

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
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| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>22215 26th Ave SE Suite 210<br>Bothell, WA 98021<br>(425) 302-0340 Fax: (425) 302-0404                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                | <small>DATE(S) OF INSPECTION</small><br>5/12/2026-5/19/2026*<br><br><small>FEI NUMBER</small><br>3003722743                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Kathy E Schwiebert, Site Head Bend                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| <small>FIRM NAME</small><br>Lonza Bend Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                | <small>STREET ADDRESS</small><br>20503 Builders St                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Bend, OR 97701-8507                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                | <small>TYPE ESTABLISHMENT INSPECTED</small><br>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><b>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</b><br/> <b>OBSERVATION 1</b><br/>           There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.</p> <p>Specifically,</p> <p>Deviations are not always trended to preventive recurrence. For example, the following deviations show repeat events:</p> <p><b>A. Gasket Deviations</b></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 5px;"><u>Deviation #</u></th> <th style="text-align: left; padding: 5px;"><u>Date</u></th> <th style="text-align: left; padding: 5px;"><u>Short Description</u></th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">DR-2025-0318</td> <td style="padding: 5px;">12/7/2024</td> <td style="padding: 5px;">(b) (4) were found to contain nitrile gaskets instead of specified (b) (4) gaskets. Error traced to (b) (4) purchased starting 9/06/2024. Nitrile gasket (b) (4) installed in IBC-(b) (4), IBC-(b) (4), and IBC-(b) (4) across multiple (b) (4) work orders. (b) (4) product lots assessed including DPI, (b) (4), and (b) (4).</td> </tr> <tr> <td style="padding: 5px;">DR-2025-0316</td> <td style="padding: 5px;">11/16/2025</td> <td style="padding: 5px;">Extraneous material observed in (b) (4) following execution of lot (b) (4) of (b) (4). (b) (4) lots assessed in total. All extraneous matter particles were found upstream of (b) (4). The particles were later found to be due to incorrect gasket(s) used.</td> </tr> <tr> <td style="padding: 5px;">DR-2025-0291</td> <td style="padding: 5px;">10/30/2025</td> <td style="padding: 5px;">During minor cleaning following manufacture of (b) (4) lot (b) (4), extraneous material observed inside (b) (4). Damaged</td> </tr> </tbody> </table> |                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <u>Deviation #</u>                                                                                                                                                             | <u>Date</u>                                                                                                                                                                                    | <u>Short Description</u>                | DR-2025-0318 | 12/7/2024 | (b) (4) were found to contain nitrile gaskets instead of specified (b) (4) gaskets. Error traced to (b) (4) purchased starting 9/06/2024. Nitrile gasket (b) (4) installed in IBC-(b) (4), IBC-(b) (4), and IBC-(b) (4) across multiple (b) (4) work orders. (b) (4) product lots assessed including DPI, (b) (4), and (b) (4). | DR-2025-0316 | 11/16/2025 | Extraneous material observed in (b) (4) following execution of lot (b) (4) of (b) (4). (b) (4) lots assessed in total. All extraneous matter particles were found upstream of (b) (4). The particles were later found to be due to incorrect gasket(s) used. | DR-2025-0291 | 10/30/2025 | During minor cleaning following manufacture of (b) (4) lot (b) (4), extraneous material observed inside (b) (4). Damaged |
| <u>Deviation #</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <u>Date</u>                                                                                                                                                                                    | <u>Short Description</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| DR-2025-0318                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 12/7/2024                                                                                                                                                                                      | (b) (4) were found to contain nitrile gaskets instead of specified (b) (4) gaskets. Error traced to (b) (4) purchased starting 9/06/2024. Nitrile gasket (b) (4) installed in IBC-(b) (4), IBC-(b) (4), and IBC-(b) (4) across multiple (b) (4) work orders. (b) (4) product lots assessed including DPI, (b) (4), and (b) (4).                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| DR-2025-0316                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 11/16/2025                                                                                                                                                                                     | Extraneous material observed in (b) (4) following execution of lot (b) (4) of (b) (4). (b) (4) lots assessed in total. All extraneous matter particles were found upstream of (b) (4). The particles were later found to be due to incorrect gasket(s) used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| DR-2025-0291                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 10/30/2025                                                                                                                                                                                     | During minor cleaning following manufacture of (b) (4) lot (b) (4), extraneous material observed inside (b) (4). Damaged                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 5px;"> <small>EMPLOYEE(S) SIGNATURE</small><br/>           Roger F Zabinski, National Expert<br/>           Ana-Maria A Plapcianu, Microbiologist<br/>           Conor J Mccarron, Investigator<br/>           Eric Zhu, Investigator         </td> <td style="padding: 5px; text-align: center;"> <small>Roger F Zabinski<br/>National Expert<br/>Signed By: Roger F. Zabinski -S<br/>Date Signed: 05-19-2026<br/>17:14:18</small><br/><br/> <div style="font-size: 2em; margin-top: 10px;">X</div> </td> <td style="padding: 5px; vertical-align: top;"> <small>DATE ISSUED</small><br/>           5/19/2026         </td> </tr> </table> |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Roger F Zabinski, National Expert<br>Ana-Maria A Plapcianu, Microbiologist<br>Conor J Mccarron, Investigator<br>Eric Zhu, Investigator | <small>Roger F Zabinski<br/>National Expert<br/>Signed By: Roger F. Zabinski -S<br/>Date Signed: 05-19-2026<br/>17:14:18</small><br><br><div style="font-size: 2em; margin-top: 10px;">X</div> | <small>DATE ISSUED</small><br>5/19/2026 |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |
| <small>EMPLOYEE(S) SIGNATURE</small><br>Roger F Zabinski, National Expert<br>Ana-Maria A Plapcianu, Microbiologist<br>Conor J Mccarron, Investigator<br>Eric Zhu, Investigator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <small>Roger F Zabinski<br/>National Expert<br/>Signed By: Roger F. Zabinski -S<br/>Date Signed: 05-19-2026<br/>17:14:18</small><br><br><div style="font-size: 2em; margin-top: 10px;">X</div> | <small>DATE ISSUED</small><br>5/19/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  |                                                                                                                                                                                |                                                                                                                                                                                                |                                         |              |           |                                                                                                                                                                                                                                                                                                                                 |              |            |                                                                                                                                                                                                                                                              |              |            |                                                                                                                          |

| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>22215 26th Ave SE Suite 210<br>Bothell, WA 98021<br>(425) 302-0340 Fax: (425) 302-0404                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                         | <small>DATE(S) OF INSPECTION</small><br>5/12/2026-5/19/2026*<br><br><small>FEI NUMBER</small><br>3003722743                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Kathy E Schwiebert, Site Head Bend                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <small>FIRM NAME</small><br>Lonza Bend Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                         | <small>STREET ADDRESS</small><br>20503 Builders St                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Bend, OR 97701-8507                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>DR-2025-0278    10/20/2025</p> <p>DR-2025-0198    8/8/2025</p> <p>DR-2025-0142    6/2/2025</p> </div> <div style="width: 65%;"> <p>O-ring and extraneous matter particles were found. The particles were identified as (b)(4).</p> <p>Unusual pressure and flow were observed during production of (b)(4) lot (b)(4). This prompted nozzle inspection. (b)(4) extraneous matter was discovered in the (b)(4) nozzle.</p> <p>Abnormal nozzle pressure and feed rate observed during execution of DPI (b)(4) lot (b)(4). Nozzle inspection revealed extraneous matter identified as (b)(4) from gasket.</p> <p>During minor cleaning of the (b)(4) a damaged gasket was observed at the base of the (b)(4) housing. Shreds of black material consistent with gasket materials visible inside the housing.</p> </div> </div> |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <b>B. Data Loss and Storage Discrepancies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <u>Deviation #</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <u>Date</u>                                                                                                                                                                                                                                                                             | <u>Short Description</u>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2026-0084                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 11/1/2025                                                                                                                                                                                                                                                                               | A data gap existed between (b)(4) migration for a period from 11/01/2025 – 12/20/2025 for the (b)(4) system. The IT department reported the servers only had backups for a (b)(4).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2026-0030                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1/24/2026                                                                                                                                                                                                                                                                               | The entire PI system at Lonza Bend (b)(4) warehouse lost data on 1/24/2026 for three minutes.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2026-0021                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1/20/2026                                                                                                                                                                                                                                                                               | Lonza Bend system PI data was lost on (b)(4) for 30 minutes on 1/20/2026 for (b)(4).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2026-0009                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12/6/2025                                                                                                                                                                                                                                                                               | During investigation of DR-2025-0330, it was discovered there was missing audit trail entries for (b)(4) from 12/04/2025 – 1/13/2026 for (b)(4) SDI.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2025-0347                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 12/19/2025                                                                                                                                                                                                                                                                              | Facility Monitoring System (FMS) lost connection with the PI data server from 12/19/2025 13:47 to 12/20/2025 10:52.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| DR-2025-0315                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3/14/2025                                                                                                                                                                                                                                                                               | During system audit trail review for (b)(4), it was found that batch                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                         | <table style="width: 100%; border: none;"> <tr> <td style="width: 60%; border: none; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small><br/>           Roger F Zabinski, National Expert<br/>           Ana-Maria A Plapcianu, Microbiologist<br/>           Conor J Mccarron, Investigator<br/>           Eric Zhu, Investigator         </td> <td style="width: 40%; border: none; vertical-align: top; text-align: center;"> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <small>Roger F Zabinski<br/>National Expert<br/>Signed By: Roger F. Zabinski -S<br/>Date Signed: 05-19-2026<br/>17:14:18</small> </div> <div style="font-size: 2em; margin-top: 10px;">X</div> </td> </tr> </table> |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Roger F Zabinski, National Expert<br>Ana-Maria A Plapcianu, Microbiologist<br>Conor J Mccarron, Investigator<br>Eric Zhu, Investigator | <div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> <small>Roger F Zabinski<br/>National Expert<br/>Signed By: Roger F. Zabinski -S<br/>Date Signed: 05-19-2026<br/>17:14:18</small> </div> <div style="font-size: 2em; margin-top: 10px;">X</div> |
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| <small>DATE ISSUED</small><br>5/19/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  |                                                                                                                                                                                |                                                                                                                                                                                                                                                                                         |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

|                                                                                                                             |                                                                               |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| DISTRICT ADDRESS AND PHONE NUMBER<br>22215 26th Ave SE Suite 210<br>Bothell, WA 98021<br>(425) 302-0340 Fax: (425) 302-0404 | DATE(S) OF INSPECTION<br>5/12/2026-5/19/2026*<br><br>FEI NUMBER<br>3003722743 |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Kathy E Schwiebert, Site Head Bend

|                                                       |                                              |
|-------------------------------------------------------|----------------------------------------------|
| FIRM NAME<br>Lonza Bend Inc.                          | STREET ADDRESS<br>20503 Builders St          |
| CITY, STATE, ZIP CODE, COUNTRY<br>Bend, OR 97701-8507 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

report data was deleted off the system with date occurrence documented on 3/14/2025, observed on 10/22/2025 and launch of the deviation on 11/17/2025.

DR-2025-0115    5/3/2025    Multiple values recorded on (b)(4) PI Data System were frozen from 12:02-14:57. Two manufacturing events were in process, including (b)(4).

**C. Missing documentation of manufacturing activities.**

| <u>Deviation #</u> | <u>Date</u> | <u>Short Description</u>                                                                                                                              |
|--------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| DR-2026-0117       | 4/21/2026   | Operator that performed clean on Commercial Skid Gasket was the same operator who performed the visual verification of that gasket.                   |
| DR-2026-0104       | 2/15/2026   | During execution of protocol (b)(4), three sample sets were not signed off.                                                                           |
| DR-2026-0080       | 3/10/2026   | During rinsing and cleaning testing for the (b)(4) on 3/10/2026, documentation did not indicate which (b)(4) the rinsate and micro were performed on. |

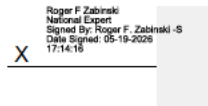
**\*DATES OF INSPECTION**

5/12/2026(Tue), 5/13/2026(Wed), 5/14/2026(Thu), 5/15/2026(Fri), 5/18/2026(Mon), 5/19/2026(Tue)

X    Ana-Maria A Plapcianu  
Microbiologist  
Signed By: ANAMARIA A. PLAPCIANU -S  
Date Signed: 05-19-2026 17:14:51

X    Conor J Mccarron  
Investigator  
Signed By: 2004153102  
Date Signed: 05-19-2026 17:15:34

X    Eric Zhu  
Investigator  
Signed By: 2003017579  
Date Signed: 05-19-2026 17:16:04

|                                     |                                                                                                                                                                 |                                                                                                                                                                                                     |                          |
|-------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <b>SEE REVERSE<br/>OF THIS PAGE</b> | EMPLOYEE(S) SIGNATURE<br>Roger F Zabinski, National Expert<br>Ana-Maria A Plapcianu, Microbiologist<br>Conor J Mccarron, Investigator<br>Eric Zhu, Investigator | <br>Roger F Zabinski<br>National Expert<br>Signed By: Roger F. Zabinski -S<br>Date Signed: 05-19-2026 17:14:18 | DATE ISSUED<br>5/19/2026 |
|                                     |                                                                                                                                                                 |                                                                                                                                                                                                     |                          |

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."