WARNING LETTER

Signature Formulations LLC

MARCS-CMS 737964 — OCTOBER 01, 2026

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Delivery Method:

VIA UNITED PARCEL SERVICE AND VIA E-MAIL

Reference #:

320-27-02

Product:

Drugs

Recipient:

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Issuing Office:

Center for Drug Evaluation and Research (CDER)

United States

October 1, 2026

WARNING LETTER

Reference number: 320-27-02

To Maria Esparza:

This warning letter advises you of significant violations identified during the analysis of **(b)(4)** drug products including **(b)(4)** that you manufacture under contract for **(b)(4)**.

Following a violative inspection of your firm, U.S. Food and Drug Administration (FDA) procured **(b)(4)** lots of your **(b)(4)** drug products marketed for **(b)(4)** and conducted laboratory analysis. FDA analysis showed all **(b)(4)** lots had contamination with at least **(b)(4)** of the following **(b)(4)**. The results indicated that your **(b)(4)** drug products were grossly

Feedback

contaminated with **(b)(4)**.

The results of the FDA laboratory testing of **(b)(4)** drug product lots distributed in the U.S. market demonstrate that these drug products manufactured at your facility 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) because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to Current Good Manufacturing Practices (CGMP).

Furthermore, based on information from the previous inspection these drug products are also adulterated under section 501(a)(2)(A) of the FD&C Act, 21 U.S.C. 351(a)(2)(A) in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health.

Violations of the Federal Food, Drug, and Cosmetic Act

After FDA's inspection of your facility documented the use of shared equipment for the production of **(b)(4)** drug products and **(b)(4)**, FDA procured samples of your **(b)(4)** drug products. Analytical testing confirmed the presence of undeclared **(b)(4)** in your **(b)(4)** drug products intended for **(b)(4)** as well as **(b)(4)**. **(b)(4)** was detected above the limit of quantitation (LOQ) of **(b)(4)** ng/mL in all lots tested. **(b)(4)** was also detected in **(b)(4)** lots tested. In many cases far higher levels of **(b)(4)** contamination were found in your **(b)(4)** products. Detection of contamination against the LOQ are below.

Product Name	Limit Of Quantitation (LOQ) Test Results
(b)(4)	(b)(4)

These contaminated drug products have the potential for serious adverse health consequences. These **(b)(4)**. For instance, your **(b)(4)** drug product is labeled for use **(b)(4)**. Daily exposure to **(b)(4)** poses particular risk to **(b)(4)**. Known harmful effects of **(b)(4)** exposure include **(b)(4)**. These effects may not appear for months or years after exposure and are not readily detectable by consumers.

The results of the FDA laboratory testing of **(b)(4)** drug product lots distributed in the U.S. market demonstrate that these drug products manufactured at your facility are adulterated within the meaning of section 501(a)(2)(B) and 501(a)(2)(A) of the FD&C Act.

Drug Recall

On September 15, 2026, FDA held a teleconference to provide you with the results of the analysis and recommended that you voluntarily recall all drug products currently in distribution from the U.S. market. You verbally committed to halt manufacturing and distribution as well as perform a voluntary recall of all **(b)(4)** drug products.

It is noteworthy that in 2025 there was a previous recall of **(b)(4)** lot of your **(b)(4)** and **(b)(4)** lot of your **(b)(4)** for **(b)(4)** contamination. It is unacceptable that you have had repeated instances of **(b)(4)** contamination with your **(b)(4)** drug products.

Cross Contamination Risks

Warning Letter 320-26-38 issued on January 21, 2026, summarized significant violations of CGMP, documented on inspection including risks of cross contamination between **(b)(4)** drug products manufactured at your facility.

We also discussed significant CGMP violations and risks of cross contamination with **(b)(4)** at a regulatory meeting held with your firm on July 16, 2024.

The risk of cross contamination at your facility is exacerbated by the physical and chemical properties of the **(b)(4)** active ingredients used in your **(b)(4)** products. **(b)(4)** have **(b)(4)**. For these reasons, operations are generally significantly segregated due to the high risk of cross contamination. Such drugs represent a high risk of cross contamination if manufacturing is not appropriately separated. You manufactured your **(b)(4)** products in the same manufacturing environment using shared equipment. **(b)(4)** residues remaining on shared surfaces and equipment following **(b)(4)** product manufacturing will not be adequately removed under standard cleaning conditions. To avoid cross contamination from shared surfaces, companies dedicate equipment, dedicate HVAC, and utilize other separation provisions (e.g., dedicated production suites, airlocks).

FDA's analysis of **(b)(4)** randomly sampled lots of your firm's **(b)(4)** drug products, including **(b)(4)**, confirmed **(b)(4)** contamination across all sampled lots. The confirmed findings across all sampled lots indicate a systemic failure that cannot be resolved through retrospective testing. Contamination is nonuniformly distributed throughout all lots, the full extent of **(b)(4)** contamination across your firm's marketed drug products is unknown, and consumers including **(b)(4)** may be exposed to doses beyond what sampling alone can reveal. Your firm has not established appropriate design and control procedures to prevent hazardous cross contamination between your drug products. The use of shared areas and equipment in conjunction with FDA confirmed contamination in your drug products demonstrates your products were manufactured under insanitary conditions and are adulterated under Section 501(a)(2)(A) of the FD&C Act.

Significant findings in this warning letter and warning letter 320-26-38 demonstrate that your firm also does not operate an effective quality system in accord with CGMP. In addition to the lack of effective management oversight of your production and laboratory operations, we found your quality unit is not enabled to exercise proper authority and/or has insufficiently implemented its responsibilities. Executive management should immediately and comprehensively assess your company’s global manufacturing operations to ensure that your systems, processes, and products conform to FDA requirements.

(b)(4) Drug Production Suspended

We acknowledge that your firm made a commitment to halt the manufacture, sale, and distribution of **(b)(4)** drug products on **(b)(4)**.

In response to this letter, provide a complete list of your inventory of **(b)(4)** drug products and your plans for disposition (e.g., destruction). Also provide a commitment that you will not manufacture **(b)(4)** containing products on shared equipment or areas utilized for the production of your **(b)(4)** products.

We strongly advise you to retain a qualified consultant with demonstrated experience in the manufacturing of highly potent materials to assess your facility's design and control approach to prevent cross contamination and implement the systemic corrective actions necessary before resuming any manufacturing operations.

Conclusion

Promptly address the violations described herein without delay, including ensuring that appropriate resources are allocated to fully address the violations and prevent their recurrence. This is not intended to be an all-inclusive list of the violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations. Failure to adequately address violations may result in regulatory or legal action without further notice including, without limitation, seizure and injunction.

You are responsible for investigating and determining the root causes of any violations and implementing corrective and preventative measures to ensure future and sustained compliance so that these violations and any others do not occur.

Unresolved violations may prevent other Federal agencies from awarding contracts. Failure to address violations may also cause FDA to withhold issuance of Export Certificates. FDA may withhold approval of new applications or supplements listing your firm as a drug manufacturer until any violations are completely addressed and we confirm your compliance

with CGMP. We may re-inspect to verify that you have completed corrective actions to address any violations.

Send your written response to CDER-OC-OMQ-Communications@fda.hhs.gov within fifteen (15) business days of receipt of this letter. Identify your written response with FEI 3011368010 and ATTN: Zachary Bogorad in the letter or in the subject line of the email.

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.

FDA posts warning letters to www.FDA.gov.

Sincerely,
/S/

Francis Godwin
Director
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

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