	Scottsdale, AZ 85255-5466
Phone:	480-927-8648
FAX:	480-927-8988
Mailing address:	8322 E Hartford Dr Scottsdale, AZ 85255-5466
Dates of inspection:	11/29/2012, 11/30/2012
Days in the facility:	2
Participants:	Natalie J. Ayoub, Investigator

On 11/29/12, I went to Vemma Nutrition Company, Inc. located at 8322 E. Hartford Dr., Scottsdale, AZ 85255. I showed my credentials and issued an FDA-482 Notice of Inspection to Allison J. Tengan, Vice President and most responsible person of the firm at the time this form was issued.

HISTORY

The firm has been in operation since 2004 and was incorporated on 09/09/04 in Arizona. The firm has (b) (4) distribution sites (b) (4) (b) (4). The location inspected, 8322 E. Hartford Dr., Scottsdale, AZ 85255 is the corporate location. The corporate location is made up of business offices, Research and Development area, and a retail facility for customers to pick up orders.

The firm is an own label distributor of dietary supplement beverages. A product brochure that includes all their current products can be seen in Exhibit 1.

The firm uses 3 different contract manufacturers for their products:

1) (b) (4)
2) (b) (4)
3) (b) (4) (b) (4) the firm's main contract manufacturing facility is AZ Production and Packaging.

The hours of operation for the office are (b) (4). The facility employs (b) (4) office and administrative employees. The firm is a registered food facility.

Any correspondence should be addressed to:
B.K. Boreyko, CEO
8322 E Hartford Dr.
Scottsdale, AZ 85255-5466

INTERSTATE COMMERCE

The firm ships approximately (b) (4)% of their product to the states of (b) (4) and (b) (4). The firm sells (b) (4)% wholesale.

Products are manufactured, packaged, and labeled at the firm's contract manufacturers in Arizona, then shipped directly to a 3rd party warehouse (b) (4) The company is a multi-level marketing company. Therefore, orders made by the brand partners are shipped directly to them or to the corporate location where the brand partners can pick up the products they ordered.

The corporate location is responsible for marketing and advertising. The products are promoted online and through their brand partners.

JURISDICTION

According to Mr. Wayment, the firm's contract manufacturer is responsible for ordering all raw materials, conducting component testing based on the Certificate of Analysis, conduct identity testing, and conducting finished product testing. The firm's contract manufacturer is required to release all finished product based on finish product test results. (b) (4) (b) (4) (b) (4) (b) (4) Any returned dietary supplements are shipped and quarantined at the firm's corporate location. The firm does not have a quality agreement with their contract manufacturers.

Vemma creates the formula for their products and works with their contract manufacturers to create the master manufacturing record. Vemma is also responsible for creating and approving all labels. All of the firm's labeled are under the brand name Vemma. The firm's brochure (Exhibit 1) shows labels and labeling for all of the firm's products.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

On 11/29/12, I went to Vemma Nutrition Company, Inc. located at 8322 E. Hartford Dr., Scottsdale, AZ 85255. I showed my credentials and issued an FDA-482 Notice of Inspection to Allison J. Tengan, Vice President and most responsible person of the firm at the time this form was issued.

The following employee assisted me during the inspection:
Brad G. Wayment, COO – He has been working for the company for approximately 3 years. He reports directly to the CEO, BK Boreyko. He has the authority to authorize expenditures, hire and fire employees, change the business operations. He was the primary source of information contained in the report and accompanied me during the inspection.

MANUFACTURING/DESIGN OPERATIONS

Quality Control

Mr. Wayment informed me that the corporate office's Research and Development (R&D) team is also the firm's Quality Assurance employees.

Vemma is responsible for creating specifications regarding the product. Vemma's R&D team works with the contract manufacturer to create the formulations and specifications for each finished product.

The firm is in the process of reviewing and implementing written procedures that are required under 21 CFR 111 (Refer to **Discussion with Management section Item #1**). The firm provided me with written procedures; however, they have not been signed into implementation.

The firm's written procedure, SOP XX. Preparation, Review, and Approval of New and Revised Labels, can be seen in Exhibit 2. The firm does conduct a quality control review of all labeling. A review of label approval documentation and their master labels for Verve, Verve Zero Sugar, and Vemma Mangosteen was conducted. The labels are reviewed and approved by multiple different departments. No discrepancies were noted.

Vemma Nutrition Company supplies their contract manufacturer with film labels, so that they can conduct labeling operations. The contract manufacturer is responsible for conducting on-site label review of the products.

Holding and Distribution

The firm uses a 3rd party warehouse for holding and distribution operations. The firm's 3rd party warehouse is responsible holding the supplements under appropriate conditions.

Distribution records are maintained at the facility and can be tracked via the firm's computer programs.

Reserve samples are maintained at the firm's Research and Development office and at the contract manufacturer's site.

Returned Dietary Supplements

The firm's written procedure, SOP XI – Product Return Procedure, can be seen in Exhibit 3. (Refer to **Discussion with Management section Item #1**)

The firm accepts returned dietary supplements. Upon receiving, returned dietary supplements are quarantined. Returned dietary supplements are reviewed by Quality Assurance for an appropriate disposition decision regarding the product.

Returned dietary supplements used to be sent to the firm's distribution center (b) (4) (b) (4) as of the week of the inspection, week of November 26, all returned dietary supplements are now sent to the corporate office.

Product Complaints

The written procedure, SOP IX – Customer Complaint Procedures, can be seen in Exhibit 4. The firm's written procedures for handling complaints was still being reviewed and not yet signed into implementation (Refer to **Discussion with Management section Item #1**).

Complaints are received by an administrative employee and documented on a (b) (4) Action Request form. The firm does not conduct a review and investigation into the problem (Refer to **Observation #1**).

A review of the firm's (b) (4) Action Request forms for the month of October was reviewed. According to the firm's written procedure for handling complaints, which was not signed into implementation yet, complaints regarding failed specifications, illness, allergic reactions, and hospitalization will result in further investigation.

Adverse Events

The firm has written procedures regarding handling an adverse event in the same SOP as their complaints SOP (Exhibit 4). According to Mr. Wayment, the firm has not received any serious adverse events.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

The FDA 483 was issued to Brad G. Wayment, Chief Operating Officer, who is the most responsible person at the time of issuance. I read the introductory paragraph on the FDA-483 form. I explained these were my observations and that upon further review they could be found to be violations to FDA regulations. I also explained regulatory sanctions available to the agency should the firm fail to correct violations to FDA regulations. The firm intends to send a written response within 15 business days.

Observations listed on form FDA 483

OBSERVATION 1

Your quality control personnel did not review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of an investigation.

Specifically, your complaint handling system does not include conducting an investigation when necessary. Additionally, a quality control disposition decision regarding whether to conduct an investigation, investigational findings, and follow-up action of the investigation is not conducted.

Reference: 21 CFR 111.560(b)

Supporting Evidence and Relevance:

An administrative employee will document complaints received from their Brand Partners (BP) in a Member Services Action Request form. Administrative documentation of calling the Brand Partner and giving them a refund is documented; however, the firm does not have any documentation of a review conducted by quality control personnel.

The firm received complaints regarding the following issues:

- Allergic reactions (Exhibit 5)
- Hospitalization/Doctor visit (Exhibit 6)
- Diarrhea/Upset stomach (Exhibit 7)
- Vomiting/Made sick (Exhibit 8)
- Swelling of joints (Exhibit 9)
- High blood pressure/heart race (Exhibit 10)

The firm has no documentation of an investigation, review, and disposition decision involving any of the complaints. I informed Mr. Wayment that conducting a review and investigation is critical to the health and safety of the consumers. For example, complaints resulting in an allergic reaction may have resulted from labeling issues or employee handling issues. However, if the complaint is never investigated then corrective actions will not be implemented and the potential issue will continue to occur resulting in more allergic reactions.

I reminded Mr. Wayment that any serious adverse event reports should be reported via Medwatch.

Discussion with Management:

Mr. Wayment stated that the firm will send in a written response within 15 days to address the observation.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

The following discussion item was discussed with the firm during the inspection and close out meeting:

1) None of the firm's written procedures are reviewed and signed into implementation by quality control personnel. Mr.Wayment was able to supply me with in-process written procedures; however, they have not been implemented yet. He stated that the firm has been working on establishing, reviewing, and implementing written procedures in regards to the dietary supplement regulations (b) (4)

SAMPLES COLLECTED

No samples were collected.

EXHIBITS COLLECTED

1. Vemma Product Brochure.
2. SOP XX - Preparation, Review, and Approval of New and Revised Labels.
3. SOP XI – Product Return Procedure.
4. SOP IX – Customer Complaint Procedures.
5. Complaints regarding allergic reactions.
6. Complaints regarding Hospitalization/Doctor visit.
7. Complaints regarding Diarrhea/Upset stomach.
8. Complaints regarding Vomiting/Made sick.

9. Complaints regarding swelling of joints.
10. Complaints regarding high blood pressure/heart race.

ATTACHMENTS

1. FDA 482, Notice of Inspection, issued to Allison J. Tengan, Vice President, on 11/29/12.
2. FDA 483, Inspectional Observations, was issued to Brad G. Wayment, Chief Operating Officer, on 11/30/12

Natalie J. Ayoub, Investigator

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	11/29/2012 - 11/30/2012
	FEI NUMBER 3005675718

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Brad G. Wayment, CEO

FIRM NAME	STREET ADDRESS
Vemma Nutrition Company, Inc.	8322 E Hartford Dr
CITY, STATE, ZIP CODE, COUNTRY Scottsdale, AZ 85255-5466	TYPE ESTABLISHMENT INSPECTED Own Label Distributor for Dietary Supplements

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Your quality control personnel did not review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of an investigation.

Specifically, your complaint handling system does not include conducting an investigation when necessary. Additionally, a quality control disposition decision regarding whether to conduct an investigation, investigational findings, and follow-up action of the investigation is not conducted.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Natalie J. Ayoub, Investigator	DATE ISSUED 11/30/2012

VeMMA

VIA OVERNIGHT MAIL

December 11, 2012

Mr. Alonza Cruse
District Director
Food and Drug Administration
Department of Health and Human Services
19701 Fairchild
Irvine, CA 92612

Re: File Number 3005675718

Dear Mr. Cruse,

Vemma Nutrition Company ("Vemma") acknowledges receipt of the inspectional observations issued to our Chief Operating Officer, Brad Wayment on November 30, 2012. Unfortunately, I was unable to be in the office during the investigation; however, it was my understanding that during the investigation, Investigator, Natalie Ayoub, was provided with excerpts from our new Good Manufacturing Practices Standard Operating Procedures. This included excerpts related to product returns, label review, and customer complaints. Ms. Ayoub was also provided with a Vemma product catalogue. In case I am mistaken about what was provided, I have cited below relevant excerpts from our current complaint handling procedures.

The Standard Operating Procedures ("SOP's") related to the Customer Complaint Procedure provides detailed direction regarding complaint investigation and the need for Quality Assurance to decide whether to conduct an investigation and who to involve in such investigation. The SOP's also provides direction regarding the investigational findings.

In this regard, section IX of our Good Manufacturing Practices SOP's, Customer Complaint Procedure, provides as follows:

4.4 QA is responsible for reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings and follow up action of any investigation performed.

4.5 QA is responsible for notifying contract manufacturers of product complaints that involve a possible failure of a dietary supplement to meet any of its specifications or any requirement of 21 CFR 111. QA is also responsible for ensuring the appropriate investigation is performed and documented by the contract manufacturer and to review and approving the findings.

4.6 QA is responsible for designating which department(s) (b) (4) will assist with the investigation.

4.7 QA will be responsible for issuing responses to the parties, which could involve assisting the Member Services employees or the Research and Development ("R&D") employees in responding directly to the consumer when required.

4.8 QA is responsible for closing complaints.

4.9 QA is responsible for the retention of records.

4.10QA is responsible for publishing (b) (4) *Complaints Report and identifying and addressing any trends that may arise through the CAPA program.*

5.8 Determine if the complaint involves a possible failure of the product to meet any of its specifications (21 CFR 111.560(a)(1)).

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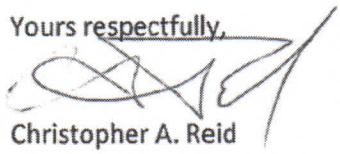
If these Good Manufacturing Practice SOP's are deficient in any way, please contact me as soon as possible. I can be reached at chris@vemma or on my cell phone, (b) (4) .

Yours respectfully,



Christopher A. Reid
General Counsel
Vemma Nutrition Company