



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  
Fax (949) 608-4415

## WARNING LETTER

### **CERTIFIED MAIL RETURN RECEIPT REQUESTED**

W/L 39-11

May 4, 2011

Mr. Valentin Horvath, Owner  
God's Garden Pharmacy  
8280 Clairemont Mesa Blvd Suite 140  
San Diego, CA 92111-1709

Dear Mr. Horvath:

On January 14, 18, and 20 of 2011 the U.S. Food and Drug Administration (FDA) inspected your facility located at 8280 Clairemont Mesa Blvd Suite 140, San Diego, California. Your firm manufactures, packages, labels, and holds dietary supplements. The inspection identified a number of significant violations of the Current Good Manufacturing Practice (CGMP) regulations for Dietary Supplements, Title 21, Code of Federal Regulations (CFR), Part 111.

The inspection revealed that your 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) [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 an FDA-483 at the conclusion of our inspection on January 20, 2011. During the inspection, our investigators also collected labels for your products. Based on our review of these labels, your Quick Action Slim Tea, Prostate Comfort, Cholesterol Tea, and Diabetina Sugar Balance Tea products are misbranded under section 403 of the Act [21 U.S.C. § 343].

You may find the Act and FDA regulations through links at FDA's home page at <http://www.fda.gov>.

The inspection revealed the following violations:

1. Your firm failed to prepare and follow a written master manufacturing record (MMR) for each unique formulation of a dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch, as required by 21 CFR 111.205(a). Our investigators found that you did not prepare an MMR for any of your products.
2. Your firm failed to prepare a batch production record every time you manufacture a batch of dietary supplement, as required by 21 CFR 111.255(a). Our investigators found that no batch production records were prepared.
3. 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 investigators found that your firm did not have written procedures for the responsibilities of your quality control operations.
4. Your firm failed to make and keep records of the written procedures for cleaning the physical plant and pest control, as required by 21 CFR 111.23(b). Our investigators found that no such records were made.
5. Your firm failed to provide hand-washing facilities that are designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature, as required by 21 CFR 111.15(i). Specifically, your hand washing sinks in the restroom and processing area failed to supply hot water.

Your January 26, 2011 response states that you are in the process of preparing written procedures and records to comply with CGMP requirements and that you will restore hot water to your hand-washing facilities. Your response is inadequate because it does not contain documentation that the corrections have occurred.

### **Misbranding**

1. Your Prostate Comfort, Cholesterol Tea, Quick Action Slim Tea, and Diabetina Sugar Balance Tea products are misbranded under sections 403(q)(5)(F) and 403(s) of the Act [21 U.S.C. § § 343(q)(5)(F) and 343(s)]. Specifically:
  - Your Prostate Comfort product is misbranded in that the label did not present nutrition information in a panel titled “Supplement Facts.” [21 U.S.C. 343(q)(5)(F) and 21 CFR 101.36(e)(1)].
  - Your Cholesterol Tea product is misbranded in that the label declares Calcium 2.9 mg with an RDI of <1%. However, because the RDI for this dietary ingredient is less than 2%, it may not be declared [21 U.S.C. 343(q)(5)(F) and 21 CFR 101.36(b)(2)].

- Your Quick Action Slim Tea, Prostate Comfort, Cholesterol Tea, and Diabetina Sugar Balance Tea are misbranded in that their labels fail to identify a part of the plant from which an ingredient is derived in the ingredient statement or in the nutrition label [21 U.S.C. 343(s)(2)(C) and 21 CFR 101.36(d)(1)].
- Your Prostate Comfort product is misbranded in that the label fails to identify the product using the term “dietary supplement” or the name of the dietary ingredient, consistent with the requirements in 21 U.S.C. 343(s)(2)(B) and 21 CFR 101.3(g). A dietary supplement must be identified by the term “dietary supplement” as part of the product’s statement of identity, except that the word “dietary” may be deleted and replaced by the name of the dietary ingredient in the product (see 21 CFR 101.3(g)).

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 written 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 Marco S. Esteves, Compliance Officer, at 949-608-4439.

Sincerely,

/s/

Alonza E. Cruse  
District Director