# FDA Observation Report

FDA Observation: Observation 1: Copy observation verbatim, including annotation, if any.

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| Field | Details |
| Response | Response: Corrective actions will be completed by December 1, 2024. |
| Completed Actions | On November 10, 2024, COMPANY completed corrective actions. See Appendix 2, Attachment A for a copy of the revised records.  On November 15, 2024, COMPANY updated training procedures. See Appendix 2, Attachment B for the new training log. |
| Planned Actions | Summary for 'planned\_actions': - By December 15, 2024, COMPANY will implement new policies. - By December 30, 2024, COMPANY will conduct a follow-up audit to ensure compliance. - COMPANY considers this item to be closed. |