



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421  
Telephone: 425-486-8788  
FAX: 425-483-4996

January 14, 2011

**VIA OVERNIGHT DELIVERY**

In reply refer to Warning Letter SEA 11-05

Jeffrey M. Gollini, President  
All American Pharmaceutical & Natural Foods, Corp.  
2376 Main Street  
Billings, Montana 59105-5792

**WARNING LETTER**

Dear Mr. Gollini:

On August 5 and 6, 2010, the U.S. Food and Drug Administration (FDA) inspected your firm located at 2376 Main Street, Billings, Montana. Our investigators found a number of serious violations of the Current Good Manufacturing Practice (CGMP) regulations in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, Title 21, Code of Federal Regulations (CFR), Part 111. At the conclusion of the inspection, you were issued a Form FDA 483, List of Inspectional Observations, which delineated a number of violations that cause your dietary supplement products 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 current good manufacturing practice regulations for dietary supplements. You may find the Act and FDA regulations through links at FDA's home page at <http://www.fda.gov><sup>1</sup>.

The following violations were observed during the inspection:

1. You failed to prepare and follow a written master manufacturing record for each unique formulation of a dietary supplement that you manufacture, and for each batch size, as required by 21 CFR 111.205(a). You presented our investigators with a bill of materials for one unit of one of your firm's dietary supplements as an example of your master manufacturing records. However, the bills of materials neither identify specifications for the manufacturing process, nor establish controls and procedures to ensure that

the specifications are met, as required by 21 CFR 111.205(b). In addition, the master manufacturing record for each supplement and batch size must include the required elements listed in 21 CFR 111.210.

Your firm's August 13, 2010, response is inadequate because it fails to provide documentation of the master manufacturing records of any of your firm's supplements. We will verify the adequacy of each master manufacturing record during our next inspection.

2. You failed to include in your batch production record (BPR), the following mandatory elements, as required by 21 CFR 111.260:

- Your BPR failed to include, when required, reconciliation of any discrepancies between issuance and use of labels, as required by 21 CFR 111.260(k)(1). Specifically, the BPR for packaging AAEFX ZMA 90 capsules, batch ticket # 9753, does not provide any space for reconciliation and no reconciliation is documented. This dietary supplement requires such reconciliation because examination for correct labels is not performed by electronic or electromechanical equipment (see 21 CFR 111.410(b)).

Your response states that label reconciliation is documented and recorded on your batch records and you provide the example of batch ticket #9753, which indicates **(b)(4)** labels used; however, there is no information recorded about the number of labels issued on the batch ticket. The nonconformance report that you indicate was added to explain discrepancies between the number of labels used and the number of completed bottles does not address discrepancies between the issuance and use of labels. Your response also states that you have added a label reconciliation procedure; however, it does not address the missing information required to be on your batch records nor does it include written instructions for reconciliation.

- Your BPR failed to include the date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch, or a cross-reference to records, such as individual equipment logs, where this information is retained, as required by 21 CFR 111.260(c). Our inspection found that your BPR did not include this information.
- Your BPR failed to include the identity of equipment and processing lines used in producing the batch, as required by 21 CFR 111.260(b). Specifically, our investigation found that batch records did not include this information. Batch ticket # 8445 failed to identify the blender used on the blend portion or any other portion of the ticket. Batch ticket # 8444, for the capsule filling (manufacturing) portion of the batch does not identify which of the **(b)(4)** capsule presses was used to produce the filled capsules.

Your response states that you have added the equipment and processing lines used to your BPR, and you provided batch ticket #9379 as an example. We will verify that your BPR includes all mandatory elements during our next inspection.

3. You failed to control the issuance and use of packaging and labels, as required by 21 CFR 111.410(b). Specifically, our investigation found that your lot code setting, start up, misalignment and otherwise damaged labels were not kept to be reconciled at the end of the labeling operation, and you employ no control measures to verify that only the correct labels are used in labeling your products. Furthermore, our investigators observed that the quantity of roll stock pressure sensitive labels returned to the label room was inaccurate because the number of labels issued only reflected the number required in the batch ticket.

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.

### **Additional Comments**

We note that our investigator observed several instances in which your firm failed to take all the necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements including segregating and identifying all containers for a specific batch of dietary supplements to identify their contents and, when necessary, the phase of manufacturing. Our investigator observed:

- a) Drums bearing no positive identification or marked with multiple identifications. For example, our investigators observed a drum in the blending room identified with an in-house QC sticker marked as Arginine AKG and "Cleared for Production" was also identified with a printed label identifying the product as Calcium **(b)(4)**.
  
- b) Raw materials in the weigh room that had not been weighed were not segregated from weighed batches ready to move from the weigh room into the blending room, nor were there controls to positively identify each weighed batch. For example, a pallet of fiber drums with three components, identified as Prota-Lynn Whey Hybrid, Karbo-Lyn, and Kre-Alkalyn, used by your firm to add partial quantities to batches containing the components, was placed directly behind a weighed and staged pallet of components in the weigh room identified by the blending batch ticket # 9457. There was no separation and no marking to distinguish the pallet containing the unweighed Prota-Lynn Whey Hybrid, Karbo-Lyn, and Kre-Alkalyn from the weighed components of batch # 9457.
  
- c) An unmarked bottle at the foot of a filling machine being used to fill bottles with the dietary supplement identified as Kre-Alklyn 120 that contained capsules of a different color and size from those being filled. The bottle was identified as being from a previous batch production.

Within 15 working days from your receipt of this letter, please notify this office in writing 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 have completed the corrections.

Your written reply should be sent to the following address: U.S. Food and Drug Administration, Attention: Heidi Marks, Compliance Officer, 22201 23rd Drive SE, Bothell, WA 98021-4421. If you have any questions regarding any issue in this letter, please contact Heidi Marks at (425) 483-4862 or via email at [heidi.marks@fda.hhs.gov](mailto:heidi.marks@fda.hhs.gov).

Sincerely,

/s/

Charles M. Breen  
District Director