AMENDED 4/26/13

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/DMPTQ/Office of Medical and Tobacco Products 12420 ~~Element Drive, ELEM 2032~~ PARKLAWN DR. ELEM2032 Rockville, MD 20857 301-796-6521 Industry Information: www.fda.gov/oc/industry	4/16-26/13
	FEI NUMBER 1621802

ADMIT 5/1/13

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Susan J. Schniepp, Vice President Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Allergy Laboratories, Inc.	1005 S.W. Second Street ADMIT 4/26/13
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Oklahoma City, OK 73109	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 (I) (WE) OBSERVED:

1. There is a lack of assurance in the environmental quality in Class 100 aseptic processing areas in that the firm does not perform adequate environmental monitoring within these areas. The monitoring is not always representative of activities taking place. For example:

A. Vial Filling Line (b) (4) is located in room that is classified as a Class 100 area for the entire room. This room consists of a (b) (4) machine and (b) (4) machine, stainless steel tables, shelves for storage of items and other equipment. There is no barrier around the critical processing areas and operators working in the area are in close proximity to the aseptic operations such as filling and stoppering. The operators (b) (4) load vials onto a (b) (4) and (b) (4) add stoppers to the stopper bowl by pouring stoppers out of a bag that is held over the stopper bowl opening. Operators were observed touching the upper portion of the stopper bags during the operation.

- Active viable air samples are taken only once every (b) (4) and are taken in only one location between the via(b) (4) and the filling station (approximately 12 inches from each). There is no other active viable air monitoring performed within this Class 100 area during the filling operation and is no passive air monitoring taking place within this facility. The firm frequently experiences OOS results for non-viable particulates.
- There is no viable or particle monitoring in the critical area where stoppers are loaded into the stopper bowl and where stoppers are seated onto the filled vials.
- Open bags of stoppers that will be used to fill the stopper bowl are kept on a table approximately 15 feet from the stopper bowl. There is no air monitoring in that area and no surface monitoring is performed in that area after the filling operations.
- Only three critical (where pre-stoppered vials are exposed) surfaces are monitored on equipment after filling operations. Those include the (b) (4)b) (4) the(b) (4) base top surface, and inside the stopper bowl. There is no monitoring along the (b) (4) where vials (b) (4) before and after filling and in the area where the operator removes and replaces vials for weight checks.

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ptrost 6/1/13

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B. Vial Filling Line (b) (4) is a Class 10,000 room that has a Class 100 barrier around the filling line. This area has (b) (4) vials that are (b) (4) from the depyrogenation oven. The stoppering loading is a (b) (4) process but instead of operators holding open bags over the stopper bowl, the stoppers are loaded by way of a (b) (4).
• Active viable air samples are taken only once every (b) (4) and are taken in only one location near filling station There is no other active viable air monitoring performed within this Class 100 area during the filling operation and is no passive air monitoring taking place within this facility
• Only three critical surfaces are monitored where open vials are located during the fill. Those are the (b) (4), top of (b) (4), and stopper bowl.

C. Extract Production Areas consist of (b) (4) (Class 100) units and a (b) (4) curtained Class 100 area located in a Class 10,000 room. The (b) (4) and (b) (4) are used in the Allergenic Extract operations. (b) (4) is used to fill prescription sets and physician stock sets.
• Active air samples are taken once every (b) (4) period and are taken in one location within the areas. There is no additional viable air monitoring and no passive monitoring.

2. SOP QC-033.00, Facility Bioburden, section 9.1.3 requires that "All environmental isolates are sent out for identification, including alert and action level samples, routine bioburden samples, media fill samples and Class 100 samples, shall be identified to the species-level". This SOP is not being followed in that isolates from Aseptic Filling line (b) (4) Aseptic Filling line (b) (4) Allergenic Extract Filling (b) (4) are not being sent out as required. For example:

A. EN # 020-011713, dated 1/17/12, documents an active air excursion during manufacturing of sterile empty vials, lot # SEV 010913. Additional excursions were found during manufacture of this product but were not sent out for identification and were not addressed in the investigation.

B. EN #018-011713, dated 1/17/13, documents a personnel excursion on the right fingers sample of operator (b) (6) who was working on Fill line (b) (4) during production of SEV 010912. Additional excursions were found during manufacture of this product but were not sent out for identification and were not addressed in the investigation.

C. Personnel Monitoring EM on Line (b) (4) Operator (b) (6) had 1 isolate on both the left and right gloved fingers on

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11/15/12. These isolates were not sent out for identification even though they occurred around the time of a sterility failure in the area.

3. Since 11/5/12 the firm has experienced sterility failures for 9 commercial products. The investigations into 5 of the failed lots are incomplete and inadequate.

Sterility testing is performed in the Class 100 hood (b) (4) within the Extract Fill Room.
The firm conducted an investigation that encompassed the first 5 lots of product (Ephedrine 110512, SEV2110512, EVC2110512, NSP 2110712, and SEV2110812). The assignable root case was deemed to be technician contamination during the sterility test performed for those lots tested on from (b) (4) and possibility that the hood was not functioning properly in that some of the same isolates from the failure were found on in the sterility test area and on the technician working in the sterility test area. The firm also investigated a potential root cause as failure to sterilize the (b) (4) units used to (b) (4) the product for the sterility test though there is no definitive proof.

The following are lots that failed:
Ephedrine
Lot #:110512
Fill Date:(b) (4)
Test Date(b) (4)
Organisms: FTM-Bacillus spTSB-Bacillus sp.
Disposition:Retested/Released

SEV*
Lot #: SEV2110512
Mfg Date:(b) (4)
Test Date:(b) (4)
Organisms: FTM-Bacillus nealsonii TSB-Paenibacillus sp
Disposition: Retested/Released

EVC*

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Lot #: EVC2110512
Mfg Date: (b) (4)
Test Date: (b) (4)
Organisms: FTM-Bacillus sp TSB-Bacillus sp
Disposition:Retested/Released

SEV*
Lot # SEV2110812
Mfg Date: (b) (4)
Test Date: (b) (4)
Organisms: FTM-Paenibacillus sp TSB-Paenibacillus sp
Disposition: Retested/Released

NSP*
Lot #: 2110712A
Mfg Date(b) (4)
Test Date: (b) (4)
Organisms: FTM- Paenibacillus sp TSB-Paenibacillus sp
Disposition: Retested/Released

SEV*
Lot #: SEV111912
Mfg Date: (b) (4)
Test Date: (b) (4)
Disposition: Not yet determined

Short Ragweed
Lot #147021813
Mfg Date: (b) (4)
Disposition: Not yet determined

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Standardized Cat Hair
Lot #: 288122012
Mfg. Date: (b) (4)
Disposition: Not yet determined

NSP*
Lot #2032212
Mfg Date: (b) (4)
Disposition: Not yet determined

*SEV – Sterile Empty Vial
*EVC – Evacuated Sterile Empty Vial
*NSP – Normal Saline with Phenol

The firm allowed for a retest, however, the firm failed to evaluate all isolates recovered from both the manufacturing areas and the test areas. The firm's SOP requires all isolates from a Class 100 operation be sent out for identification, this does not always occur if the counts are less than the alert level. (See FDA-483 Item # 2) Examples include, but are not limited to:

A. Personnel Monitoring EM on Line (b) (4). Operator (b) (6) had 3 isolates on the right cuff of his gown after working in the aseptic processing area on 11/5/12, around the time of the sterility failures. This was not sent out for identification to determine if this isolate may have matched an isolate taken from the sterility test failure samples.

B. Personnel Monitoring EM on Line (b) (4). Operator (b) (6) had 1 isolate on both the left and right gloved fingers. This occurred on 11/15/12, around the time of the sterility failures. These isolates were not sent out for identification to determine if this isolate may have had any influence on the sterility failures.

C. Personnel Monitoring EM on Line (b) (4). Operator (b) (6) had 1 isolate on one of the glove samples from a sample date of 11/1/12, around the time of the sterility failures. This was not sent out for identification to compare with the isolates from the sterility failures.

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D. Personnel Monitoring EM on Line (b)(4). Operator (b)(6) had 1 isolate on the right fingers sample taken on 11/5/12, the time of the sterility failures. This was not sent out for identification to compare with sterility failure isolates.

E. Personnel Monitoring Allergenic Extracts Area. Operator (b)(6) had 3 isolates found in the chest area during filling of Standardized Cat Hair Allergenic Extract that failed sterility testing. These organisms were not identified in order to compare with the sterility failure isolates.

F. Personnel Monitoring Allergenic Extracts. Operator (b)(6) had 1 isolated found in the chest area during filling of Short Ragweed that failed sterility testing. This isolate was not identified in order to compare with the sterility failure isolates.

4. Actions taken regarding non-viable particulate excursions that occur during aseptic filling or (b)(4) are inadequate. For example:

A. The firm continues to experience non-viable particulate monitoring excursions during the (b)(4) loading of vials on Filling Line (b)(4) and no actions have been taken to address these excursions. In 10/10 Environmental Monitoring records reviewed for aseptically filled drug products or sterile empty vials at least 1 excursion was documented as having occurred during (b)(4) vial loading. In each case no corrective or preventive actions were taken to address this issue. All but 1 of the lots associated with the excursions were released and 1 lot is pending release.

B. Preventive actions associated with Problem Analysis and Corrective Action Report (PACAR) PAC-013-071712 have not been initiated and there is no due date for their completion. This PACAR was created to investigate excursion level particulate counts related to allergenic extract sterilization in the (b)(4). The (b)(4) is the dedicated Class 100 space where open activities related to allergenic bulk sterilization (by (b)(4)). The investigation indicated that even limited movement within the space by technicians can cause non-viable particulate excursions. The preventive actions recommended by the PACAR (which have not been initiated) include: re-evaluation of the design of the (b)(4), evaluation of the size of the space, and evaluation of whether the activity conducted in the (b)(4) could be conducted within a laminar flow hood. Additionally the investigation did not document a review of critical operations such as the aseptic connection of the sterilizing (b)(4)

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5. Non-viable particulate excursion alarms are not reacted to in real time. Filling Lines [redacted] (b) (4) have monitors that are visible to the operators which show particulate alarms. There is no written requirement for the filling operators to take any action if these monitors indicate an excursion. Additionally, Hood [redacted] (b) (4) has no non-viable particulate alarm system observable by the operator.

6. The only non-viable particulate monitoring tube located inside of Class 100 Hood [redacted] (b) (4) is located near the top of the hood protruding approximately 3 inches from the HEPA filter grate. No non-viable particulate monitoring is performed closer to the work surface. All allergenic extracts are [redacted] (b) (4) aseptically filled in this hood.

7. Investigations into environmental monitoring excursions are inadequate and/or inappropriate. Environmental Notices (EN) are the investigations that take place when the firm experiences either alert or action limits for personnel, active air, and surface monitoring. Environmental Notices are lacking in that the investigations are inadequate, incomplete, and fail to appropriately address or document corrective action and preventive. Examples include, but are not limited to:

A. EN # 027-012513, dated 1/25/13, documents an active air excursion during operations for filling 50 ml L-Cystine Lot # 201113 on Filling Line [redacted] (b) (4) The investigation summary discusses the identification of the organism and trend data but does not attempt to identify a root cause for the excursion. There is no corrective action and no preventive action documented and no assurance that production personnel were properly advised. Additional excursions were found during filling of this product but were not sent out for identification and were not addressed in the investigation.

B. EN # 020-011713, dated 1/17/12, documents an active air excursion during manufacturing of sterile empty vials, lot # SEV 010913. The investigation summary does not address investigation into root cause or discuss product impact. The corrective action states "This investigation serves to ensure product quality and patient safety" but does not explain the statement. There is no further corrective action and no preventive action and no assurance that personnel were properly advised. Additional excursions were found during manufacture of this product but were not sent out for identification and were not addressed in the investigation.

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C. EN # 017-011713, dated 1/17/13, documents a personnel excursion in the Extract Area with 5 (b) (4) for a chest sample for operator (b) (6). The investigation summary does not address corrective or preventive actions. Additional excursions were found during filling of this product but were not sent out for identification and were not addressed in the investigation.

D. EN #018-011713, dated 1/17/13, documents a personnel excursion on the right fingers sample of operator (b) (6) who was working on Fill line [redacted] during production of SEV 010912. The investigation summary does not investigate a root cause but states that there is evidence of excursions in the vial production area and states that because this organism is normal human flora, it was likely shed by the technician and states that there is no evidence of product quality impact. There is no corrective action and no preventive action. Additional excursions were found during filling of this product but were not sent out for identification and were not addressed in the investigation.

8. Product impact is not adequately addressed for incidences where contamination occurs on product contact services. For example:

A. Environmental Notice (EN) 004-010813 (dated 1/8/13) documents an out of limit result for a Class 100 surface sample in the Stopper Bowl after filling Sterile Empty Vial (SEV) Lot # SEV122812 on (b) (4) on Filling Line. During manufacturing, stoppers are staged in this bowl and [redacted] (b) (4) to where either aseptically filled drug products or sterile empty vials are stoppered. Stoppers have direct contact with product after seating on the vials. The organism was identified only to the family level as Paenibacillaceae sp. (a gram positive spore former). Paenibacillus sp. was also isolated from a surface sample taken from the Class 100 fill room floor and on the de-gown room (Class 10,000) airlock floor for Filling Line [redacted] after filling of lot SEV122812. Paenibacillus odorifer was also isolated from a sample taken from the de-gown room floor. There were additional monitoring excursions in the area that were not identified (See 483 Item 2) . The investigation is lacking in that the root cause of the contamination is not documented and the investigation does not address the possible impact of product contamination nor is there documentation that operators working in the area were addressed for this specific issue. No corrective/preventive action took place as a result of this deviation. The vials were released to inventory on 4/4/13.

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B. Environmental Notice 010-011113 (dated 1/11/13) documents an out of limit result for a Class 100 surface sample taken in the Stopper Bowl after filling Sterile Empty Vials Lot # SEV010313 on (b) (4) on Filling Line [redacted]. Stoppers that are staged in this bowl [redacted] (b) (4) and are used to stopper aseptically filled drug products and sterile empty vials manufactured on this line. Stoppers have direct contact with product after seating on the vials. The organism isolated from the stopper bowl sample was identified as Bacillus aryabhattæ, a spore forming organism. Personnel monitoring results and additional surface monitoring samples found additional organisms present on operators working in the Class 100 area during manufacture of this lot. Bacillus pumulis was isolated from a finger sample of an operator and from the de-gown floor. Micrococcus luteus was isolated from two finger samples and from one gown sample (chest). Staphylococcus hominis and Sphingomonas mucosissima were also isolated from chest samples and Paenibacillus taichungensis were isolated from the de-gown room floor. The investigation, which involved a review of video from the filling operation, revealed that the person sampling the stopper bowl had opened the [redacted] (b) (4) plate lit earlier than they should have, exposing the surface of the plate and then when sampling, the operator looked down into the bowl while sampling. Based on this, the root cause was deemed to be sampling, however, there is no definitive proof that this is the case. There is no corrective action and no preventive action documented.

9. Aseptic processing deficiencies include:

A. During the [redacted] (b) (4) loading of empty vials from trays onto the [redacted] (b) (4) on Line [redacted] during the aseptic filling of Ephedrine Sulfate Injection Lot 041713 a portion of an operator's hand was observed directly over open empty vials at the edge of the tray.

B. An operator was observed adding stoppers over a portion of the top of the stopper bowl during the aseptic filling of Ephedrine Sulfate Injection Lot 041713.

C. The bottles used to contain [redacted] (b) (4) disinfectants that are used on Filling Lines [redacted] (b) (4) and Hood [redacted] (b) (4) are not rendered sterile prior to use.

D. Fill checks for drug product were observed as being performed by removing an empty vial from the line, and taking that vial to a scale near the pass through (approximately [redacted] (b) (4) away from the filling line) above which there

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is no HEPA filter. The operator then returns the empty vial to the fill in a gloved hand and with a forcep removes another empty vial from the line, places also in the gloved hand then takes the tared vial and places it on the fill line (the tared vial has no markings to distinguish it from actual product vials). The operator then watches the vial and when it is filled, removes it with a forcep and takes it to the scale and weighs it. This activity, as well as the activity of removing downed vials from the infeed table, makes it possible for the operator to touch the surface of vials with a gloved hand as well as the surface of the forceps that are not sanitized during the filling operation.

E. Sterilized stoppers that are used for stoppering aseptic product were stored in open bags on a table near where the depyrogenation oven is unloaded. This is approximately (b) (4) ft away from the stopper bowl. The bag was observed to be routinely open. There is no monitoring performed in that area either non-viable or viable. Further, there is no surface monitoring of that table.

F. Depyrogenated vials contained in foil covered but not sealed stainless steel trays used for the (b) (4) aseptic filling of allergenic extracts are staged in Class 10,000 Room (b) (4) Building (b) prior to use. As per SOP MFG-018.00 "Sterile Filling of Bulk Allergenic Extract" (and validated under Validation Report VP-026.01) these vials may remain in a Class 10,000 area for up to (b) (4), however no inspection of the integrity of the foil is required prior to filling nor are the trays surface monitored after use.

G. During the (b) (4) aseptic filling of False (Bur) Ragweed Lot 145032113 the filling operator touched the top of her gloved hand to her leg.

H. The goggles of operators who perform (b) (4) aseptic filling of allergenic extracts are disinfected but not rendered sterile prior to use. No monitoring of the goggles is performed.

I. During the (b) (4) aseptic filling of False (Bur) Ragweed Lot 145032113 in Hood (b) (4) the operator removed forceps from a (b) (4) solution and after tapping the forceps on the solution container immediately began using the forceps to manually stopper the aseptically filled vials. There is no assurance that residua (b) (4) solution did not enter the first vials stoppered in this manner.

J. During the (b) (4) aseptic filling of False (Bur) Ragweed Lot 145032113 in Hood (b) (4) the operator performing the filling was observed with exposed skin at the right cheek. Although the operator's head was not observed to

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/DMPTQ/Office of Medical and Tobacco Products 12420 ~~Element Drive, ELEM 2032~~ Parklawn Bldg ELEM 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	4/16-26/13
	FEI NUMBER 1621802

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	
TO: Susan J. Schniepp, Vice President Quality and Regulatory Affairs	
FIRM NAME Allergy Laboratories, Inc.	STREET ADDRESS 1005 S.W. Second Streetf
CITY, STATE AND ZIP CODE Oklahoma City, OK 73109	TYPE OF ESTABLISHMENT INSPECTED Manufacturer

enter the Class 100 Hood (b) (4) during the filling her head was observed to come within approximately 1 foot of Hood (b) (4) As per SOP QA-006.00 "Aseptic Technique" operator gowning is to cover all exposed skin.

K. During the aseptic filling of Sterile Empty Vials Lot SEV041913 on Filling Line (b) (4) an operator was observed standing with her hands clasped behind her back touching her gowning. As per SOP QA-006.00 "Aseptic Technique" operators are to stand with arms unfolded and positioned to the sides. The room that contains Filling Line (b) (4) is designated as a Class 100 area.

L. As per SOP FAE-017.00 "Operation of the (b) (4) Filling and Stoppering Assembly for Filled Vials" (b) (4) in the Class 100 Room 1131 that contains Filling Line (b) (4). This (b) (4) activity is an open operation and may be performed multiple times during the filling of a lot.

M. Non-sterile lubricant is used to lubricate the non product contact (b) (4) located on Filling Line (b) (4) There is no documentation demonstrating that this lubricant is suitable for use in an aseptic processing area. No monitoring of the lubricated portion of the (b) (4) is performed.

N. Room (b) (4) which contains Filling Line (b) (4) has 2 areas located on the floor within the Class 100 area where utility lines supporting the filling equipment are covered with rubber covers. SOP MFG-031.01 "Cleaning Procedure for Vial Production Areas" contains no instructions as to how to sanitize underneath these covers. The areas of the floor underneath these covers are not routinely sanitized nor are the areas routinely monitored.

10. There is a lack of assurance that limits set in the aseptic processing area are adequate. There is no justification or rationale for counts that are set up by the firm for surface sampling in aseptic processing areas or for personnel working in aseptic processing Class 100 areas. Further, some floors in the Class 100 areas have stricter limits than gloves and garments in the Class 100 filling areas. For example:

A. Gloves of operators working in critical Class 100 aseptic filling areas have Alert Limits of (b) (4) and an Action Limit (b) (4). There is no rational or justification for allowing these levels. Operators were observed passing their gloved hands over open vials during production operations.

B. The gowns of operators working in critical Class 100 aseptic filling areas have Alert Limits of (b) (4)

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and Action limits of (b) (4) The floors in Class 100 areas have Alert Limits of (b) (4) and an Action Limit (b) (4) There is no rational or justifications for allowing these levels. Operators were observed standing in Class 100 areas with their hands touching their gowns during production operations.

11. Allergenic extract vials that have been sampled for sterility testing are retained for use by the prescription department. The vial stopper is punctured in order to withdraw the sterility sample and as per SOP QA-018.00 "Release of Allergenic Extracts" the vials that were used for sterility testing are forwarded to the prescription department. As described in SOP MFG-018.00 "Sterile Filling of Bulk Allergenic Extract" the vials that are intended for sterility testing are sealed with a "(b) (4)" after filling. This seal is not the same type of seal as used on commercial product. After sampling for sterility the "(b) (4)" is (b) (4) removed and the vial with the original (punctured) stopper is (b) (4) re-sealed with a commercial cap. There is no documentation that this practice has been performed in media fills. The firm has documented 8 sterility test failures for prescription Treatment Sets or Custom Allergenic Extracts so far in 2013 (Compounded under Orders: (b) (4)). Although each failing lot was rejected, no root cause was determined for any of these failures.

12. The investigation conducted under PACAR PAC-021-081312 did not include a product impact assessment. PACAR PAC-021-081312 was opened because during the calibration of the temperature recorder of the (b) (4) on 8-10-12 the temperature recorder was found to be out of tolerance, giving readings 25C higher that the reference temperature. This oven is used to depyrogenate vials for Filling Line (b) where the aseptic filling of Ephedrine Sulfate Injection, Phenylephrine HCl, and L-Cysteine Injection may be performed. Information from the temperature recorder is part of the information that is reviewed to determine that the cycle ran at a minimum (b) (4) as required by SOP FAE-015.00 "Operation of the (b) (4) Sterilizer" (and the previous version of the SOP). The last time the temperature recorder had been calibrated prior to 8-10-12 was in July 2009. No review was conducted to determine if the vials processed in the oven (and used in the production of drug product lots produced since the last calibration of the temperature recorder) were depyrogenated in accordance with the established procedure. Approximately (b) (4) lots of aseptically filled drug products (including Ephedrine Sulfate Injection, Phenylephrine HCl Injection, L-Cysteine Injection) manufactured using vials processed in the (b) (4) prior to 8-10-12 were released and remain within expiry. A review of only a portion of the batch records for these products showed that the following aseptically filled products were manufactured with vials that were depyrogenated below (b) (4) for part of the (b) (4) depyrogenation

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time. Each of these lots has been released:

A. Ephedrine Sulfate Injection Lot 062512

B. Ephedrine Sulfate Injection Lot 062912.

C. Ephedrine Sulfate Injection Lot 093011

D. Ephedrine Sulfate Injection Lot 081511

E. Ephedrine Sulfate Injection Lot 100711

13. The firm's procedures allow the release of allergenic extracts exhibiting cloudiness. As per SOP MFG-030.01 "Inspection of Allergenic Extract Final Container Vials" an extract may appear cloudy and still pass visual examination. For example, Standardized Short Ragweed Lot 147030112 exhibited cloudiness (not classified as precipitation) during visual inspection. There was however no investigation into why this lot exhibited cloudiness. Two other lots of Standardized Short Ragweed manufactured after this lot were not found to exhibit cloudiness. Lot 147030112 was released and distributed.

14. The validations of [redacted] (b) (4) used for the [redacted] (b) (4) of aseptically filled allergenic extracts and drug products are inadequate:

A. The validation of the [redacted] (b) (4) used for aseptically manufactured allergenic extracts and diluents documented under Validation Report VP-023.01 "Validation of the [redacted] (b) (4) for Diluents and Extracts" is inadequate. Specifically,

i. The validation of microbial retention was not performed with actual product and there is no justification as to the reason for not using actual product. The allergenic extracts are contained in a 50% glycerin solution.

ii. The [redacted] (b) (4) that were tested as part of the microbial retention validation were only incubated for [redacted] (b) (4) at [redacted] (b) (4) and only using [redacted] (b) (4). No positive control was used showing that the target

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organism could be detected in that time.

iii. Extract (b) (4) used in the testing failed the (b) (4) specification but were reported as passing.

iiii. Critical parameters such a (b) (4) were not documented during the microbial retention validation.

B. The (b) (4) validation studies for Ephedrine Sulfate Injection, Phenylephrine HCl Injection, and L-Cysteine Injection do not include documentation demonstrating that a low level of the challenge organism was detectable when incubated in a manner consistent with the (b) (4).

15. The following facility and equipment maintenance issues were observed:

A. Rubber bands were observed holding a guide rail on the Line (b) (4). Also a cardboard and foam vial tub loading ramp was observed on this line. No work orders were created for these in-house modifications. Aseptically filled drug products and diluents manufactured on Line are labeled using this equipment.

B. Apparent dust on grating directly above (b) (4) (b) (4) (which is located in an unclassified area). This (b) (4) is used to (b) (4) Benztropine Mesylate Injection, Levetiracetam Injection, and Tranexamic Acid Injection.

C. Nicked and rough flooring in the Line (b) (4) Class 100 filling area (Room (b) (4) The following products are aseptically filled on this filling line: Ephedrine Sulfate Injection, Phenylephrine HCl Injection, L-Cysteine HCl Injection, various diluents, and Sterile Empty Vials. This is a repeat observation from the June 2012 Form FDA 483.

D. (b) (4) on the (b) (4) were observed leaking during the aseptic filling of Ephedrine Sulfate Lot 041713 on Filling Line

E. Foil wrapped stainless steel plates were observed on the Line (b) (4) visual inspection (b) (4) . Ephedrine Sulfate

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Injection, Phenylephrine HCl Injection, L-Cysteine HCl Injection and various diluents are visually inspected on this line. No work order was created for this in-house modification.

F. Two sprayer bottles (containing sanitizers) missing a portion of the sprayer were observed in the Filling Line [(b)] Class 100 filling area during the aseptic filling of Ephedrine Sulfate Lot 041713. An operator was observed using one of these bottles to spray hands during the aseptic filling of Ephedrine Sulfate Lot 041713.

16. No limits have been established for the amount of time allergenic extracts may be exposed to ambient temperature during filling, inspection, labeling and packaging, packing for shipping. Additionally, the time the extracts are exposed to ambient temperature during these operations is not recorded. All allergenic extracts manufactured at the firm indicate storage at [(b) (4)]

17. Stoppers used with allergenic extract ([(b) (4)] glycerin) final product vials have not been demonstrated to be non reactive, additive, or absorptive. Extractable studies have not been conducted on 13mm and 20mm [(b) (4)] stoppers. A protocol for testing has been drafted (Quality Protocol# 13-005) but this protocol has not been signed nor is there any formal documentation that a due date for completion has been established. This is a repeat observation from the June 2012 Form FDA 483.

18. Batch records are inadequate. Specifically,

A. The batch records for Ephedrine Sulfate Injection, Phenylephrine HCl Injection, and L-Cysteine Injection do not include documentation of, or limits for, pressure and [(b) (4)] during [(b) (4)]. Additionally SOPs FAE-017.00 "Operation of the [(b) (4)] Filling and Stoppering Assembly for Filled Vials" and SOP Operation of the [(b) (4)]" do not specify the maximum allowable pressure or [(b) (4)] during [(b) (4)].

B. [(b) (4)] pressure is not documented in allergenic extract batch records. Additionally, no second operator verification is performed of the [(b) (4)] (the test is performed manually).

19. The firm's change control program is not followed. As per SOP QA-008.01 Effective Date Jan 03 2013

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"Change Control" (and previous change control SOPs) equipment and facility changes are to be made upon initiation and approval of "Change Control Protocols". For example, the following facility and equipment changes were not handled under a Change Control Protocol:

A. The addition of an approximately (b) (4) square foot warehouse for raw materials storage and shipping and receiving.

B. The installation of a Building Management System (BMS) and the decommissioning of the previous temperature monitoring system. The BMS is currently in use to monitor temperature and humidity in various areas of the facility including for Filling Lines (Building (b) (4) Room (b) (4) and (b) (4) Building (b) (4) Room (b) (4) the allergenic extract filling area (Building (b) (4) Room (b) (4)), the Animal Facility (Room (b) (4)), and the warehouse (Building (b) (4) As of the date of this inspection the BMS has not been validated. Installation of this system was performed as a corrective action to the Form FDA 483 of June 2012.

20. During the labeling of Phenylephrine HCl Injection Lot 042413 the vials after inspection and labeling were observed traveling down a (b) (4) from the (b) (4) and then dropping into a bin. There is no validation demonstrating that this practice does not damage the vials. Vials are only given a cursory inspection after this step during final cartoning.

21. SOP MFG-031.01 "Cleaning Procedure for Vial Production Areas" does not contain sufficient detail explaining how filling equipment is to be cleaned. During the cleaning of Filling Line (b) (4) on 4-24-13 an operator was observed cleaning near the bottom of the filling line and then subsequently without re-gloving cleaning the top of the filling equipment including the (b) (4) where open filled vials pass during filling operations. The SOP contains no instructions to clean equipment from top to bottom.

22. The 100% visual inspection of (b) (4) products filled on Line (b) is performed prior to (b) (4) Only a cursory inspection of the units during (b) (4) packaging is performed post (b) (4) n and labeling. The following products are visually inspected in this manner: Benztropine Mesylate Injection, Levetiracetam Injection, and Tranexamic Acid Injection.

23. The firm's supplier of animals which are used for the general safety testing of allergenic extracts has not been

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AMENDED 5/1/13 Sheet

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qualified. Since 8/2012 the firm has documented 3 deaths of mice during General Safety Testing of allergenic extracts (during the testing of Halibut Extract Lot 401070512, Russian Thistle Extract Lot 154090512, Pullularia pullulans Extract Lot 186082912). In each case repeat testing passed. None of the investigations associated with these animal deaths documented a review of the animal supplier. In 2 of the investigations lower than typical weight of the test animal used for the test was assessed as a possible cause of the animal death. In 1 of the investigations no definitive cause was found.

24. Operators working in the filling suites monitor their own gloves and garments after working in the area. SOP QC-024.00, Personnel Environmental Monitoring Post Filling Operations (Section 9.6) states that operators should clean garments after they perform personnel monitoring and should not touch items within the Class 100 area when they have agar on their gloved hands from the sampling. Two operators were observed performing monitoring on themselves after filling but did not clean their garments prior to leaving. One of the operators was observed touching a marker pen with his gloved hand after sampling the glove, before removing the outer glove. The SOP states "Residue from (b) (4) plates can contaminate cleanroom surfaces as it provides and excellent growth medium for contaminants".

25. Smoke studies performed on Line (b) in Building (b) revealed the following:

A. There is no Quality assessment for smoke studies performed to evaluate directional flow of air in aseptic processing areas.

B. Turbulence was observed over the stopper bowl on Fill line (b). No assessment was performed.

26. It is the firm's routine process to (b) (4) . The firm's SOP MFG-048.00, Line Clearance, is a written procedure describing how to perform a line clearance. The SOP applies to filled and sterile empty vials. This SOP addresses label control but does not address line clearance within the filling areas or cleaning the area (b) (4). There is no assurance that there is not carry over of the drug product (b) (4) in that:

A. There is no cleaning conducted (b) (4)

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(b) (4)

B. There is no procedure that instructs operators regarding clearance of vials that were used for filling of drug products.

C. There is no procedure dealing with the clearance or allowance of use of stoppers that have used during the filling of the drug product.

D. There is no procedure that addresses clearance of equipment (forceps) that has been used during filling of drug products.

E. There is no procedure that instructs operators to change garments and gloves [redacted] (b) (4) [redacted]

27. There is no SOP that instructs laboratory technicians as to how to perform the task of detection and counting microorganisms on [redacted] (b) (4) nutrient agar environmental monitoring plates after the plates have completed incubation. There is no written procedure to instruct technicians as to the correct lighting and background to use for optimal detection of microorganism colonies on the nutrient agar plates. One incidence was observed where several organisms were not detected on one plate during the routine reading but re-checking of the plates with a lighted background yielded additional colonies.

28. The number of qualified personnel is inadequate to supervise the manufacture of Allergenic Extract products. Personnel engaged in manufacture of allergenic products have no definitive assigned supervisor.

29. Growth promotion testing for environmental monitoring plates is not performed in a manner to challenge the test plate in that the firm's SOP for growth promotion testing allows for incubation of plates for up to [redacted] (b) (4).

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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 judgement, 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."