from clear colorless solution to a dark color pink after a week."

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E. On 3/18/16, a Manufacturing Quality associate identified a critical container defect in the (b) (4) Area, during the manufacturing operations for Precedex (Dexmedetomidine HCl Injection) 4 mcg/mL, 100 mL in 100 mL vail, lot no. 63075DD. This involved over (b) (4) lots of product with at least (b) (4) of them being rejected and potentially affected product being in distribution. The Initial Field Alert was not filed until 4/13/16.

F. On 12/31/15, Regulatory Affairs Operations Specialist GCM, received an email regarding a complaint (no. 3129061) on Vancomycin Hydrochloride for Injection, lot no. 565003A. The complaint reports a vial containing particulates which "looks like a small insect or speck of dust". On 1/08/16, you performed an examination of (b) (4) reconstituted reserve units and found one unit, which confirmed this complaint. The Initial Field Alert was not filed until 1/08/16.

G. The following Vancomycin Hydrochloride particulate complaints were also received for this lot 565003A, which you tested and identified as "cardboard":
   1. Complaint no. 3188939 was reported on 2/24/16 for particulates which reported "a piece of cardboard particulate was found floating in the vial". You did not file a Field Alert within three working days of receipt of this complaint information.
   2. Complaint no. 3256909 was reported on 4/15/16, which was described a floater which looked like a brown paper towel or corrugated paper. You did not file a Field Alert within three working days of receipt of this complaint information.

Repeat Observation from 8/16/2013

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OBSERVATION 4

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

A. You did not recognize trends and repeat deviations and you did not initiate effectiveness plans or provide adequate justification for an exemption, as required by your SOP QC0215.03:

1. In 2015, for (b) (4), you identified (b) (4)-related failures which caused (b) (4) excursions (impacting (b)(4) different lyophilizer runs/lots of product), all of which resulted in critical process parameters not being met. You did not recognize this as a trend by the end of your final investigation closing on 11/24/15.

   Beginning in January 2015, you saw (b)(4) lots of product impacted by (b) (4) excursions that caused critical process parameters not to be met, but you did not put into place any effectiveness checks:

(b) (4)

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From July-October 2015, (b) (4) more lots were affected by (b) (4) excursions which caused critical process parameters not to be met, and they were all caused by an identical control module:

- ER 234614: On 7/30/15, during production (b) (4), a failure in the (b) (4) occurred. The unit was replaced and no effectiveness check was put in place.

- ER 246191: On 10/27/15, during production of Vancomycin lot 58310DD, a failure occurred. At the time, the cause was believed to be the failure of a (b) (4) on the (b) (4), and the (b) (4). No official investigation was opened at this time and you continued to manufacture. No effectiveness check was put into place.

- ER 246191: On 10/29/15, during production of Vancomycin lot 58320DD, another failure occurred. An investigation was opened but the lyophilizer remained in use. No immediate corrective action was taken.

- ER 246191: On 10/31/15, during the production of Vancomycin lot 58326DD, another failure occurred. The investigation above was expanded to include this deviation and found the (b) (4) had failed, causing the all excursions on 10/27/15, 10/29/15, and 10/31/15. However, the investigation did not recognize the failures from 10/27/15-10/31/15 were caused by the same (b) (4) that failed on 7/30/15.

Despite the (b) (4) lots impacted by (b) (4) excursions in the last year, and the last (b) (4) being caused by an identical part, your final investigation (ER246191) stated there was no trend or repeat failure. No effectiveness check was ever put into place.

2. As noted in Observation 1, you had numerous complaints of the same label defect. Your only investigation (ER 214194, closed 4/22/15) stated there was no repeat occurrence of this issue. Additionally, you did not put in place an effectiveness check.

B. During the investigation of your Vancomycin Hydrochloride for Injection, USP, involving complaints received for particulates from cardboard, you did not extend your investigation to review of other distributed lots. After your evaluation of the retain sample for lot no. 56-500-3A where you identified a unit which contained fibrous particles, you did not evaluate other retain samples.

In addition, your Risk Assessment Register (RAR) #991 dated 02/12/16, you did not include information regarding an additional complaint no. 3133219 which was received on 1/6/2016. This Vancomycin Hydrochloride for Injection, USP, lot no. 421503A (Canada), was reported to have particulates which were also found to be cardboard.

OBSERVATION 5

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. In your Annual Product Reviews for the following products you identify label defects but fail to initiate appropriate corrective and preventive actions to address and correct this failure:

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1. Diltiazem HCl Inj. 100 mg/Vial, ADD-Vantage, for the review period of 12/18/2014 to 12/17/2015: You identified a trend for labeling complaints "through an investigation and determined to be due to the incorrect adhesive used on labels with plastic vials".
2. Vancomycin HCl, USP, 1 g, vial, ADD-Vantage, for the review period of 7/02/2014 to 7/01/2015: You report three complaints were received for "misplaced labeling". You document "A visual retains evaluation was performed with multiple units with varying degrees of label flagging identified." "All the complaints were confirmed as manufacturing related."

B. Five complaints for Dobutamine Inj., 12.5 mg/mL, 20 mL in 20 mL Vial product, lot no. 52175DD were received between 1/13/16 through 4/27/16. These complaints reported product which was discolored and/or contained particulates. As of 5/25/16, you have not completed an investigation identifying the cause of this complaint and/or initiated a corrective and preventive action to address this product specification failure.

Repeat Observation from 4/23/2014

Device QSR / Combination Products:

OBSERVATION 6

You did not notify the agency of the changes in a drug product container closure system that controls the drug product delivered to a patient or changes in the type (e.g., glass to (b) (4)

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(b) (4), vial to syringe) or composition (e.g., (b) (4) to another (b) (4)) of a packaging component that may affect the impurity profile of the drug product.

Specifically, you did not properly notify the agency of a major design changes in the drug delivery system, iSecure, a class II device for the following drugs:

Product Description	Product Code	List Number	Submission Number	Submission Date	Submission Type	Manuf. Date	Release Date	Lot Number
iSecure Version 2								
Hydromorphone	(b) (4)		200-403	29-04-10	Original NDA	(b) (4)		25540LL
				29-04-10	Original NDA			25600LL
				29-04-10	Original NDA			20550LL
Morphine Sulfate			202-515	14-01-11	Original NDA			41560LL
				14-01-11	Original NDA			40720LL
				14-01-11	Original NDA			34750LL
				14-01-11	Original NDA			32590LL
Ketorolac			74-993	3-09-10	PAS			30720LL
Midazolam			75-856	6-Aug-10 7-Dec-11	Annual Report CBE-0			91710LL

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Ondansetron	(b) (4)	77-840	10-01-11	CBE-30	(b) (4)	07695L L

In May, 2009, you completed a major design change in the drug delivery system from iSecure 1, a class II device to iSecure 2. You did not properly notify the agency of the design changes for iSecure 1, and the above listed drugs are currently manufactured and shipped in iSecure 2, drug delivery system. The above drug applications referenced Hospira's 510(K) clearance for iSecure 1 as the drug delivery system, while you manufactured and assembled the products in iSecure 2 devices.

OBSERVATION 7

The design history file does not demonstrate that the design was developed following the requirements of 21 CFR 820.

Specifically, you did not establish and maintain a design history file for each type of device. You did not document design changes in DHF (Design History File) for a major design change in a class II device. iSecure, a class II devices was approved in 2006 for use in the withdrawal and administration of sterile materials under aseptic conditions. In 08/01/2008, your firm initiated a design change for iSecure that included new delivery sizes (1.5mL, 2.5mL and 5.0mL), materials, packaging and instruction for use. No design changes were documented in DHF prior to initiation of the new product design. As of 05/27/2016, the redesigned device, "iSecure 2" is used for withdrawal and administration of sterile materials under aseptic conditions for the following drug products:

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- Hydromorphone HCl Inj. USP (1mg/mL, 0.5 mL in 1.5mL cartridge, 1mg/mL, 1mL in 1.5mL cartridge and 2 mg/mL, 1mL in 1.5mL cartridge)
- Morphine Sulfate Inj. USP (2 mg/mL, 1mL in 1.5mL cartridge, 4 mg/mL, 1mL, in 1.5mL cartridge, 8 mg/mL, 1mL in 1.5mL cartridge, 10 mg/mL, 1mL in 1.5mL cartridge and 15 mg/mL, 1mL in 1.5mL cartridge)
- Ketorolac Tromethamine Inj. USP (30 mg/mL, 1mL in 1.5mL cartridge)
- Midazolam HCl Inj. USP (1mg base/mL, 2mL in 2.5mL cartridge)
- Ondansetron Inj. USP (2 mg/mL, 2mL in 2.5mL cartridge).

OBSERVATION 8

The acceptance status of product was not identified to indicate conformance or nonconformance with acceptance criteria

Specifically, you did not identify by suitable means, the acceptance status of product, to indicate the conformance or nonconformance with acceptance criteria.

You did not perform final acceptance activities for iSecure 2, a class II device to assure the device is functioning as intended. iSecure 2 is used in the withdrawal and administration of sterile drug materials under aseptic conditions. During the walk-through of manufacturing (b) (4) filing line) and packaging ((b) (4)) on May 17th 2016, an FDA investigator observed manufacturing and packaging of Hydromorphone HCl Inj. USP 1mg/mL, lot no. 64560LL. The FDA investigator observed Hydromorphone HCl Inj. USP 1mg/mL, lot no. 64560LL were being placed in iSecure 2 and prepared for shipment. Device functionally test was not conducted to ensure the device is functioning as intended.

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Drugs – Production System:

OBSERVATION 9

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

Specifically,

A non-sterile surface was introduced for use in the (b) (4), which is prohibited by your SOPs: On 5/21/16, while Hydromorphone lot 651903A was being manufactured in the (b) (4), a bottle of (b) (4) tamper resistant seal was observed in the (b) (4). Inserting bottles with tamper seals is specifically prohibited by your procedure MF0732.00.

According to your records, a (b) (4) was originally loaded into the (b) (4) on 5/19/16 by a (b) (4). A surface sterilization cycle was run, but due to a separate manufacturing issue, the (b) (4)) were unloaded into the grade D area. Later on 5/19/16, a (b) (4) from the grade D area into the (b) (4). The (b) (4) on 5/20/16, and then the (b) (4) was opened and operators began using the items inside. On 5/21/16, our inspection discovered the (b) (4) (b) (4). You do not know whether the (b) (4)) was improperly loaded and placed/verified by (b) (4) or if the error only encompasses the (b) (4) operators.

Repeat Observation from 10/24/2012

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OBSERVATION 10

In-process specifications are not consistent with drug product final specifications, derived from previous acceptable process average and process variability estimates where possible or determined by the application of suitable statistical procedures where appropriate.

A. You currently have no in-process defect alert (and/or action) limits for either your semi-automated vial inspection process or your fully-automated vial inspection process despite the approximately 175 particulate complaints you have received since your visual inspection remediation process began in response to the January 2012 FDA inspection. The following applies to the approximately (b) (4) products which you visually inspect, such as Precedex, Marcaine HCl, Hydromorphone, Diltiazem, and (b) (4):

Whenever any change is made to your manufacturing process (including a change to your visual inspection program) you completely remove the in-process defect limits for approximately (b) (4) of that product. During this time, your SOP QC1310.10 directs you not to investigate any batches despite any number of defects found during inspection.

You have reset (i.e. eliminated) your defect limit multiple times since 3/25/15 and plan to continue this practice in the future:

- On 3/25/15, you began using fully-automated visual inspection and have moved approximately (b) (4) different products to this process (and inspected approximately (b) (4) different batches) without any defect limit. You will inspect approximately (b) (4) batches until limits are in place.

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- On 1/11/16, you changed certain defect categories for your semi-automated visual inspection, resulting in another reset/elimination of your limits on (b) (4) products, of which you have already inspected (b) (4) batches without any defect limits in place. Until fully implemented, this will result in approximately (b) (4) batches being inspected without limits.

- As part of your visual inspection remediation plan made in response to the January 2012 FDA inspection, you are still in the process of moving approximately (b) (4) more products to fully automated inspection, which will result in another defect limit elimination for those products affecting another approximately (b) (4) batches in the future.

- You plan to remove the semi-automated (b) (4) from the beginning of your process, which (per your current procedure/practice) will result in up to another approximately (b) (4) batches inspected without defect limits in the future.

Although you have past defect rate data on all of your vial products (which, per your defect mapping, can be directly applied to your current defect categories), you have not used that to set appropriate limits for your current inspection process.

B. In addition, for the (b) (4)) Injectable product manufactured at your site, you received numerous complaints for particulates which were identified as (b) (4). In the Investigation Summary Section of the complaint investigation you document "there are no accept/reject limits for the (b) (4)" for this (b) (4) check.

The following complaints also include quality defects reported on (b) (4)) product which was processed through your (b) (4) and (b) (4)

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Semi-Automated Visual Inspection System. You document in these investigations "there are no accept/reject limits" for defects identified at these stations.

1. Complaint no. 3082386, Registration Date: 11/14/15: Ten percent of the defects which are undefined are evaluated and found the following: two glass particles, eight fiber particle, fifty-six red particle, two components particles, fifteen other particles, one plunger foreign substance stain product contact, and one plunger (b) (4).

2. Complaint no. 2772497, Registration Date: 2/26/15: Ten percent of the defects which are undefined are evaluated and found the following: ten units with glass particle, thirteen units with fiber particles, forty-seven units with red particles, thirteen units with other particles, one unit Glass: Foreign Substance Stain (product contact) twenty three units with Plunger: foreign substance stain and two units with Plunger: Foreign Substance – Glass debris (product contact).

3. Complaint no. 3218670, Registration Date: 3/17/16: Ten percent of the defects which are undefined are evaluated and found the following: one plunger foreign substance glass debris in product contact, nine plunger (b) (4), seventy five red particle, seven fiber particle, seven glass particle, and eighteen other particles.

OBSERVATION 11

Rejected in-process materials are not controlled under a quarantine system to prevent their use in manufacturing or processing operations for which they are unsuitable.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	May 16-21,23-27/16 & 6/8/16
	FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jonathan J. Rushford, Site Head/Vice President Operations	
FIRM NAME Hospira Inc. A Pfizer Company	STREET ADDRESS 1776 Centennial Dr.
CITY, STATE, ZIP CODE, COUNTRY McPherson, KS 67460	TYPE ESTABLISHMENT INSPECTED Human Drug/Device Manufacturer

Specifically,

A) Your SOP for semi-automated visual inspection of vials (SOP MF0502.00) allows rejected units to be re-inspected (b) (4) and included with the other acceptable units. It states: "VIII. SEGREGATING AND RECORDING REJECTS A. All units that have been inspected (b) (4) to confirm reject status. This procedure (b) (4). Any units that are considered acceptable will be included with the other acceptable units from the lot." There are no records for any of your products showing how many units have been subject to this procedure and the re-inspection results.

B) You do not keep attributable records of defects found by (b) (4) during semi-automated visual inspection. You perform visual inspection (b) (4) Visual inspectors (b) (4) which tracks each type of defect found, but no record is kept of how many defects were found by each inspector (b) (4). (b) (4).

OBSERVATION 12

A written record of the program along with appropriate validation data has not been maintained in situations where (b) (4).

Specifically,

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Original quality data is not maintained when it is eliminated by your computerized (b) (4).

You use (b) (4)) for the aseptic fill and packaging lines. The electronic data from these (b) (4)s is not documented, recorded, or saved. This directly impacted investigations into Exception Report 262824 and 255648 when the (b) (4) to the capping line was turned off accidentally. You were unable to track the electronic data back to see who performed what commands via the (b) (4) or when it occurred, because the (b) (4) for rooms (b) (4) and (b) (4). The (b) (4) is designed to (b) (4)

OBSERVATION 13

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

On 5/18/16 we observed (b) (4) employees use (b) (4), write on some paperwork, and then perform personnel touch plates on line (b) (4), when Nimbex NX20, lot 65105DD, was being aseptically filled.

On 5/19/16 we observed an employee use (b) (4) immediately before performing personnel touch plates on line (b) (4) when Vancomycin M-6535, lot 65090DD, was being aseptically filled.

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Drugs – Packaging and Labeling System:

OBSERVATION 14

Labeling or packaging materials which did not meet written specifications were not rejected to prevent their use in operations for which they are unsuitable.

Specifically,

All (b) (4) batches of incoming ADD-Vantage labeling from 7/3/2013 until 4/9/2015 were accepted for use despite not meeting internal specifications outlined in Monograph Y-011, even though the Certificate of Conformance for each of these batches specifically listed the wrong adhesive.

X
Carl A. Huffman
Investigator

X
Shafiq S. Ahadi
Investigator

X
Brett R. Havranek
Investigator

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."