



Department of Health and Human Services

Public Health Service  
Food and Drug  
Administration  
Dallas District  
4040 North Central  
Expressway  
Dallas, Texas 75204-3128

March 30, 2010

**2010-DAL-WL-08**

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. Billy C. Coats, President and CEO  
Coats International Holdings, Inc.  
9660 Dilworth Road  
Dallas, Texas 75243

Dear Mr. Coats:

On September 1 through September 18, 2009, the U.S. Food and Drug Administration (FDA) performed an inspection of your firm located at 9660 Dilworth Road, Dallas, Texas. Our investigator found a number of violations of 21 CFR Part 111, Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements.

The inspection revealed that your Herbalife Ready Herbal Aloe for Digestive Health Dietary Supplement and Herbalife Herbal Aloe Concentrate for Digestive Health Dietary Supplement, products manufactured in your facility, are adulterated within the meaning of Section 402(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the dietary supplements have been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations for dietary supplements. These observations were presented to you in an FDA-483 at the conclusion of our inspection on September 18, 2009.

The inspection revealed the following deficiencies:

1. Your firm failed to conduct at least one appropriate test or examination to verify the identity of a dietary ingredient prior to its use, to comply with 21 CFR 111.75(a)(1)(i). Specifically, your firm uses aloe as an ingredient in your Herbalife Ready Herbal Aloe for Digestive Health Dietary Supplement (32 fl oz and 1 gallon sizes) and Herbalife Herbal Aloe Concentrate for Digestive Health Dietary Supplement, but your firm does

not perform an appropriate identity test or examination on the aloe raw material. Although your firm performs (b)(4) and appearance testing for this material, such testing is not appropriate. As discussed with your staff, such testing would not indicate whether, for example, a dietary component was a mixture of aloe, thickeners, and/or other ingredients.

We acknowledge receipt of your October 12, 2009, response to the FDA 483; however, it does not adequately address your failure to conduct at least one appropriate test or examination to verify the identity of the aloe ingredient prior to its use. Your letter stated that you have ordered an aloe standard and that you would use the (b)(4) chromatography methodology accompanying the standard to verify the identity of aloe if you were able to successfully replicate that methodology. However, you did not specify how you intended to verify the identity of aloe used to manufacture your dietary supplements until December 18, 2009 (your anticipated correction date). Similarly, your letter did not specify the identity test or examination your firm would implement in the event that your firm could not successfully replicate the proposed identity methodology.

2. Your firm failed to make and keep documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition; and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement, to comply with 21 CFR 111.95(b)(3). Specifically, you have no documentation to explain the rationale behind the specifications that you have for raw materials (such as aloe, chamomile, water, citric acid, and preservatives) used in your dietary supplements and in-process samples (samples taken of product before packaging) of these dietary supplements. Additionally, you did not make and keep documentation demonstrating why the results of appropriate tests or examinations for the product specifications selected under 111.75(c)(1) ensure that your dietary supplements meets all product specifications, in accordance with 21 CFR 111.95(b)(4).

Your October 12th response indicates your firm has begun implementation of a HACCP plan. While we acknowledge the evaluation of critical control points in the processing of dietary supplements can be useful, this response is inadequate because it did not indicate that your HACCP plan will document the rationale required under 21 CFR 111.95(b)(3) and (b)(4). Further, your letter states that you have created a new SOP titled "Development of a New (b)(4) Product," which was to be implemented by October 31, 2009. Your response states that the SOP will explain the rationale behind your manufacturing process, product specifications, and testing practice. However, your response is inadequate because you did not submit this SOP for our evaluation, and therefore, we cannot determine whether it meets the requirements of 21 CFR 111.95(b)(3) and (b)(4).

3. You did not follow your written procedure, "Approval/Rejection of Raw Materials and Packaging Components" for collecting representative samples of each unique

shipment of components. Under 21 CFR 111.153, you must establish and follow written procedures for fulfilling the requirements of subpart G. This subpart includes the requirement that you collect representative samples of each unique lot of components (21 CFR 111.155(c)(1)). Specifically, you did not follow your written procedures stating that you will sample the (b)(4) of the number of containers in a shipment. Our investigator observed that only one box of potassium sorbate had been opened for sampling out of a shipment of (b)(4) boxes. Also, only one bag of trisodium citrate dihydrate had been opened for sampling out of a shipment of (b)(4) bags.

Your October 12th response indicated that your firm's SOP "Approval/Rejection of Raw Materials and Packaging Components" was revised to better define "container." Your response states that "container" is now defined as a (b)(4) and, with this change, multiple cases will be sampled across a single manufacturer's lot of raw material or packaging components. The revised SOP was to be implemented by November 20, 2009. Your response does not adequately address this observation because it does not provide assurance that your staff has been trained to follow your written procedures for collecting representative samples.

4. Your quality control program is not adequate. For example:

a. Your quality control operations did not include periodic review of all records for calibration of instruments and controls, as required by 21 CFR 111.117(b). Specifically, your firm does not periodically review calibration records for production equipment, including scales and water meters used to measure dietary supplement ingredients.

Your response letter indicates SOP 1590, "Quality Review of Equipment/Instrument Calibrations" was implemented on October 7, 2009, and that QC will review records for all equipment requiring calibration through the plant. However, your response did not include a copy of the new SOP or evidence of implementation. We will address the sufficiency of this correction during the next inspection.

b. Your master manufacturing record does not include written instructions for manual operations that include one person verifying the addition of a component, as required by 21 CFR 111.210(h)(3)(ii)(B). Specifically, you have one employee working in the food compounding area (b)(4). This employee adds components of your dietary supplements without a second employee verifying the addition. According to management, a (b)(4) employee checks the next day to ensure that the (b)(4) employee has completed the required paperwork, and signs off on the paperwork to indicate that he has done so. However, your master manufacturing record does not include instructions that the addition of components by one employee must be verified by another employee.

Your response indicates that all dietary supplement compounding activities were moved to (b)(4) and your firm is currently evaluating resources to support future (b)(4). This response is not adequate because it does not indicate that you have revised your master manufacturing record to include a second employee verifying the addition of a component by another employee. We will address the sufficiency of this correction during the next inspection.

c. Your firm failed to include documentation, at the time of performance, in the batch production record that quality control personnel approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement, to comply with 21 CFR 111.260(1)(4). Specifically, our investigator observed that quality control personnel did not document approval and release, or rejection, of the finished product in the batch production record. Although the quality assurance forms in your batch records document review of appropriate records, they do not document release of finished product.

Your response letter indicates that forms QA041 and QA042 will be revised to clearly state: "Batch Released by Quality Assurance: \_\_\_\_\_," the line indicating signature and date. Your letter specifies that corrections were to be completed by October 31, 2009. This response is inadequate because it does not explain that your personnel have been trained to use these revised forms to document release or rejection of a dietary supplement at the time of performance. We will address the sufficiency of this correction during the next inspection.

5. Your master manufacturing record did not include a statement of the theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, and the expected yield when you finish manufacturing the dietary supplement, to comply with 21 CFR 111.210(f).

Your response indicates that your batch production records will be revised to include a section to record bulk yields, and a bulk yield specification will be added to the in-process release specification section of the batch production records. This response is inadequate because it addresses changes you intend to make to your batch production records, rather than your master manufacturing records.

6. Your batch production records did not include a statement of the percentage of theoretical yield at appropriate phases of processing in accordance with 21 CFR 111.260(f).

Your response indicates revisions will be made to all batch production records for dietary supplements to include a section for recording bulk yields. Your response states, in addition, that a bulk yield specification will be added to the in-process release specification section of the batch production records, and that your firm will also revise the Job Completion Report to include a statement of the percentage of theoretical yield at appropriate phases of processing. However, this response is

inadequate because you have not provided a copy of these revisions. We will address the sufficiency of these corrections during the next inspection.

7. The written instructions in your master manufacturing records did not include corrective action plans to use when a specification is not met, in accordance with 21 CFR 111.210(h)(5).

Your letter indicates the statement, "If the above standard specifications are not met, a product investigation will be initiated to determine the root cause," will be added to the Standard Specifications section of the batch production record. This response is inadequate because it indicates that you intend to revise your batch production records, rather than your master manufacturing records.

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 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. 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.

Please send your reply to the Food and Drug Administration, Attention: Sherrie L. Krolczyk, Compliance Officer, at the above letterhead address. If you have any questions regarding any issue in this letter, please contact Sherrie L. Krolczyk at (214) 253-5312.

Sincerely,

/s/

Reynaldo R. Rodriguez, Jr.  
Dallas District Director