DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	12/20/2021-1/28/2022* FEI NUMBER 3004161147

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Kevin D. Orfan, President	
FIRM NAME Sharp Packaging Services, LLC	STREET ADDRESS 7451 Keebler Way
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18106-9302	TYPE ESTABLISHMENT INSPECTED Contract Packager

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:

Quality System

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. You failed to perform the cleaning validation (CV) for (b) (4) as required per Document #VALD-0037 Rev. 1.0 (*Cleaning Validation Risk Assessment –* (b) (4) *Filler Bottle Line Equipment Train Fixed Dose Coated Tablets Cleaning Validation Risk Assessment) using* (b) (4), (b) (4), 03/02/2021 approved date). In addition, you did not initiate a deviation for not performing the CV for (b) (4).

B. Change controls are not adequately reviewed and assessed by the Quality Unit. We observed at least nine (9) change controls (listed below) that were not adequately assessed and lacked consistency in final classification by your Quality Control Unit.

- Change Controls #QE-000084, QE-000085, and QE-000234 were processed to "Define the SPT rework file in the Metadata on product in (b) (4). Create a rework (b) (4) for the reprinting of labels." All three changes are similar but were issued different severities or classifications. Change Controls #QE-000084 and QE-000234 were issued a "Minor" severity or

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classification whereas Change Control #QE-000085 was issued a "Major" severity or classification when in fact they are the same type of changes.

- Change Controls #QE-001220 and QE-004540 were processed to relocate the (b) (4) Equipment train from Sharp's Allentown Campus to the Macungie facility for short-term storage. However, your quality control unit assessed Change Control #QE-001220 as a "Minor" severity, but assessed Change Control #QE-004540 as a "Major" severity when in fact they are both the same type of changes.

- Change Controls #QE-000584, QE-000655, QE-000884, and QE-004724 were processed to update bill of material (BOM), obsolete and create new specification due to customer artwork change. All four changes are similar and were issued different severities or classifications. Change Controls #QE-000584, QE-000884, and QE-004724 were issued a "Minor" severity or classification whereas Change Control #QE-000655 was issued a "Major" severity or classification. These changes relate to the following products: (b) (4) (intended for the treatment of adults and pediatric patients 1 year of age and older with Short Bowel Syndrome (SBS)), (b) (4) (intended to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC)), (b) (4) (intended for the management of pain), and (b) (4) (intended for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain).

C. On 12/21/2021, we observed your Quality Line Associate (QLA) performed in-process checks (tablet counts using (b) (4) Tablet counter equipment) in the primary packaging Room (b) (4) around 4:10pm for (b) (4) Bottle Serialized, Bulk Lot (b) (4) and packaging Lot (b) (4) with 2023SEP17 expiry date (b) (4)) without the packaging batch records. However, the entries were not being recorded contemporaneously in the packaging batch records as the records were being held in the secondary packaging room located in the other room. QLA recorded the entries in the packaging batch records at 4:20pm (Page 25 of 30 or 33/166 of the packaging records). This practice is contrary to SOP-0902 (*Good Documentation Practices*) and SOP-0916 (*Data Integrity Requirements*).

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D. You failed to document in the packaging batch records the total failures observed for the following parameters in the (b) (4) System (ID #62471) located in Packaging Room (b) (4) on 01/25/2022 during the packaging of (b) (4) and 12/2023 expiry date.

Parameters	Total Failures
Label Web Print Inspection	9
Label ID Inspection	1

E. On 12/20/2021, we observed that your production supervisor (b) (6) accessed the primary packaging room (b) (4) without the required N95 mask with his beard exposed (a violation of *Dress and Conduct for CGMP Areas* SOP-0901). We were informed that entry to this primary room is restricted ONLY to individuals who have been fit-tested and medically cleared. Additionally, we found that he was not fitted and medically cleared for N95 mask (as of 12/20/21) in order to access the primary packaging room. Room (b) (4) was being utilized to package (b) (4) (b) (4), Lot (b) (4) with 21 MAY 2024 expiry date. (b) (4) is a combination hormonal drug (b) (4) intended for the treatment of heavy menstrual bleeding associated with uterine leiomyomas in premenopausal women.

F. You have not established a procedure or work instruction for performing/handling facility repairs. On 12/20/2021, we observed one of the walls inside Room (b) (4) (Primary Packaging Room) is under repair (cemented) during the bulk packaging operations of (b) (4) or (b) (4) (b) (4), Lot (b) (4) with 21 MAY 2024 expiry date. We observed during the review of work order request #WR-000140 that it was not initiated until 12/23/2021.

G. The Weighing label printed from the scale printer attached to the scale printer form (QF-02-20-1338 Rev. 01) does not include the initials or signature and date of the person who performs the task. The printed label is generated after weighing the samples of receiving bulk drugs.

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H. We observed on 01/27/2022 that you do not maintain a use and cleaning logbook for all (b) (4) balances located in the Incoming Inspection Room which are used for weighing collecting samples. The Incoming Inspection Room is used for sampling of received bulk drugs.

OBSERVATION 2

The quality control unit lacks the responsibility and authority to approve all components, labeling and drug products.

Specifically,

Your quality unit (QU) lacks appropriate responsibility and control over your drug packaging operations. During the inspection on 12/21/2021, we observed a discarded sample label for (b) (4) (with 04/25 expiry date and item #125605) in the trash bin located between Production Room 120 and 121. This discarded label had approval notations from your employees (b) (6) and (b) (6) dated 12/17/2021. However, we observed another sample label in the sample label page associated with the executed packaging batch record for (b) (4) with 2025/04 expiry date and item #125605. This sample label included in the executed batch record was documented as completed by approximately four different personnel on 12/17/2021. The executed packaging batch record did not include any documentation or notation to indicate if any sample labels were discarded. Discarding of batch record documentation is not an acceptable practice as per your written procedure SOP-0902 dictating good documentation practices.

OBSERVATION 3

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

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A. The following product complaint investigations were deemed incomplete. These complaint investigations lacked information such as, but not limited to, who conducted the investigation, probe on other potentially impacted batches if any, documented verification of retain samples as part of investigation, and consideration for any CAPA to prevent recurrence.

- Complaint #QE-000726: (b) (4), received on 02/04/2021 for accidental actuation of device (Damaged/Defective). (b) (4) is intended for the treatment of seizure clusters in adults and children 6 years of age and older.
- Complaint # QE-002391: (b) (4), received on 05/03/2021 for damaged/defective component such as plunger.
- Approximately twelve (12) (b) (4) short-count complaint investigations were received between 03/2017 and 04/2020. Among the twelve complaints, nine (9) were received between 08/2019 and 04/2020 as follows. (b) (4) is intended for the maintenance treatment of opioid dependence.

    - CR-005412-E
    - CR-003683-E
    - CR-006079-E
    - CR-009123-E
    - CR-009124-E
    - CR-009306-E
    - CR-009307-E
    - CR-009308-E
    - CR-009309-E
    - CR-009310-E
    - CR-009695-E
    - CR-010500-E

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B. Complaint #QE-003082: (b) (4), received on 06/08/2021 for foreign tablet in a sealed bottle. You stated in the investigation that "the foreign tablet could be a (b) (4) tablet and no longer packaged at the Allentown site. This lot was confirmed to have been packaged after the site stop the packaging of (b) (4) products." However, you failed to state in the investigation report when Sharp stopped packaging (b) (4) products at the Allentown site and which packaging rooms were associated with the complaint. You extended a review of the cleaning logbooks for previous lots packaged only and not to lots packaged after. You further stated based on your findings, there is no indication the subject foreign tablet would have been packaged in a bottle of (b) (4) and attributed the root cause as External to Sharp Control. However, it is the 11th complaint for foreign tablets received within 12 months (as of 06/21/2021) for (b) (4) products packaged by Sharp Corporation and no actions have been taken to prevent further recurrences other than entering it into your quality management system (QMS) to be monitored.(b) (4) and (b) (4) are prescription drug products intended to prevent strokes or blood clots.

C. Complaint #QE-000549: (b) (4) received on 01/28/2021 where the pharmacy reported that one (1) labeled syringe was found to be missing. You attributed the root cause to process design, but it is the 10th complaints received for missing labeled syringes within 12 months (as of 02/17/2021). You then entered it into your quality management system (QMS) to be monitored but no actions have been taken to prevent further recurrences.

D. Complaint #QE-001632: (b) (4) received on 03/25/2021 where presence of hair was observed at the bottom of the bottle. You stated in the investigation that "all personnel are required to wear labcoat, hairnet, beard cover (if necessary), designated shoes or shoe covers." You concluded based on the packaging design, it is unlikely to occur at your facility. However, during our walkthrough on 12/20/2021, we observed a production supervisor accessed the primary packaging Room (b) (4) with his beard exposed (a violation of *Dress and Conduct for CGMP Areas* SOP-0901).

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E. Complaint #CR-010991-E: (b) (4) received on 07/29/2020 where the consumer reported one of the boxes of (b) (4) films was short of 24 films. You attributed the root cause to "External to Sharp Control – SPS" and stated (b) (4) inspections include verifying the quantity of pouches in each carton (b) (4) pouches/carton) at a Major Level AQL 0.65% (Ac/Re: 1/2). You further stated a total of (b) (4) cartons were inspected and no defects were identified.

F. You received four critical complaints (CR-010800-E, CR-011740-E, QE-003044, and QE 003167) for (b) (4), where (b) (4) syringes were missing. You attributed the root cause for all four complaints (listed below) as "External to Sharp Control – SPS". However, during our walkthrough of Packaging Room (b) (4) on 01/25/2022, we observed (b) (4) (b) (4) that were rejected in the checkweigher bin; these rejected syringes from the checkweigher bin were not documented in the packaging batch record. (b) (4) is intended to treat symptoms of cardiac arrest, hypotension associated with Septic Shock, and severe allergic reaction.

- **Complaint #CR-010800-E:** received on 06/12/2020 for (b) (4) (b) (4), where a pharmacist stated that they noticed that the box containing the syringes was light in weight. After inspecting the product that was sealed, the pharmacist stated the two (b) (4) syringes were missing and there was only 1 (b) (4) cap trainer injection & PI in the carton. They concluded that there was no sign of damage or tampering with the box.

- **Complaint #CR-011740-E:** received on 12/16/2020 for (b) (4) (b) (4), Expiration: 09/2021), where a pharmacist stated that they received a box of (b) (4) injection and there was one (b) (4) missing.

- **Complaint #QE-003044:** received on 06/05/2021 for (b) (4) (b) (4), where a pharmacist stated that the two (b) (4) syringes were

missing and only the trainer was available. Pharmacist confirmed that the box was sealed upon receipt.

- **Complaint #QE-003167:** received on 06/11/2021 for (b) (4) (b) (4), where a pharmacist calling for a patient stated that the two (b) (4) syringes were missing and only the trainer "pen" was available. Pharmacist confirmed that the box was sealed upon receipt.

OBSERVATION 4

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically,

You initiated Deviation Report #DR-010654-E for (b) (4) on 03/19/2020 and attributed the root cause to Sharp (Not following SOP or Work Instruction) where you observed during the batch record review that AQL report for visual pouches Single Normal, Level II Critical and 0.65% was not met based on the quantity ordered. The sample plan requires (b) (4) pouches for the lot but only (b) (4) pouches were inspected. However, no consideration for any CAPA to prevent recurrence was taken. (b) (4) is intended to treat narcotic dependence.

Material Management System

OBSERVATION 5

Procedures describing the warehousing of drug products are not established and followed.

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Specifically,

A. The (b) (4) (inventory management software) could not provide an accurate location tag for pallet (K3546057) of (b) (4). Bulk Lot (b) (4) observed sitting on 12/21/2021 in the component area and unattended outside Production Room #450 without any documentation. The pallet movement in your (b) (4) software revealed the bulk drug pallet (K3546057) was moved to Room (b) (4) However, this pallet (K3546057) was not accounted for by your (b) (4) (inventory management system) in the transaction by item and location under "Trans – 12/21/2021 4:06:26pm".

B. Floor stock components and Packaging components are not adequately labeled to prevent mix-ups. We observed on 12/20/2021 that pallets of packaging components are issued a single loose status label which is placed on top of the material. For example, you initiated Deviation #DR-007132-E on 05/07/2019 for (b) (4) where two QA Incoming Bulk Inspectors found a pallet of another drug (b) (4) with a white plastic tray on top that belonged to the lot the just completed inspecting placed on top of a pallet containing (b) (4), Item # 2C0465, Lot# (b) (4) You attributed the root cause to training issue.

C. You do not perform an inspection of the incoming bulk drugs at time of receipt. For example, you received bulk (b) (4) on 11/11/2021 in your warehouse and was not inspected by your Quality Unit until 11/29/2021.

D. Although you received incoming bulk drug products into Quarantine status in your inventory management system (b) (4), there is no way of knowing the status of the receiving/incoming bulk drug pallets prior to being received into (b) (4). We observed that the bulk drug pallets can remain in the warehouse for many days prior to being inspected and entered into (b) (4)

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Facilities & Equipment System

OBSERVATION 6

Failure to maintain a backup file of data entered into the computer or related system.

Specifically, you do not maintain a backup of the PLCs and HMIs electronic data recorded during packaging operations from the packaging lines. These packaging data include number of bottles and cartons rejected at the checkweighers, (b) (4) , etc. Per your Production Supervisors, the packaging data resides locally and cannot be backed up and/or exported for review.

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

Specifically,

A. There is no assurance that detected products with metals are completely removed from the packaging lines according to the equipment design. During our walkthroughs on 12/20/2021 and 12/21/2021, we observed that the metal detectors located on the packaging lines (Room (b) (4)) are not equipped with rejected/ejected bins where the product with metal will be held until inspected/verified by QA. The Metal detector in Room (b) (4) are located before the bottles are capped. The firm was packaging (b) (4) and (b) (4) during our walkthroughs.

B. We observed on 12/20/2021 the tablet hopper/dispenser and the bottle unscrambler uncovered in Packaging Room (b) (4) On 12/21/2021, we observed the tablet hopper/dispenser uncovered in Packaging Room (b) (4). The firm was packaging (b) (4)

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(b) (4) on 12/20/2021 and (b) (4), (b) (4) on 12/21/2021. You received Complaint #QE-004167 (foreign matter/foreign object in bottle) on 08/06/2021 where the pharmacy found a foreign object that appears to be wood and is a gray/brown color inside one of three stock bottles used to fill supply for a bottle of (b) (4) (b) (4).

C. We observed on 12/21/2021 in Production Room (b) (4) the bottle caps are shedding material during the retorquing process while packaging (b) (4) (b) (4) Per your line mechanic (b) (6) this issue only occurs with this capper. However, you have not taken any actions to correct the issue.

D. You have not established a gowning area where employees are to garb prior to accessing the primary packaging rooms. We observed during our walkthroughs that personnel are being garbed inside the (b) (4) rooms. There are no anterooms prior to accessing the primary packaging rooms although Section 4.2 (Personnel Gowning Controls) of QM-0047 Rev. 1.0 (Cross Contamination Controls - Allentown Facilities) states (b) (4) (b) (4)

OBSERVATION 8

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

A. We observed several clear tapes around and above the bulk hopper located in Production Room (b) (4) on 12/20/2021 during the packaging of (b) (4)

(b) (4), 21 MAY 2024 expiry date. In addition, we also observed several checkweighers being taped and with visible cracks in Production Rooms (b) (4) and (b) (4)

B. During the walkthrough of the Incoming Inspection Room on 01/27/2022, we observed presence of (b) (4) applied to the HEPA filter cover and the sides. The room is used for sampling of received bulk drugs and the bulk drug pallet is placed and opened directly under the HEPA filter.

In addition, several open gaps were observed in the room between the air conditioner unit and the wall, and the ceiling/wall tiles. Presence of clear tapes observed on the wall holding a posted paper.

Packaging & Labeling System

OBSERVATION 9

Inspection of the packaging and labeling facilities immediately before use is not done to assure that all drug products have been removed from previous operations.

Specifically,

A. Your Quality Control Unit failed to perform an effective line clearance and product assessment. You initiated Deviation #DR-010361-E on 02/21/2020 where you discovered three (3) pouches of (b) (4) from the previous batch after completion of (b) (4) shift packaging operations in Room (b) (4) while cleaning for (b) (4) (Item: 404070, Lot (b) (4), and Work Order #S109944-1). You attributed the failure to failed line clearance and the root cause to machine/design Sharp Packaging Services (SPS). The subsequent product assessment revealed no impact on the quality of (b) (4) Lot (b) (4) although you

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found three (3) pouches from the previous lot ((b) (4)) and you recommended to release the lot. Although no action plans were assigned, you proposed to add (b) (4) (b) (4) to detect hot spots and to create a work instruction which would be tracked under AF-01508-1. The investigation did not include the names of personnel involved in the line clearance and interviewed during the investigation and whether they were identified for retraining and/or completed the training for Cleaning Guidelines for Associates Specific to Production Room (b) (4).

The review of Document #AF-01508-I initiated on 07/03/2019 revealed it was unrelated to Deviation #DR-010361-E and occurred prior to the discovery of three pouches from previous operations (02/21/2020) where you failed to implement corrective measures to conduct effective cleaning ensuring all products are removed from the equipment during cleaning operations. In addition, there is no indication in the document if training was required and provided to affected personnel. (b) (4) drug is received in bulk format and is packaged into pouches at the firm. (b) (4) is a prescription drug product intended to relieve severe pain.

B. During our walkthroughs on 12/20/2021 and 12/21/2021, we observed several metal screws and washers next to the tablet hopper in Room (b) (4), underneath the checkweigher in Room (b) (4), and at least three (3) (b) (4) zippers by the bottle dispenser located in Room (b) (4). Room (b) (4) was packaging (b) (4) with 21MAY2024 expiry date on 12/20/2021. Room (b) (4) was packaging (b) (4) (b) (4) with 2023AUG11 expiry date (b) (4) on 12/21/2021.

OBSERVATION 10

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of packaging of the drug product.

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Specifically,

You failed to document the total of bottles collected at the checkweigher recovered bins in the master packaging records for (b) (4). We observed on 12/21/2021 approximately 19 bottles of (b) (4) with 2023SEP17 expiry date (b) (4) in the recovered/rejected bins in Room (b) (4). These items when removed are not accounted for in the batch packaging records. In addition, you utilized the (b) (4) tablet counter to perform Quality in-process inspection for tablets count. However, you do not challenge and/or perform a verification of the (b) (4) equipment prior to use. (b) (4) is a (b) (4) drug.

In addition, you failed to document in the packaging batch records the total of rejects for underweight (b) (4) and overweight (b) (4) observed on 01/25/2022 for checkweigher ID #61710 during the packaging of (b) (4) (b) (4) and for the previous batch during our walkthrough. (b) (4) is intended to treat symptoms of cardiac arrest, hypotension associated with Septic Shock, and severe allergic reaction.

	Parameters	Total Amount Rejected
Current Batch Lot (b) (4)	Under Reject	(b) (4)
	Over Reject	
Previous Batch	Under Reject	
	Over Reject	

OBSERVATION 11

Control procedures are not established which monitor the output and 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.

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	Yvins Dezan, Investigator Jessica S Estriplet, Investigator	X Yvins Dezan Investigator Signed By: 2001997410 Date Signed: 01-28-2022 09:51:45	1/28/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	12/20/2021-1/28/2022* FEI NUMBER 3004161147

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Kevin D. Orfan, President	
FIRM NAME Sharp Packaging Services, LLC	STREET ADDRESS 7451 Keebler Way
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18106-9302	TYPE ESTABLISHMENT INSPECTED Contract Packager

Specifically,

A. You do not document in the master packaging records the total of bottles collected at the vision system recovered bins and metal detectors. For example, we observed on 12/21/2021 approximately 15 bottles of (b) (4) with 2023SEP17 expiry date (b) (4) in the recovered/rejected bins in Room (b) (4)

B. You do not document, investigate, track, and trend alarms encountered during packaging operations in the master packaging records. We observed the following alarms on 12/20/2021 in the (b) (4) (b) (4) (Asset #50371) during the packaging of (b) (4) (b) (4) and no actions were taken other than acknowledging the alarms:

Time	Alarm Description
2:10:17 PM	Left dispenser CAM 1- Consecutive Inspection fail
2:10:00 PM	Left dispenser CAM 1- Consecutive Inspection fail
2:09:55 PM	Left dispenser CAM 1- Consecutive Inspection fail
2:09:44 PM	Left dispenser CAM 1- Consecutive Inspection fail
2:09:58 PM	Left Dispenser CAM2 – No Match Left dispenser – Label Pitch not equal to recipe
2:09:44 PM	Left dispenser CAM 1- Consecutive Inspection fail

In addition, we observed similar practices on 01/25/2022 during the walkthrough of Packaging Room (b) (4) and packaging of (b) (4), 05/2023 expiry date where you do not document, investigate, track, and trend alarms encountered during packaging operations in the master packaging records.

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Date & Time	Alarm Description
1/25/2022 8:51:27AM	A0114 / Load "B" Assembly Wrong Color Detected
1/25/2022 8:51:15AM	A0114 / Load "B" Assembly Wrong Color Detected
1/25/2022 8:51:01AM	A0114 / Load "A" Assembly Wrong Color Detected
1/25/2022 8:49:23AM	A0585 / Syringe Reject Bin Maintenance Required
1/25/2022 8:49:21AM	A0588 / Reject not confirmed at Reject Syringe Station
1/25/2022 8:49:21AM	Left dispenser CAM 1- Consecutive Inspection fail

C. You do not verify the clocks/time located on the (b) (4) HMIs and PLCs (Concep equipment) as part of your equipment start-ups and line clearances. We observed on 01/25/2022 at 10:38 AM during the walkthrough of Packaging Room (b) (4) and packaging of (b) (4), 05/2023 expiry date discrepancies in time/clock for the following equipment. The HMIs and PLCs retain GMP packaging data related to the packaging operations including alarms.

Equipment	Reporting time on 01/25/2022
HMI	12:00:08 PM
PLC	10:5:42
Room Clock	10:38 AM

In addition, we observed similar issue at 2:50 PM in the (b) (4) System (ID #62471) located in Packaging Room (b) (4) where the clock/time was an hour ahead (3:50 PM) during the walkthrough of Packaging Room (b) (4) and packaging of (b) (4).

D. There are no instructions in the approved batch packaging records on how to challenge the vision systems located at 7451 Keebler Way Building. The vision systems are used to verify printed labels, lot numbers, expiry dates, and product inserts/ prescriber information (PI) or med guides. For example,

- Pages 15-16 of 30 (In-Process Challenges) of Master Packaging Record (Document #MCPR099) for (b) (4) with 2023AUG11 expiry date (b) (4) showed the parameters to be checked for labeler, bottle serialization, and printer shipper label. However, it does not state how to challenge these parameters.

- Pages 14-15 of 35 (In-Process Challenges) of Master Packaging Record (Document #MPR-404932 Rev. 0 & Work Order #S130250-1) for (b) (4) (b) (4) with 5/31/2024 expiry date showed the parameters to be checked for labeler, bottle serialization, and printer shipper label. However, it does not state how to challenge these parameters. In addition, Page 23/35 (Quality In Process Inspection – Count) does not state which equipment is to be used for performing the task. Per your line supervisor, the firm utilizes (b) (4) to count the number of tablets in bottles during quality in-process inspection.

E. Step (b) (4) (Page 5 of 35) of Master Packaging Record (#MPR-404932 Rev. 0) states "Bottles will be appropriately cleaned, filled with (b) (4) tablets, (b) (4) (b) (4). Unacceptable bottles are ejected from the line. Follow all bottle recovery steps." We observed on 12/20/2021 that Step (b) (4) does not exist during the packaging of Work Order #S130250-1, (b) (4) (b) (4) & expiry date 31May2024), which was affirmed by your Director Quality Head of Bottling, Quality Supervisor, Production Supervisor, and Associate Director Technical Manufacturing.

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F. Pages 20-24 of 30 "Quality In Process Inspection – Bottles, Drug Product, and Shipper" for (b) (4) with 2023AUG11 expiry date (b) (4) do not reflect the person making the entries.

G. You utilize (b) (4) unlabeled bottles filled with product marked with the letter (b) (4) and (b) (4) to challenge the checkweigher during packaging operations for (b) (4) t (b) (4) with 5/31/2024 expiry date. However, this practice including bottle contents is not described in any of the master packaging records and there is no assurance to prevent product mix-ups.

OBSERVATION 12

Excess labeling bearing lot or control numbers is not destroyed.

Specifically, several printed labels for (b) (4) were observed on 12/20/2021 in trash containers located in packaging Room (b) (4) during the packaging of (b) (4) (b) (4) 21 MAY 2024 expiry date.

OBSERVATION 13

The batch production and control records are deficient in that they are not an accurate reproduction of the appropriate master production or control record and checked for accuracy, dated, and signed.

Specifically,

We observed several manual corrections to the parameters on Page 7/21 or Page 8/22 (Equipment Verifications) of #MPR-319512 Rev. 0 (b) (4) and on Page 7/21 or Page 8/23 of MPR-319514 Rev. 0 (b) (4) (b) (4), as listed below. These manual corrections are made on the approved Master Packaging Records for (b) (4) without undergoing any formal impact assessment.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Yvins Dezan, Investigator Jessica S Estriplet, Investigator	X Yvins Dezan Investigator Signed By: 2001997410 Date Signed: 01-28-2022 09:51:45	1/28/2022

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CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18106-9302	TYPE ESTABLISHMENT INSPECTED Contract Packager

(b) (4)

Equipment	Parameter	Manual Change in Executed Batch Record	Operating Range in the Master Packaging Record
(b) (4) Sealer	Pressure	85 psi	unspecified
	Temperature	240-250 F	(b) (4)
	Time	3.0 – 4.0 sec	unspecified

(b) (4)

Equipment	Parameter	Manual Change in Executed Batch Record	Operating Range in the Master Packaging Record
(b) (4) Sealer	Pressure	85 psi	unspecified
	Temperature	235-250 F	(b) (4)
	Time	3.0 – 4.0 sec	unspecified

- (b) (4) Master Packaging Records was approved on 09/27/2019 and made effective on 09/30/2019.
- (b) (4) Master Packaging Records was approved on 09/16/2019 and made effective on 09/17/2019.

***DATES OF INSPECTION**

12/20/2021(Mon), 12/21/2021(Tue), 12/22/2021(Wed), 12/23/2021(Thu), 1/05/2022(Wed), 1/25/2022(Tue), 1/26/2022(Wed), 1/27/2022(Thu), 1/28/2022(Fri)

X Jessica S Estriplet
Investigator
Signed By: Jessica S. Estriplet -S
Date Signed: 01-28-2022 10:07:00

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Yvins Dezan, Investigator Jessica S Estriplet, Investigator	X Yvins Dezan Investigator Signed By: 2001997410 Date Signed: 01-28-2022 09:51:45	1/28/2022

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."