



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900
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WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

W/L 40-11

May 13, 2011

Mr. William P. Mountanos, CEO
Nuvonyx, Inc. DBA Real Aloe, Inc. and U.S. Aloe
2045 Corte Del Nogal
Carlsbad, CA 92011

Dear Mr. Mountanos:

On October 18 through October 21, 2010 and January 10 through January 20, 2011, the U.S. Food and Drug Administration (FDA) inspected your firm located in Carlsbad, CA. Your firm manufactures, packages, labels, and holds dietary supplements. The inspection identified significant violations of Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements (CGMP) regulations, Title 21, Code of Federal Regulations (CFR) Part 111 (21 CFR Part 111).

These violations cause your dietary supplement products AloeAdvanced and AloeControl to be adulterated within the meaning of Section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 342(g)(1)] in that the dietary supplements have been prepared, packed, or held under conditions that do not meet CGMP regulations for dietary supplements. These observations were presented to you in a FDA-483 at the conclusion of our inspection on October 21, 2010. During our January 2011 inspection, our investigator verified that these violations have not been corrected.

The inspection revealed the following violations:

1. Your firm failed to conduct appropriate testing of finished batches of dietary supplements to determine whether such dietary supplements met established specifications for identity, purity, strength, and composition, as required by 21 CFR 111.75(c).

Specifically, you failed to test your AloeControl (batch # **(b)(4)**) and AloeAdvanced (batch # **(b)(4)**) dietary supplements to verify that they met finished product specifications for identity, purity, strength, and composition. Your statements and the records provided to our investigator show that you performed **(b)(4)** tests on these batches of finished products, but this type of test does not verify the identity, purity, strength, and composition of the finished product, as required by 21 CFR 111.75(c).

2. Your firm failed to establish component specifications that are necessary to ensure that specifications for the identity, purity, strength, and composition of dietary supplements manufactured using the components are met, as required by 21 CFR 111.70(b)(1) and (b)(2).

Specifically, you did not establish component specifications for any components used in your AloeAdvanced and AloeControl dietary supplements. During our October 2010 inspection, you indicated you would take corrective action by January 1, 2011. However, our recent inspection from January 10-20, 2011 revealed that corrections were not made.

3. Your firm failed to conduct at least one appropriate test or examination to verify the identity of a component that is a dietary ingredient, prior to its use, as required by 21 CFR 111.75(a)(1)(i).

Specifically, your firm uses dietary ingredients such as ecklonia cava kelp, gymnema sylvestre, and Vitamin C in your AloeAdvanced Dietary Supplement and chromium piccolinate, Co10, Pancreatin, Conjugated Linoleic Acid, Green Tea and Vitamin C in your AloeControl Dietary Supplement; however, our investigator found that you did not conduct identity testing on any dietary ingredients, but instead relied on **(b)(4)** from your suppliers. **(b)(4)** from suppliers do not fulfill the requirements of 21 CFR 111.75(a)(1)(i) for dietary ingredients. The regulations require you to conduct identity testing or examination for dietary ingredients.

4. Your firm failed to qualify suppliers of components other than dietary ingredients by establishing the reliability of the suppliers' COA through confirmation of the results of the suppliers' tests or examinations, as required by 21 CFR 111.75(a)(2)(A).

Specifically, our investigator found that you sent out **(b)(4)** to your suppliers who provide you with a **(b)(4)** to "validate" the use of the **(b)(4)**. However, this is inadequate because it does not show that you confirm the results of the suppliers' tests or examinations.

5. Your firm failed to establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing, as required by 21 CFR 111.103. Our investigator found that you had no written procedures for your firm's quality control operations.

6. Your firm failed to make and keep records that show that water, when used in a manner such that the water may become a component of the dietary supplement, meets the requirements of 21 CFR 111.15(e)(2), as required by 21 CFR 111.23(c).

Specifically, our investigator found that your firm did not make records to show that the (b)(4) water used in your AloeAdvanced and AloeControl products complies with applicable Federal, State, and local requirements and does not contaminate the dietary supplements.

This letter is not an all-inclusive list of violations at your facility. It is your responsibility to ensure that your establishment and the products you market comply with the Act and its implementing regulations. Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing within 15 working days from your receipt of this letter of the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur in the future. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, state the reason for the delay and the date by which you will complete the corrections.

Your response should be sent to:

Blake Bevill
Director, Compliance Branch
Food and Drug Administration
Los Angeles District Office
19701 Fairchild
Irvine, CA 92612

If you have any questions about the content of this letter, please contact Jessica Mu, Compliance Officer, at 949-608-4477.

Sincerely yours,

/s/

Alonza E. Cruse
District Director