

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410) 779-5455 Fax: (410) 779-5707		<small>DATE(S) OF INSPECTION</small> 5/5/2025-5/9/2025 <small>FEINUMBER</small> 3000718267	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Ms. Leslie D. Walden, Site General Manager			
<small>FIRM NAME</small> Barr Laboratories Inc.		<small>STREET ADDRESS</small> 1235 Mays Mill Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Forest, VA 24551-1864		<small>TYPE ESTABLISHMENT INSPECTED</small> Vaccine Manufacturer	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Written procedures are not established for evaluations conducted at least (b)(4) to review records associated with a representative number of batches, whether approved or rejected.</p> <p>Specifically, your firm does not adequately conduct (b)(4) product reviews of (b)(4) (b)(4) to account for evaluating trends of quantitative data for (b)(4) batch release. For example, the following data is not trended: (b)(4)</p> <div style="border: 1px solid black; height: 30px; width: 100%; text-align: center; margin-top: 10px;">(b)(4)</div> <p>Written procedure (b)(4) instructs that the firm "will continue to monitor the validation status through: ... production and/or product data to monitor trends, demonstrate that the process is in state on[sic] control and can consistently produce product within desired quality attributes."</p>			
<p>OBSERVATION 2 The establishment of test procedures including any changes thereto, are not drafted by the appropriate organizational unit.</p> <p>Specifically, test methods are not adequately established. For example:</p> <p>a. Test Method (b)(4) in the finished product (b)(4) does not specify the technique by which (b)(4) should be conducted in (b)(4) for quantifying (b)(4). Currently (b)(4)</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Scott T Ballard, Investigator <div style="text-align: right;"> <small>Scott T Ballard Investigator Signed By: Scott T. Ballard-S Date Signed: 05-09-2025 14:23:44</small> X </div>	
		<small>DATE ISSUED</small> 5/9/2025	

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<p>(b)(4) is conducted using automatic software but parameters are not standardized in the written method.</p> <p>b. Test Method (b)(4) for acceptance of (b)(4) used in the formulation of (b)(4) does not utilized a (b)(4) technique for detection of (b)(4) (specified in (b)(4)). It currently specifies a visual solution -- change by (b)(4).</p> <p>c. Test Method (b)(4) for batch acceptance testing of finished (b)(4) (b)(4) time references (b)(4). The written method does not specify an alternate end-point and your Site Quality Head stated the endpoint for this (b)(4) may not exactly match --.</p>		
<p>OBSERVATION 3</p> <p>Written procedures are not drafted, reviewed and approved by the appropriate organizational units.</p> <p>Specifically, written procedures for (b)(4) into manufacturing areas for (b)(4) are not adequate in that there is no requirement for (b)(4) or (b)(4) by manufacturing employees.</p> <p>Written procedures (b)(4) speak to personnel entry to the facility and (b)(4) into processing core but lack requirements for (b)(4).</p>		
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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."