U.S. FOOD & DRUG ADMINISTRATION

VIA UPS AND EMAIL
SIGNATURE REQUIRED

July 7, 2026

CBER 26-731752

Mr. Alvin M. Peralta Faulkner
General Manager Puerto Rico Operations
Fenwal International, Inc.
Road #357, Km 0.8
Maricao, PR 00606
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Dear Mr. Peralta Faulkner:

The United States Food and Drug Administration (FDA) inspected your facility, located at the above address, between January 27, 2026, and February 5, 2026. During the inspection, FDA documented evidence significant deviations from current good manufacturing practice (CGMP) requirements, see 21 U.S.C. § 351(a)(2)(B) and 21 CFR parts 210 and 211, in the manufacture of your blood-pack units (BPUs) as well as component solutions intended for collection and storage of whole blood and blood components (collectively, "your products") which you distribute in interstate commerce.

At the conclusion of the inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations (Form FDA-483). The CGMP deviations applicable to your products include, but are not limited to, the following:

1. **Failure to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements, as required by 21 CFR 211.67(a).** For example:

    a) White and black residues as well as apparent corrosion were observed inside your (b) (4) which are used to generate (b) (4) used to formulate the solutions for your products.

    b) Black, yellow, and green residues were observed inside the (b) (4) along with apparent corrosion. This (b) (4) is used to formulate the solutions for your products.

2. **Failure to maintain buildings used in the manufacture, processing, packing, or holding of drug products in a good state of repair, as required by 21 CFR 211.58.** For example:

   a) In Filling Room #(b)(4), black material was observed on the surfaces of (b) (4) HEPA filters in the ceiling that supply room air where product is filled.

   b) In Mixing Room #(b)(4), the following maintenance failures were observed above the (b) (4) used for your products: cracked ceiling light fixtures with missing light panel material, unknown (b) (4) inside a ceiling light fixture, and peeling stickers. These conditions were observed above solution (b) (4) where bulk formulations are made and held for production.

   c) (b) (4), apparently biological, residue and standing pools of water were observed adjacent to and within the air handling unit (AHU) that supplies air to Filling Room #(b)(4) where product is filled.

Responses to the Form FDA-483

We have reviewed your responses, dated February 27, 2026, April 30, 2026, and June 25, 2026, to FDA's Form FDA-483 in detail. Your responses are inadequate to address the deviations noted above. While you have committed to making improvements to your facilities and equipment in response to the conditions noted on the FDA-483, you have not fulfilled your responsibility to ensure ongoing compliance. For example, your response to Item #1, listed above, states that the (b) (4) were cleaned after the previous inspection; however, you have failed to maintain these (b) (4) over time. Your response also states that you most recently cleaned the (b) (4), mentioned in Item #1, in June 2024 and that the (b) (4) are subject to (b) (4) cleaning (b) (4). However, as observed during the most recent inspection, your cleaning frequency is inadequate.

FDA has previously noted your facility and equipment deficiencies, including through a Warning Letter dated September 14, 2023, a Regulatory Meeting held December 15, 2023, as well as written communications and meetings following your inspection ending September 18, 2024. During our most recent inspection, our investigators identified new or continued deficiencies related to your facilities and equipment. Your corrective actions appear limited in scope to only what is pointed out during our inspections as noted by subsequent inspections that identify additional examples of deteriorated conditions. We are concerned that, as you work to transfer product manufacturing to your (b) (4) facility, these deficient practices will follow your quality unit to this site. You have not demonstrated that you are able to maintain your facilities and equipment in a state of repair that is suitable for the products you manufacture. In response to this letter, provide a comprehensive plan to address the state of your facilities and equipment as a whole. Include your plans to ensure that adequate

resources will be dedicated to prevent recurrence at your Maricao facility and to ensure ongoing compliance once your products are transferred to (b) (4) .

Conclusion

Neither this letter nor the observations noted on the Form FDA-483, which were discussed with you at the conclusion of the inspection, are intended to be an all-inclusive list of deficiencies that may exist in connection with your products. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure full compliance with the FD&C Act, PHS Act, and all applicable regulations.

This letter notifies you of our concerns and provides you an opportunity to address them.

Please submit your response in writing within thirty (30) days from your receipt of this letter, outlining the specific steps you have taken or plan to take to address any violations and prevent their recurrence. Include any documentation necessary to show that the matters have been addressed. If you cannot address these matters within thirty (30) days, please explain the reason for your delay and the timeframe for completion. If you do not believe your products are in violation of the FD&C Act, PHS Act, or applicable regulations, include your reasoning and any supporting information for our consideration.

Send your electronic response and any questions regarding this letter to CBER's Office of Compliance and Biologics Quality, Division of Case Management at CBERDCMRecommendations@fda.hhs.gov.

Sincerely,

Vincent Amatrudo
Acting Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

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