Establishment Inspection Report	FEI:	**1317302**
Marietta Corporation	EI Start:	08/18/2008
Cortland, NY 13045-3096	EI End:	08/19/2008

SUMMARY OF FINDINGS

Inspection of this firm was conducted as part of the FY 08 workplan under FACTS assignment #951846 as per a CFSAN-issued assignment for inspections to be conducted during the 4th quarter of FY08 under the Dietary Supplement Current Good Manufacturing Practice Regulations, 21 CFR Part 111. Pac code 21008A was utilized for reporting. As per the assignment, inspectional coverage was limited strictly to the firm's operations related to dietary supplements. This particular firm was selected for inspection based on the number of employees it employs. The compliance date for the regulations under 21 CFR Part 111 is based on the number of full-time equivalent employees. Firms with 500 or more employees are required to comply with the new regulations as of 6/25/08.

The previous inspection of this firm was conducted 1/28-2/5/08 and was classified as VAI. As directed by the assignment issued by CFSAN, follow-up to the FDA-483 issued at the previous inspection was not conducted as this was a limited coverage inspection conducted under the new dietary supplement regulations.

The firm continues to operate primarily as a contract manufacturer, packager and repacker of various cosmetic products, including shampoos, conditioners, soaps and lotions. The firm also packages one dietary supplement product, (b) (4) , under contract for (b) (4) (b) (4)

The current inspection covered the firm's receipt and packaging of the (b) (4) which are received from drums and repackaged by Marietta Corporation.

A FDA-483, Inspectional Observations, was not issued. No samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	Marietta Corporation
Location:	37 Huntington St
	Cortland, NY 13045-3096
Phone:	607-753-6746
Mailing address:	37 Huntington St
	Cortland, NY 13045-3096
Dates of inspection:	8/18/2008, 8/19/2008
Days in the facility:	2
Participants:	Linda M. Sacco, Investigator

INITIAL INTERVIEW

Credentials were displayed and a FDA-482, Notice of Inspection, was issued to Allen D. Schaar, CEO and most responsible person at this location. Mr. Schaar directed that Robin S. Bushnell, QA Director, be present for the inspection and provide all information necessary during the course of the inspection. Ms. Bushnell was present for the entire inspection and provided all information relevant to this firm and its operations as they relate to dietary supplements.

It was determined that this firm is owned by a holding company, Ares Corporation- Los Angeles, CA. Marietta Corporation has 5 sites in the U.S. as follows: Huntington St., Cortland, NY (approximately (b) (4) employees); Central Ave., Cortland, NY (approximately (b) (4) employees); Olive Branch, MS (approximately (b) (4) employees); Chicago, IL (approximately (b) (4) employees); and Los Angeles, CA (approximately (b) (4) employees). As directed by the inspectional assignment, based on the total number of employees employed by Marietta Corporation, the firm was subject to inspection under the new dietary supplement regulations. As of 6/25/08, the firm is required to comply with 21 CFR Part 111, Dietary Supplement Current Good Manufacturing Regulations.

Marietta Corporation, Huntington Ave., Cortland, NY packages (b) (4) for (b) (4). The firm has been performing this under contract for (b) (4) for approximately (b) (4) years. The firm packages this product approximately (b) (4) times per year. March 2008 was the last date repackaging of this item was performed. The firm has not repackaged this product since the regulations went into effect for this firm (6/25/08). There were no records to review since the compliance date of 6/25/08 so a walk-through inspection of the packaging room and storage areas was conducted and SOPs with respect to dietary supplement operations were reviewed in detail with the firm.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Allen D. Schaar, CEO, is the most responsible person at this location. Mr. Schaar has been employed by Ares Corporation for several years and was appointed CEO of Marietta Corporation approximately 4 months ago.

Several changes in top management have taken place since the previous inspection. Mr. Schaar replaced Brian Jones as CEO. (b) (4), is no longer employed by the firm and the position has been eliminated. (b) (4), is no longer employed by the firm as of February, 2008.

Kevin E. Hill serves as Plant Manager of this facility. Mr. Hill was absent for the inspection. David Moreau, Engineer, was present for the walk-through portion of the inspection in the absence of Mr. Hill. Mr. Moreau reports to Mr. Hill.

Robin S. Bushnell, QA Director, accompanied me throughout the entire inspection and provided relevant information with respect to the firm and its dietary supplement operations. Ms. Bushnell is the QA Director for both Marietta plant locations in Cortland, NY. She reports directly to David Hempson, Senior Vice President-Quality Assurance.

Organizational charts are attached as Exhibit #1.

This location serves as the corporate headquarters for Marietta Corporation. Annual corporate sales are estimated at $(b) (4).

PERSONNEL, PHYSICAL PLANT AND EQUIPMENT/UTENSILS

Subpart B-Personnel

The firm has adequate SOPs in place for preventing microbial contamination and hygienic practices for employees. The firm's production employees participate in the following training courses throughout the course of their employ with the firm: orientation training, microawareness training, GMP training as well as GMP refresher training, participation in case studies, and audit training.

I reviewed training documentation for 2 employees who work specifically on the dietary supplement packaging line. Records appeared adequate and included dates of training and the type of training.

Robin S. Bushnell serves as the firm's QA Director. She is a former laboratory manager with the firm and has been employed at the firm for over 15 years. Ms. Bushnell currently oversees the microbiology and analytical laboratories, document control, incoming inspection technicians, line technicians, and compliance management. Ms. Bushnell has approximately (b) (4) quality personnel under her direction in the QA department but not all are direct reports to her. All QA personnel receive the general job training given to all Marietta employees as well as job-specific training both through SOPs and on the job training. Qualifications are based on the job functions the employees are hired to perform. Curriculum Vitae are maintained for all QA employees.

Subpart C-Physical Plant and Grounds

Written procedures were reviewed for cleaning operations as well as pest control. Procedures appeared adequate. A walk-though of the plant and the dietary supplement packaging room revealed that the written procedures for cleaning are followed. (b) (4) handles the firm's pest control inside and outside the building. The plant manager is responsible for interpreting and implementing the pest control procedure and the QA Director is responsible for enforcing the procedure. The firm

employs a Director of Environmental Health and Safety which is a corporate position. This person qualifies as the sanitation supervisor. Marietta employs a full-time cleaning staff and they report to the Building Maintenance Supervisor.

Subpart D-Equipment and Utensils

The firm utilizes one dedicated line to perform the packaging of the (b) (4) and the line is located in a room dedicated to that particular line and the packaging of the (b) (4) product.

The firm has been packaging the (b) (4) product for (b) (4) for approximately [redacted] years and follows stringent SOPs related only to that particular product as well as stringent SOPs and oversight provided by (b) (4) themselves. It was confirmed that there are sufficient controls in place to assure that changes are approved by QC personnel and that they are instituted by authorized personnel. There are also sufficient controls in place to ensure the equipment functions in accordance with its intended use.

Written procedures are in place for calibrating instruments, controls and equipment used in the packaging of the dietary supplement. I specifically reviewed the following documents: M155-Vacuum Tester Calibration; M104- Calibration of Production Packet/Bottle Balances, Case Scales and Retail Production Line Scales; and M088- (b) (4) Temperature/Humidity Char t recorder Calibration Procedure.

The temperature/humidity chart recorder is monitored and values are recorded during the course of the packaging process at the beginning, middle and end of each shift at minimum.

I confirmed that the firm has written cleaning procedures for cleaning, sanitizing, and maintenance of all equipment, utensils and contact surfaces utilized in the packaging of dietary supplement products.

PRODUCTION AND PROCESS CONTROLS SYSTEMS

Subpart E-Requirements to Establish a Production and Process Control System

Marietta Corporation receives (b) (4) in finished bulk form. The product is received in (b) (4) drums with plastic liners. A temperature tail that tracks temperature and humidity curing shipment is attached to each drum. The product is received from Wyeth locations in Puerto Rico and Philadelphia, PA. Shipments can be as small as (b) (4) or as large as [redacted] (b) (4). Marietta Corp. has not packaged (b) (4) since March 2008.

(b) (4) sends a Certificate of Analysis with each shipment of tablets. Upon receipt, Marietta Corp. monitors the temp tails attached to each drum and physical tablet standards such as color and appearance. Samples are then collected by Marietta QA staff and forwarded to (b) (4) for assay testing. According to Ms. Bushnell, (b) (4) tests for items such as (b) (4) content to assure that product hasn't degraded in transit.

The tablets are packaged in film; (b) (4) (b) (4). Examples of packaging are attached as Exhibit #2.

Production machine operators are responsible for in-process inspections. The inspections are performed every (b) (4) minutes, +/- (b) (4) minutes, during line running time. Seal integrity testing; humidity monitoring; and verification of label control numbers on the shipping case, display box and pouch film are performed during the course of production. The machine operator is responsible for completing the production batch record, ensures the accuracy of the batch record and signs off on the batch record. The production supervisor/group leader reviews the entire record and signs the batch record. The document is then reviewed by QA personnel in the document control department before the product is released.

The following documents were reviewed during the course of the inspection with respect to production and process controls:

M030- Document and Change Control Procedure
M060- Validation Procedure
M101-4- Incoming Inspection of Secondary Packaging Components
M257- Inspection Quality Levels/Finished Goods
M262- Batch Record Review
M101-2- Incoming Inspection of Film
M101-6- Incoming Inspection of Labels

The SOPs reviewed appeared adequate with respect to 21 CFR Part 111.

The firm collects retention samples that are pulled periodically during the course of a production run. The retain samples are stored in a temperature and humidity controlled room.

Subpart F-Quality Control

I verified that the firm has written procedures in place for quality control operations. During the course of the inspection I confirmed through the review of QA SOPs that QC performs the following: review and approval of documentation with respect to supplier qualifications (in this

case, [redacted]); meeting in-process and finished product packaging specifications; review and approval of calibration of instruments and records; inspection of tablets and secondary packaging components upon receipt; approval and release from quarantine the finished ingredients, packaging and labeling to be used in production of the finished product; and final review of all packaging and labeling batch records before release of finished product.

I verified that production packaging and labels are stored in a locked, secure area that is accessible only to QA.

Once the product is packaged and in its final state, Marietta Corp. returns the product to [redacted]. Marietta Corp. does not distribute the product any further.

According to Ms. Bushnell, the finished [redacted] dietary supplements have never been returned for reprocessing to Marietta Corporation for any reason.

Product complaints are received through [redacted]. If the complaint has to do with the packaging of the product, the complaint is forwarded by [redacted] to Marietta Corp. and an investigation is initiated.

Subpart G-Components, Packaging and Labeling

I verified that the firm does comply with the requirements for packaging and labels received including the examination, quarantine, QC review and approval, collection of representative samples and use of identifiers to allow for trace back of each unique lot. The firm keeps records including written procedures, receiving records, and documentation that each of steps was performed.

The [redacted] are received in bulk and packaged under one purchase order but under multiple Marietta Corp. assigned lot numbers. The lot numbers change daily (if the production run lasts more than one day) and QC testing is performed on each lot. [redacted] determines the unit code and expiration date for the [redacted] product packaged under contract by Marietta. The unit code designated by [redacted]. Marietta assigns a unique lot number which is stamped on the outside cardboard shipping case.

Subpart H-Master Manufacturing Record

Marietta Corp. is not a manufacturer of dietary supplements. They package and label one dietary supplement finished product for [redacted]. A master manufacturing record is not in place.

Subpart I-Batch Production Record

I confirmed through SOP review and discussions with the firm that the firm is in compliance with the requirements for batch records under 21 CFR Part 111. I was unable to review a representative number of batch records from the date of implementation of the new regulation because the firm has not packaged any dietary supplements since the implementation date of 6/25/08. March 2008 was the last time this product was packaged by Marietta Corp.

Subpart J-Laboratory Operations

Marietta Corp. performs physical tablet standards such as color and appearance. Samples are collected by Marietta QA staff and forwarded to (b) (4) for assay testing.

Subpart K-Manufacturing Operations

See Packaging and Labeling Operations; Subpart L.

Subpart L-Packaging and Labeling Operations

I reviewed the firm has written procedures in place for control, issuance and reconciliation of labels; assurance that products are not contaminated during packaging and labeling operations; and assignment of lot numbers. SOPs appeared adequate.

Subpart M-Holding and Distributing

The firm has written procedures regarding the holding of product before and after packaging and labeling operations are performed. The procedures appear adequate to assure that product is held under appropriate conditions so the identity, purity, strength, and composition of the dietary supplement are not affected.

PRODUCT COMPLAINTS AND RETURNS

Subpart N-Returned Dietary Supplements

Procedures are in place in the event a dietary supplement product was returned to the firm.

Subpart O-Product Complaints

The firm has procedures in place for handling product complaints and they appear adequate. Product complaints are received through (b) (4). If the complaint has to do with the packaging of the product, the complaint is forwarded by (b) (4) to Marietta Corp. and an investigation is initiated. There were no product complaints to review.

RECALL PROCEDURES

The firm has recall procedures in place in the event a dietary supplement product would need to be recalled. Mock recalls are performed yearly.

GENERAL DISCUSSION WITH MANAGEMENT

A closing discussion was held with Ms. Robin S. Bushnell, QA Director. I informed Ms. Bushnell that no observations were noted with respect to dietary supplement operations during the inspection and a FDA-483, Inspectional Observations, would not be issued to the firm. I noted that the firm was prepared for the implementation of the new dietary supplement GMP regulations that became effective for Marietta Corporation on 6/25/08.

No samples were collected. The inspection was concluded.

ATTACHMENTS

FDA-482, Notice of Inspection

EXHIBITS

1. Organizational Charts
2. Example of product packaging

Linda M. Sacco, Investigator