



**CERTIFIED MAIL**  
**RETURN RECEIPT REQUEST**

**WARNING LETTER**

**FLA-04-21**

March 5, 2004

Ms. Victoria M. Morton  
President & Owner  
VMM Enterprises, Inc.  
172 N. Belcher Road  
Clearwater, FL 33765

Dear Ms. Morton:

Inspections conducted by the Food and Drug Administration (FDA) on October 2001, April 2002, and August 2003, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). Since the issuance of the FDA 483, Inspectional Observations form, at the 2001 inspection, your firm has failed to address the adulteration issues for your products and continues to operate with almost no adherence to current Good Manufacturing Practice (cGMP) regulations. Analysis of samples collected during the August 2003 inspection shows high microbial, yeast, and mold counts.

While you contend that your firm's body concentrates and powder products are cosmetics or dietary supplements, FDA has determined that they are drugs as defined in section 201(g) of the Act. This conclusion is based on your firm's claims about the products concerning their intended effect on the structure or function of the body (structure/function claims). Structure/ function claims are not permitted for cosmetics. Further, these products cannot be dietary supplements because they are not ingested or used to supplement the diet. Rather, the labeling for these products states they are for body tightening and slimming applications. The drug products that your firm manufactures and distributes, which include, but are not limited to, Gold Water Concentrate Solution, Power Wrap Concentrate Solution, Anti-Aging Wrap Concentrate Solution, Lipase Concentrate Solution, Slender Tone Solution Powder, and MSM Slender Tone Solution Powder are in violation of the Federal Food, Drug, and Cosmetic Act, as follows:

Section 502(j)

A drug shall be deemed to be misbranded within the meaning of section 502(j) if it is dangerous to health when used in the dosage or manner; or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof. Specifically:

- Your raw materials and finished products were analyzed and found to be contaminated with *Pseudomonas aeruginosa* in an earlier inspection. In addition, the analysis of samples collected during the August 2003 inspection shows high counts of microorganisms, yeast, and mold ( $> 10^5$  cfu/g).
- Citricidal and Today's Healthy Solution Liquid Silver are used by your firm as preservatives. Neither of these ingredients is acceptable as a preservative or adequate to control microbial growth. You did not conduct studies or provide data to demonstrate that these ingredients function as preservatives or have antimicrobial properties.
- Your firm's technical bulletins and training sessions instruct your salon licensees to indefinitely retain and store the Body Wrap solutions in a manner (i.e. maintain warm temperatures and reuse the product) that could increase the likelihood of bacterial proliferation in the products.
- A number of salon customers, who had the body wrap treatment, experienced skin rash injuries. State health departments have several reports of customer injuries and some rashes have been diagnosed as caused by *Pseudomonas aeruginosa*.

Section 501(a)(2)(B)

Your products are adulterated within the meaning of section 501(a)(2)(B) of the Act in that the controls and procedures used in their manufacturing, processing, packing, and holding of drugs do not conform to current Good Manufacturing Practice regulations, Title 21, Code of Federal Regulations, parts 210 and 211. Deviations from these regulations include, but are not limited to, the following:

1. Failure to establish procedures designed to prevent objectionable microorganisms in drug products not required to be sterile (21 CFR 211.113(a)).

Specifically, there are no procedures to prevent objectionable microorganisms. In fact, there have been two outbreaks of adverse reactions (rashes) reported in September 2001 and March 2002 by body wrap clients. The drug products were contaminated with *Pseudomonas aeruginosa*.

2. Failure to establish and perform appropriate laboratory testing on the drug products required to be free of objectionable microorganisms (21 CFR 211.165(b)).
3. Failure to establish responsibilities and procedures applicable to the quality control unit (21 CFR 211.22(a)).
4. Failure to establish an adequate control system for incoming components, materials, and container/closures (21 CFR 211.84).

For example, there are no procedures for receipt and storage of components and there is no adequate documentation of the testing and approval or rejection of components, drug product containers, and closures.

5. Failure in laboratory controls to establish scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that the components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity (21 CFR 211.160(b)).

For example, acceptance and release specifications have not been established for components, drug product containers, closures, and finished drug products. Finished drug products also include products manufactured under contract by

- [REDACTED]
6. Failure to perform finished product testing prior to distribution (21 CFR 211.165(a)).
  7. Failure to establish written procedures for production and process control of the drug products in order to assure that the drug products have the identity, strength, quality, and purity they purport to possess (21 CFR 211.100(a)).
  8. Failure to establish complete batch production and control records for each batch of drug product (21 CFR 211.188 (b)).

For example, the batch records do not document that each significant step in the manufacture of the batch was performed. In addition, batch production and control records were missing for lots LW8020625 and PW8020731.

9. Failure to establish complete master production and control records to ensure drug product uniformity from batch to batch (21 CFR 211.186).

For example, the master production and control records lack an accurate statement of the weight or measure of each component used in making body wrap powders.

10. Failure to establish procedures and keep records of cleaning and maintenance of manufacturing equipment (21 CFR 211.67(b) and (c)).
11. Failure to routinely calibrate, inspect, or check automatic, mechanical, and electronic equipment according to a written program designed to assure proper performance (21 CFR 211.68(a)).
12. Failure to provide training to employees in current good manufacturing practice as required by the employee's function (21 CFR 211.25(a)).
13. Failure to establish a stability testing program to assess the stability characteristics of the drug products (21 CFR 211.166(a)).

Specifically, there is no stability data on which to base the expiry or shelf life of any of the drug products.

14. Failure to establish procedures by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary (21 CFR 211.150(b)).
15. Failure to establish written procedures describing the handling of all written and oral complaints regarding a drug product (21 CFR 211.198 (a)).
16. Failure to maintain a written record of each complaint in a file designated for drug product complaints (21 CFR 211.198(b)).

Specifically, there is at least one complaint regarding an alleged reaction to a body wrap treatment for which no record was made and an investigation was not conducted.

We acknowledge receipt of your written response to FDA dated April 12, 2002, June 10, 2002, and July 31, 2003. Your response is inadequate because you did not address any of the CGMP violations or offer any corrective actions to these deviations. Overall, your firm does not demonstrate that your manufacturing process is in a state of control.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that all drug products manufactured and processed at VMM Enterprises, Inc. are in compliance with federal laws and regulations. Failure to promptly correct these violations and prevent future violations may result in regulatory action, such as seizure and /or injunction, without further notice.

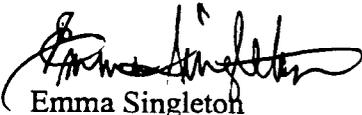
Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step being taken to prevent the recurrence of the violations.

Your reply should be directed to the Food and Drug Administration at the address shown below:

Florida District Office  
555 Winderley Place, Suite 200  
Maitland, FL 32751

If you have questions or concerns regarding this letter, please contact Shari H. Shambaugh, Compliance Officer, at 407-475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton". The signature is fluid and cursive, with a large initial "E" and "S".

Emma Singleton  
Director, Florida District Office