U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Via UPS
Return Receipt Requested

June 2, 2026

Mr. Victor Swint
Chief Executive Officer
Formulated Solutions, LLC
11775 Starkey Road
Largo, Florida 33773

Dear Mr. Swint:

Your facility is registered with the United States Food and Drug Administration (FDA) as a manufacturer of over-the-counter (OTC) drug products. FDA has reviewed the records you submitted in response to our September 8, 2025 request, and subsequent correspondence, for records and other information pursuant to section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for your facility, Formulated Solutions, LLC, FEI 3005779557, at 11775 Starkey Road, Largo.

This letter summarizes violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals. See Title 21 Code of Federal Regulations, parts 210 and 211 (21 CFR, parts 210 and 211).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding of drugs as described in your response to our 704(a)(4) request do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(B)).

Following review of records and other information provided pursuant to section 704(a)(4) of the FD&C Act, violations were observed including, but not limited to, the following:

1. **Your firm failed to test samples of each component for identity and conformity with all appropriate written specifications for purity, strength, and quality (21 CFR 211.84(d)(1) and 21 CFR 211.84(d)(2)).**

Your firm manufactured (b) (4) an OTC (b) (4) drug product labeled to contain the active drug ingredient (b) (4) This drug product is also labeled and formulated to contain the inactive ingredient (b) (4) The formulation contains more than (b) (4) (b) (4) are (b) (4) that may be found in (b) (4) (b) (4) (b) (4) (b) (4) is a potential contaminant in (b) (4) and is a known human carcinogen when (b) (4) Additionally, published scientific literature dating back to the 1960s has suggested a

(b) (4)

possible association between the use of (b) (4) containing (b) (4) in the (b) (4) and the incidence of (b) (4) potentially linked to (b) (4) contamination of the (b) (4) The (b) (4) (b) (4) drug product you produced can be used on areas of the body which may be an exposure risk (e.g., (b) (4) You (b) (4) drug products are considered a higher risk drugs as it pertains to patient safety regarding (b) (4) contamination of (b) (4) due to the risk of inadvertent (b) (4)

While your firm stated to have ceased to manufacture drug products containing (b) (4) no specific date was provided. The most recent manufactured batch record was provided containing the manufacture date of March 11, 2024, with an expiration of March 2026. We remain concerned about the adequacy of your incoming component testing and the processes used to validate supplier reliability at appropriate intervals.

You have not demonstrated that you appropriately tested incoming (b) (4) drug components used in the manufacture of (b) (4) drug products for identity, purity, strength, and quality. The results for (b) (4) testing appear on the supplier certificate of analysis (COA), however, you failed to provide requested records for your supplier COA test result validation, as required under CGMP if you do not test every incoming lot of (b) (4) for absence of (b) (4) Although 21 CFR 211.84(d)(2) provides for some reliance on a COA from the supplier of the component, such reliance is permissible only if the drug product manufacturer establishes the reliability of the supplier's test results through appropriate validation of the test results at appropriate intervals.

Additionally, you provided records to demonstrate you had conducted identity testing pursuant to the applicable United States Pharmacopeia (USP) test to satisfy the requirements for identity testing in 211.84(d)(1) and (2), but the testing does not conform to the current USP testing method, in that it is incomplete (i.e., lacks identification (b) (4) Without adequate testing, you lack scientific evidence that the components conform to appropriate specifications prior to use in the manufacture of your drug products.

As a manufacturer, you have a responsibility to sample, test, and examine, as appropriate, drug components before use in production to ensure acceptable specifications for identity, strength, quality, and purity are met. Because you have not performed appropriate testing that detects (b) (4) in your (b) (4) components, among other things, you failed to assure the acceptability of these drug components for use in manufacture of your drug products.

In response to this letter, provide:

- A description of how you will test each component lot for conformity with all appropriate written specifications for identity, purity, strength, and quality. If you intend to accept any results from your supplier's COA instead of testing each component lot for strength, quality, and purity, specify how you will establish the reliability of your supplier's results through initial validation as well as periodic revalidation. In addition, include a commitment to always conduct at least one specific identity test for each incoming component lot.

(b) (4)

- The chemical quality control specifications you use to evaluate each incoming lot of drug component to determine acceptability for use in manufacturing.

- A gap analysis for specifications for drug components (active and inactive) between your current specifications and test procedures against the USP, where applicable. Based on your gap analysis, provide a comprehensive plan for conformance of your drug component specifications and testing to USP standards, where applicable.

- A summary of results obtained from testing all components to evaluate the reliability of the COA from each component manufacturer. Include your standard operating procedure (SOP) that describes this COA validation program.

2. Your firm's quality control unit failed to exercise its responsibility to ensure drug products are manufactured in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity (21 CFR 211.22).

You did not demonstrate that your quality unit (QU) effectively exercised its responsibility to ensure the acceptability of drug components. For example, your QU does not have appropriate procedures to ensure that test results taken from the supplier's COA are validated at an appropriate interval. Your procedure SOP-MAT-0003, Supplier Management Program, includes a requirement for review of COA but instructions are not included regarding the validation of test results at an appropriate interval. Your QU approved and accepted (b) (4) for use in drug manufacturing without ensuring compliance with CGMP.

Your QU is responsible for fully exercising its authority and responsibilities, including responsibility for approving or rejecting all procedures or specifications impacting the identity, strength, quality, and purity of the drug product. Your firm's quality systems are inadequate. See FDA's guidance document *Quality Systems Approach to Pharmaceutical CGMP Regulations*, for help implementing quality systems and risk management approaches to meet the requirements of CGMP regulations 21 CFR, parts 210 and 211 at https://www.fda.gov/media/71023/download.

In response to this letter, provide a comprehensive assessment and remediation plan to ensure your QU is given the authority and resources to effectively function. The assessment should also include, but not be limited to:

- A determination of whether procedures used by your firm are robust and appropriate

- Provisions for QU oversight throughout your operations to evaluate adherence to appropriate practices

No Longer Manufacture or Distribute Drug Products Containing (b) (4)

In your response to our request for records you indicated that "there are no commercially active SKUs which contain (b) (4) at Formulated Solutions" as of September 8, 2025. If you plan to resume production with drug products containing (b) (4) notify this office in writing and include thorough documentation for (b) (4) testing.

Responsibilities as a Contractor

Drugs must be manufactured in conformance with CGMP. FDA is aware that many drug manufacturers use independent contractors such as production facilities, testing laboratories, packagers, and labelers. FDA regards contractors as extensions of the manufacturer.

You are responsible for the quality of drugs you produce as a contract facility regardless of agreements in place with product owners. You are required to ensure that drugs are made in accordance with section 501(a)(2)(B) of the FD&C Act for safety, identity, strength, quality, and purity. See FDA's guidance document *Contract Manufacturing Arrangements for Drugs: Quality Agreements* at https://www.fda.gov/media/86193/download.

Conclusion

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations.

This letter notifies you of our findings and provides you an opportunity to address the above deficiencies. After you receive this letter, respond to this office in writing within 30 working days. Specify what you have done to address any violations and to prevent their recurrence. If you cannot complete corrective actions within 30 working days, state your reasons for delay and your schedule for completion. If you have information that you believe demonstrates that your products are not in violation of the FD&C Act and FDA regulations, include that information for our consideration.

Send your electronic reply to CDER-OC-OMQ-Communications@fda.hhs.gov. Identify your response with FEI 3005779557 and ATTN: Nancy Espinal.

Sincerely,

/s/
Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research