

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 60 Eighth Street NE Atlanta, GA 30309 (404) 253-1161 Fax: (404) 253-1202		DATE(S) OF INSPECTION 12/10/2024-12/18/2024* FEI NUMBER 1011574			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Cheryl Gailes, Senior Director of Quality Assurance					
FIRM NAME Greer Laboratories, Inc.		STREET ADDRESS 639 Nuway Circle			
CITY, STATE, ZIP CODE, COUNTRY Lenoir, NC 28645-3646		TYPE ESTABLISHMENT INSPECTED 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: OBSERVATION 1 processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, on December 16, 2024, (b)(4) of vials in ISO (b)(4) suite (b)(4) building 4, was observed with the following deficiencies: a. After the (b)(4) activities at station (b)(4), and Bayberry/Mix Myrtle, (b)(4) no (b)(4) sample was taken from the (b)(4) after completing the final (b)(4) process that would capture all activity that took place at that (b)(4) during the (b)(4). <i>SOP-LAB-0122, Environmental Monitoring in (b)(4) Manufacturing and Support Areas, rev. 07, eff. 04Nov2024</i>, states on page 5, sec. 7.2, that ISO (b)(4) areas must be monitored while (b)(4) is occurring but are not required when manufacturing operations have been completed for the day. On 16Dec2024, an environmental monitoring technician was observed taking a (b)(4) sample from the (b)(4) at station (b)(4) while the (b)(4) technician was actively working. However, no (b)(4) sample was taken at this same station upon completion of the final (b)(4) processing activities, prior to the (b)(4) technician cleaning the (b)(4) with an (b)(4) as she performed her (b)(4). b. The environmental monitoring sampling sites used to monitor the (b)(4) activity on the (b)(4) in (b)(4) are insufficient in that they are (b)(4) activity and are potentially blocked from filling activities due to the setup of materials and equipment on the (b)(4) during (b)(4). <i>SOP-LAB-0122, Environmental Monitoring in (b)(4) Manufacturing and Support Areas, rev. 07, eff. 04Nov2024</i>, sets forth the					
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locations to set-up environmental monitoring equipment. Page 7, section K (3) indicates that a (b)(4) to monitor (b)(4) air is to be set up to the (b)(4) of the operator (b)(4) being filled. During observation of the (b)(4) operations on 16Dec2024 at station (b)(4), it was observed that the non-viable air particle counter was (b)(4) to the (b)(4) to the (b)(4) of the operator, the (b)(4) was placed (b)(4) of the (b)(4) counter, and the operator performing (b)(4) activities was (b)(4) away from them. The (b)(4) used to hold the empty vials (b)(4) were observed to be placed between the (b)(4) and the operator once the operator removed the vials for (b)(4), creating a (b)(4) between the (b)(4) and the (b)(4) activity. Additionally, the (b)(4) sample taking during the (b)(4) operation was taken from the (b)(4) and the (b)(4) and not from the (b)(4) in from of the operator where the (b)(4) activities take place. c. <i>SOP-LAB-0133, Personnel Monitoring, rev. 09, eff. 23May2024</i> states on page 21, sec. 8.6, that the (b)(4) of (b)(4) should be performed immediately after completing the final (b)(4) process or sterility test using (b)(4). The (b)(4) used by the firm for personnel monitoring is too small to adequately capture the required surface of all (b)(4) being sampled.					
OBSERVATION 2 Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess. Specifically, during a review of standard operating procedures (SOP) and interviews with subject matter experts, the following deficiencies in SOPs were observed: a. Your license requires the (b)(4) allergenic extract to be (b)(4) through a series of mixed (b)(4) of (b)(4) to clarify and reduce bioburden, (b)(4). Instructions on how to determine how many (b)(4) are needed and which (b)(4)					
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[redacted] to use for the further [redacted] (b)(4) step of the initial [redacted] allergenic extract manufacturing process or the extract re-processing are not included in either SOP-FP-0098, Manufacturing of [redacted] Allergenic Extracts ([redacted] (b)(4)), rev. 05, eff. 10Oct2024, or SOP-FP-0089, Extract Reprocessing, rev. 13, eff. 15Aug2024. The batch record forms filled out during manufacturing requires manufacturing operators to check off the type of [redacted] used, as well as how many [redacted] steps were taken, during manufacturing. The forms are silent as to how an operator makes those decisions. b. SOP-FP-0042, Extract Department [redacted] (b)(4) and [redacted] (b)(4) Procedures, rev. 11, eff. 03Oct2024, states that the [redacted] (b)(4) work area is to be wiped with [redacted] (b)(4) of activities and [redacted] (b)(4) campaigns, among other times. There are no instructions on how to properly wipe down the work area. On 16Dec2024, during [redacted] (b)(4) operations in [redacted] (b)(4) suite [redacted] (b)(4), two (2) operators were observed wiping down their workstations in between [redacted] (b)(4) campaigns of different products and at the end of [redacted] (b)(4) operations using [redacted] (b)(4) per the SOP. It was also observed that each operator [redacted] (b)(4) in their hand as they wiped down the entire [redacted] (b)(4) using the [redacted] (b)(4), potentially smearing any spills or other contaminants that may have been deposited during [redacted] (b)(4) activities. c. Your SOPs designed to instruct on the review and release of batch records and finished drug product for commercial distribution do not contain a control between when a QA reviewer has released product in your enterprise system and when the batch record review is finalized. During a review on 17Dec2024 with QA personnel of batch record [redacted] (b)(4), a [redacted] (b)(4) Aspergillus mix, it was observed that [redacted] (b)(4) allergenic extracts can be released in the [redacted] (b)(4) system for use in production [redacted] (b)(4) to the batch records being completely reviewed by quality. In practice, the batch record [redacted] (b)(4) is fully reviewed by one QA reviewer who then releases the product in [redacted] (b)(4). That same batch record is then given to a 2nd QA reviewer to confirm certain information and then is signed off. This effectively leaves a gap of time to where the batch is released for use in production without having been fully reviewed. This practice is the same for batch record review and release across all [redacted] (b)(4) extracts and [redacted] (b)(4) vial products.					
OBSERVATION 3					
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Written procedures are not followed for the cleaning and maintenance of equipment, including (b)(4) used in the manufacture, (b)(4) of a drug product. Specifically, A. From January 10th, 2023, to November 30th, 2024, 174 equipment preventative maintenance work orders were overdue, ranging from 1 to 120 days. Examples of overdue work orders include the following: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 25%;">Equipment</th> <th style="width: 25%;">Due Day</th> <th style="width: 25%;">Completion Date</th> <th style="width: 25%;">Days Elapsed</th> </tr> </thead> <tbody> <tr> <td rowspan="6" style="text-align: center; vertical-align: middle;">(b)(4)</td> <td>April 30th, 2024</td> <td>August 28th, 2024</td> <td>120</td> </tr> <tr> <td>April 8th, 2024</td> <td>July 10th, 2024</td> <td>93</td> </tr> <tr> <td>May 9th, 2024</td> <td>July 1st, 2024</td> <td>53</td> </tr> <tr> <td>December 22nd, 2023</td> <td>January 16th, 2024</td> <td>25</td> </tr> <tr> <td>December 31st, 2023</td> <td>January 16th, 2024</td> <td>16</td> </tr> <tr> <td>October 18th, 2024</td> <td>October 31st, 2024</td> <td>13</td> </tr> </tbody> </table>				Equipment	Due Day	Completion Date	Days Elapsed	(b)(4)	April 30 th , 2024	August 28 th , 2024	120	April 8 th , 2024	July 10 th , 2024	93	May 9 th , 2024	July 1 st , 2024	53	December 22 nd , 2023	January 16 th , 2024	25	December 31 st , 2023	January 16 th , 2024	16	October 18 th , 2024	October 31 st , 2024	13
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(b)(4)			
B. The periodic performance qualification and periodic review assessment for the (b)(4) Vial (b)(4) and Vial (b)(4) used for the manufacture of finished drug products has not been performed since 2000. C. On December 10, 2024, the (b)(4) in Building (b)(4) was observed to have dust accumulation in the (b)(4) portion of the unit. This (b)(4) is located in the (b)(4) and is used to store (b)(4) awaiting quality inspection.			
OBSERVATION 4 Buildings used in the manufacturing and holding of a drug product are not maintained in a good state of repair. Specifically, A. On December 13th, 2024, one (b)(4) located in the (b)(4) leading to the (b)(4) and (b)(4) the labeling of Sterile Diluent and (b)(4) Vials (b)(4) was observed to be improperly seated, leaving the area exposed. B. On December 17th, 2024, a (b)(4) was observed in (b)(4) used for the transport of (b)(4) in Building (b)(4) Work Order #62431 was created on June 26th, 2024 to initiate the repair and it was not observed to be completed on December 17th, 2024.			
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OBSERVATION 5 The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, a. Deviations are not always closed in a timely manner and the timeframe to open a deviation from the date discovered is not properly justified. <i>US-SOP-QA-0004, Deviation Management System, rev. 03, eff. 21Jun2024</i>, allows (b)(4) to initiate a deviation in your (b)(4). This means there is the potential for (b)(4) to (b)(4) before a deviation is opened after it has been discovered. Additionally, the SOP allows for (b)(4) to close a deviation. From 10/01/2022 to 12/10/2024, approximately 49% of 346 deviations were closed (b)(4) of which were classified as critical or major. b. Out of specifications (OOS) for chemistry are not always closed in a timely manner. <i>SOP-LAB-0053, Procedure for Handling Out of Specification Laboratory Testing, rev. 10, eff. 20Aug2024</i>, allows for a (b)(4) timeframe during which to close chemistry related OOSs and no closure date extensions are allowed. From 10/01/2022 to 12/10/2024, 35 out of 133 OOSs were closed after (b)(4) – 18 of which remained open longer than (b)(4).			
*DATES OF INSPECTION 12/10/2024(Tue), 12/11/2024(Wed), 12/12/2024(Thu), 12/13/2024(Fri), 12/16/2024(Mon), 12/17/2024(Tue), 12/18/2024(Wed)			
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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."