



Department of Health and Human Services

Public Health Service
Food and Drug Administration
New England District
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WARNING LETTER

NWE-10-11W

VIA UPS Next Day Air

February 16, 2011

Mr. Thomas J. Petrarca, President and CEO
RHG & Company Inc., dba Vital Nutrients
45 Kenneth Dooley Drive
Middletown, CT 06457

Dear Mr. Petrarca:

On August 12, 13, 17-19 and September 1, 2, 2010, the U.S. Food and Drug Administration (FDA) inspected your manufacturing facility located at 45 Kenneth Dooley Drive, Middletown, CT. The investigators noted serious violations of the Current Good Manufacturing Practice (CGMP) regulations for Dietary Supplements, Title 21, Code of Federal Regulations (CFR), Part 111. These violations cause your dietary supplement products PreNatal Multi-Nutrients Capsules, Garlic Extract 300 mg Capsules, Milk Thistle 80% Capsules, and Vitamin D3 5000iu Capsules 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 products 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 September 2, 2010.

Violations observed at your facility include:

1. You failed to conduct appropriate tests to verify that your finished batch of dietary supplements met product specifications for strength, as required by 21 CFR 111.75(c)(2). For example:

a. You failed to test each finished batch of Vitamin D3 5000iu capsules Lots 10F10 and 9M34 to verify it met the finished product specification for strength.

b. You failed to test each finished batch of PreNatal Multi-Nutrient capsules Lot 10B22 to verify it met the finished product specification for strength for molybdenum, beta and total carotenes, biotin, boron, copper, vitamin D, d-alpha tocopherol succinate, vanadium, vitamin K-1, vitamin A acetate, folic acid, manganese, niacinamide, potassium, iodine, pyridoxine HCL, and riboflavin B-2.

c. You failed to test each finished batch of Garlic Extract 300 mg capsules Lot 9K11 to verify it met the finished product specification for strength of garlic extract (12,000 mcg/g Allicin).

We have reviewed your response letter dated November 4, 2010, and concluded that it is inadequate with respect to this violation. Your letter stated that you will conduct full profile finished product testing until you “have adequate data and documentation on file to exempt any testing.” However, you did not provide documentation that you conducted finished product testing of each finished batch of dietary supplement to verify that each batch met the finished product specification for strength and did not provide documentation that your firm is currently conducting such finished product testing for strength.

2. You failed to establish component specifications for each component that you use in the manufacture of a dietary supplement to ensure that specifications for the purity, strength and composition of the dietary supplements manufactured using the components are met as required by 21 CFR 111.70(b)(2). Specifically, your Raw Material Specification Sheet for garlic powder extract 13 mg/g does not provide a specification for strength but instead reads “No scientifically valid method currently exists to quantify active ingredients or marker compounds.” Your finished product specification for strength of garlic extract states the quantity of Allicin that should be present in a 300 mg capsule and you have tested for Allicin concentration in the past. Therefore, you must establish a component specification for the strength of garlic extract (the quantity of Allicin) in the raw material in order to ensure that you will be able to meet the finished product specification for strength of **(b)(4)** Allicin. Further, you must determine whether such specification is met, as required by 21 CFR 111.75(a)(2). To determine whether component specifications are met, you must either conduct appropriate tests or examinations or rely on a certificate of analysis from the supplier of the component provided that certain requirements listed under 21 CFR 111.75(a)(2)(ii) are met.

3. You failed to establish in-process specifications for any point, step, or stage in the Master Manufacturing Record (MMR) where control is necessary to help ensure that specifications are met for the strength and composition of the dietary supplements, as required by 21 CFR 111.70(c)(1). Specifically, you did not include bulk powder density as an in-process specification in your MMR for PreNatal Multi-Nutrients and Milk Thistle 80% capsules. Bulk powder density is directly related to capsule weight which is a finished product specification for these dietary supplement products and can affect both the strength and composition of the finished product. We also note that the Production Notes sections of the Batch Production Record (BPR)

for PreNatal Multi-Nutrients Lot 10B22 and Milk Thistle 80% capsules Lot 10B27 reveal that there was difficulty achieving target capsule weights.

We have reviewed your response letter dated November 4, 2010, and concluded that it is inadequate with respect to this violation. Your letter stated that you do not agree that establishing bulk density of blended product is a workable solution to remediate and control any bulk density issue and have modified your SOP C004 to incorporate control of bulk density for raw materials. Controlling the bulk density of raw materials does not have the effect of controlling the bulk density of the in-process blend. The bulk density of the blend will be different from each of the individual bulk densities of the raw materials. Your response is inadequate because it still does not establish a specification for bulk powder density of the in-process product or propose another suitable in-process parameter to address finished capsule weight issues.

4. You failed to prepare and follow a written MMR for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished product from batch to batch, as required by 21 CFR 111.205(a) For example:

a. PreNatal Multi-Nutrients Capsules Lot 10B22 were manufactured based on a batch encapsulation production record for (b)(4) capsules, "REV. 12/31/09." However, the MMR for this product that was maintained on file at the time of this inspection was "REV. 11/30/05" for (b)(4) capsules. There is no MMR for a batch size of (b)(4) capsules. Further, the batch production record for Lot 10B22 differs from the MMR in blending instructions and production equipment used to produce the dietary supplement.

b. Milk Thistle 80% Capsules Lot 10B27 were manufactured based on a batch encapsulation production record for (b)(4) capsules, "REV. 12/31/09." The Master MMR for this product that was maintained on file at the time of this inspection was "REV. 11/30/05" for (b)(4) capsules. There is no MMR for a batch size of (b)(4) capsules. Further, the batch production record for lot 10B27 differs from the MMR in weighing instructions, blending instructions, production equipment set-up and weight check instructions.

c. Vitamin D3 5000iu Capsules Lot 10F10 were packaged based on a batch production record for bottles of (b)(4) capsules each, "REV. 4/5/10." The MMR for this product/bottle size that was maintained on file at the time of this inspection was "REV. 8/1/03" for bottles of (b)(4) capsules each. However, the batch production record for lot 10F10 differs from the MMR in room setup, labeling setup and in-process monitoring, boxing and completion, and changes in the format for reconciliation calculation.

We have reviewed your response letter dated November 4, 2010, and concluded that it is inadequate with respect to this violation. Your letter stated that starting on October 1, 2010, you began preparing and following a written MMR for each batch size of dietary supplement that you manufacture. However, you did not provide these MMRs and corresponding batch records. We will verify the adequacy of your correction at the time of our next inspection.

5. Your quality control personnel failed to conduct a material review and make a disposition decision when an established specification was not met as required by 21 CFR 111.113(a)(1).

Specifically, your testing of Thiamin in PreNatal Multi-Nutrients Capsules Lot 10B22 revealed a high out-of-specification result for strength of (b)(4) (specification is (b)(4)). No material review was conducted, as required and as per your own procedures (SOP B014 “Finished Product Specifications and Testing Requirements”). This lot was released for distribution on 4/15/10.

We have reviewed your response letter dated November 4, 2010, and concluded that it is inadequate with respect to this violation. Your letter stated that you will ensure that a material review be written and attached to the batch production record when an out-of-specification result is found. You did not explain or provide any documentation of what you have done to ensure that this takes place.

The above violations are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure that the dietary supplement products that you manufacture or distribute meet all applicable requirements of 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.

Additionally, we note that your BPR did not include complete information relating to the production and control of each batch (see 21 CFR 111.255(b)). Specifically, in the BPR for PreNatal Multi-Nutrients capsules Lot 10B22 and Milk Thistle 80% capsules Lot 10B27, in-process (b)(4) were recorded on the set-up (b)(4) sheet instead of the in-process (b)(4) sheet. We also note that you failed to routinely check your equipment to ensure proper performance (see 21 CFR 111.30(c)). Specifically, you failed to check your capsule counters on the two automated encapsulation machines (Machines # 2 and # 3). Your SOP B004 “Mechanical Systems and Production Equipment Maintenance” does not include provisions for checking the accuracy of the capsule counters and the instruction manuals for these machines do not contain instructions for calibration. The counts generated by these machines are used to calculate percent yield which is recorded in the BPR for encapsulated dietary supplements. (b)(4) must be recorded on the correct pages and machines must be routinely checked.

You must notify this office in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations and to assure that similar violations will not recur in the future. Your response should include any documentation to show that correction has been achieved. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Address your reply to the U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180, Attention: Amber Wardwell, Compliance Officer.

Sincerely,
/S/
Mutahar S. Shamsi
District Director
New England District