U.S. FOOD & DRUG ADMINISTRATION

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

Via electronic mail with read and delivery receipt requested

October 27, 2026

Stephen R. Walker
President
ABC Compounding Company, Inc
2600 Dogwood Dr. SE
Conyers, GA 30013
(b) (4)

To Mr. Stephen Walker:

This letter advises you of violations identified during a U.S. Food and Drug Administration (FDA) review of records submitted from your facility and provides you an opportunity to address them. Promptly address any 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 that exist in connection with your products. It is your responsibility to ensure that you comply with all requirements of federal law, including FDA regulations. Failure to adequately address any violations may result in regulatory or legal action without further notice including, without limitation, seizure and injunction.

**FDA Review**

Violations were identified and documented during review of your drug manufacturing facility, ABC Compounding Company, Inc, FDA Establishment Identifier (FEI) 3012553246. This review was conducted under FDA's statutory authority and public health responsibilities to protect the public from unsafe, ineffective, and poor quality drugs.

Your facility is registered with the FDA as a manufacturer of over-the-counter (OTC) drug products. FDA has reviewed the records you submitted in response to our April 24, 2026, request 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.

More than twenty of your topical drug products as described in your response to our 704(a)(4) are adulterated under section 501(a)(4)(A) as this drug product bears or contains a color additive that is unsafe within the meaning of section 721 of the FD&C Act, 21 U.S.C. 379e.

**Violations of the Federal Food, Drug, and Cosmetic Act**

The following are violations identified during our review. As a reminder, this is not an all-inclusive list of violations at your facility.

**Drug Products Containing Cancelled Color Additive Ext. D&C Red No. 11**

You manufacture topical OTC drug products. Based on our review of batch records and labeling, the following products you manufacture contain the color additive “Acid Red 1” or “Food Red 10” (also known as Ext. D&C Red No. 11):

- “aerocare Sani MANGO Antiseptic Hand and Body Wash”
- “People’s FM-24 FOAMING High Foaming Antiseptic Hand and Body Wash”
- “HANDTASTIC Foamy Mango Antiseptic Foam Soap Hand & Body Wash”
- “PRO CHEM Suds Hand SOAP High Foaming Antiseptic Hand and Body Wash”
- “Medicascrub High Foaming Antiseptic Hand and Body Wash Mango Fresh”
- “Delta Foremost FM 4024-ES Sani-Foam Mango High Foaming Antiseptic Hand and Body Wash”
- “WECHEM Hand Guard HIGH FOAMING ANTISEPTIC HAND and BODY WASH”
- “aero Foamy Mango ALOE VERA Antiseptic Hand & Body Wash”
- “FresHands PREMIUM FOAMY ANTIBACTERIAL HAND SOAP Mango Fragrance”
- “1611 Lynx. foamy PCMX antiseptic hand and body wash”
- “CERTUS MEDICAL Satin Foam High foaming antiseptic hand wash”
- “PRO CHEM BAN AID Antiseptic Hand Soap”
- “Rochester Midland Corporation Chemseptic One Step Hand Cleaner and Sanitizer Antiseptic Hand Soap”
- “image supply, inc. Antiseptic Hand Soap”
- “1606 Lynx antibacterial hand soap ANTISEPTIC HAND WASH”
- “aerocare Palm ANTISEPTIC HAND SOAP”
- “PRO CHEM Fresh Start Antibacterial Hand Soap”
- “WECHEM SENTRY ANTISEPTIC HAND SOAP”
- “SPURRIER 1012 ANTIMICROBIAL HAND SOAP”
- “SunCoast Paper Inc. Surgent ANTISEPTIC HAND SOAP”
- “Lynx LX0864 peachy-foam antiseptic hand soap”

In 1966, FDA cancelled the certification and delisted Ext. D&C Red No. 11 due to lack of safety data from any manufacturer. Under 21 CFR 81.30(d), using Ext. D&C Red No. 11 after October 4, 1966, results in the drug being adulterated. Accordingly, the introduction or delivery for introduction of the drug products listed above into interstate commerce is a prohibited act under section 301(a) of the FD&C Act, 21 U.S.C. 331(a).

**Drug Product Containing Unlisted Color Additive Acid Blue 25**

Based on our review of batch records and labeling, your “Rochester Midland Corporation Hand San Sanitizing Lotion” drug product contains an unlisted color additive, “Acid Blue 25” (an anthraquinone dye which is primarily used in textile dying).

Any color additive not explicitly listed as safe for its intended use is deemed unsafe within the meaning of section 721(a) of the FD&C Act. The inclusion of a delisted or unlisted color additive in your drug product formulations indicates that your quality unit’s review (as required under 21 CFR 211.22) of your raw material qualification process and formulation review procedures is inadequate.

Your response states that you discontinued manufacturing all the affected drug products on May 5, 2026, and planned to reformulate the products.

**Drug Recall**

On September 8, 2026, FDA held a teleconference with you recommending you consider removing any batches of the affected topical drug products listed above currently in distribution from the U.S. market.

On September 22, 2026, you issued a voluntary recall of the affected topical drug products due to the products containing the delisted color additive Ext. D&C Red No. 11 or the unlisted color additive Acid Blue 25.

**Revocation of FD&C Red No. 3**

FDA revoked the authorization for the use of FD&C Red No. 3. We recommend manufacturers review their drug product formulations. Manufacturers who use FD&C Red No. 3 in ingested drugs will have until January 18, 2028, to reformulate their products. For more information see https://www.fda.gov/food/hfp-constituent-updates/fda-revoke-authorization-use-red-no-3-food-and-ingested-drugs.

**Conclusion**

As previously stated, 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.

Send your written response to CDER-OC-OMQ-Communications@fda.hhs.gov within thirty (30) business days of receipt of this letter. Identify your written response with FEI 3012553246 and ATTN: Lynnsey Renn 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.

Sincerely,

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

cc:
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Quality Assurance
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