TABLE OF CONTENTS

SUMMARY

Inspection was conducted in accordance with HFS-615 Assignment Memo dated 6/30/08 "Inspections to be Conducted Under the Dietary Supplement Current Good Manufacturing Practice Regulations (21 CFR Part 111)" (FACTS Assignment 951846), FLA-DO FY 08 Work plans, under Compliance Program 7321.008, Domestic and Import Dietary Supplements. Inspection focused on production and process controls for Naturalist Milk Thistle Complex, and Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength.

Previous 10/3-9/2001 inspection was classed NAI, no FDA-483 was issued.

Current inspection was the initial inspection of this firm under the Dietary Supplement cGMPs, 21 CFR Part 111. The inspection covered specific categories listed in the Assignment Memo, which included, but was not limited to the receipt of raw materials, testing, storage, manufacturing, packaging, labeling, and distribution of finished products, and quality assurance activities related to

the aforementioned operations. The inspection resulted in issuance of FDA-483 to Raymond Stadnick, Vice President, Quality Compliance, listing the following:

1. Failure to keep documentation of the date of use, cleaning and sanitizing of equipment used to prepare coating solutions for dietary supplement tablets. The last entry by the operator on the cleaning log for the Solution Prep Room was 7/26/2008. Coating solutions were prepared routinely in this room after 7/26/2008, and as recent as 8/27/2008.
2. Batch production records did not include the actual results obtained during a monitoring operation. Records for monitoring raw materials ("Raw Material Dispensing Sheet") in the Weigh Room did not include each partial raw material weight and the identification of the equipment used.
3. Personnel did not use hygienic practices to the extent necessary to protect against contamination of dietary supplement ingredients.
    a. Personnel did not wear outer garments in a manner that protected against contamination of dietary supplement ingredients.
    b. Personnel used gloves that were not clean or stored in a sanitary condition.

Discussion Items not listed on the FDA-483:

Batch records did not contain required documentation of cleaning performed or a cross reference to the cleaning logs. Mr. Stadnick stated that he would add a cross reference to the batch records to comply with this requirement.

(b)(4)

The firm's Raw Material Specification and Evaluation Report for [redacted] Component #10623 shows the method of identification testing as "HPLC", but the firm actually uses UV for this test. Mr. Stadnick had the form changed to reflect the actual method. He said that the firm planned to switch to HPLC when they obtain the appropriate standard.

The MMR's contained specifications for each step in the manufacturing process but did not include examples of the product labels. Mr. Stadnick stated that an example of product labels would be included in the MMR's.

Mr. Stadnick stated that the firm would address the deficiencies discussed during the inspection. Corrective actions completed during the inspection included writing new SOPs for all three items listed on the FDA-483, and providing individual training on these procedures. Sanctions available to FDA were discussed with Mr. Stadnick.

Follow-up investigation was conducted for several complaints listed on the FACTS Assignment. An Alert brochure and wallet cards were provided to the firm's management and food defense was discussed. There were no refusals. No samples were collected.

ADMINISTRATIVE DATA

Inspected firm:	NBTY Inc. dba NBTY Rexall Sundown
Locations:	• 901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528 (Manufacturing Plant): FEI 1047582 • 1111 SW 30th Avenue, Deerfield Beach, FL 33442 (Raw Material Warehouse / Quarantine / Packaging): FEI 3003762014 • 1297 Clint Moore Road, Boca Raton, FL 33487 (Finished Product Distribution / Returned Goods Warehouse): FEI 3000203614
Phone:	561 999-2400
FAX:	561 999-6800
Mailing address:	901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528
Dates of inspection:	8/25, 8/26, 8/27, 8/28, 8/29, 9/5/08
Days in the facility:	6 days
Participants:	Mary F. Bodick, Investigator Susan M. Turcovski, Supervisory Investigator

NBTY Inc. dba NBTY Rexall Sundown (referred to in this report as NBTY Rexall) operates out of three separate locations: 901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528 (Manufacturing Plant) referred to in this report as Building 901; 1297 Clint Moore Road, Boca Raton, FL 33487 (Finished Product Distribution / Returned Goods Warehouse) referred to in this report as Building 1297; and 1111 SW 30th Avenue, Deerfield Beach, FL 33442 (Raw Material Warehouse / Quarantine / Packaging) referred to in this report as Building 1111. Inspection was performed at all three locations due to their interrelated processing operations.

On 8/25/08, federal credentials were displayed and FDA-482, Notice of Inspection was issued to Gentry E. Ellis, Manufacturing Manager, 901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528 (Manufacturing Plant). Mr. Ellis was the most responsible individual present at the firm by his own admission. Mr. Raymond (NMI) Stadnick, Vice President, Quality Compliance, arrived at the firm later that day. Mr. Stadnick stated that he was designated by the NBTY corporate office to be the primary contact for FDA inspections. Credentials were displayed to Mr. Stadnick, and he directed personnel to provide information to the inspectional team.

On 8/25/08, I discussed the ALERT initiative and provided Mr. Stadnick with 3 brochures, 3 wallet cards, and a printout from FDA's website dated July 17, 2006 entitled Food Defense and Terrorism, ALERT: The Basics.

On 8/28/08, federal credentials were displayed and FDA-482, Notice of Inspection was issued to Michael E. Ollry, Distribution Manager, NBTY Inc. dba Rexall Sundown, 1297 Clint Moore Road, Boca Raton, FL 33487 (Finished Product Distribution / Returned Goods Warehouse).

On 8/29/08, federal credentials were displayed and FDA-482, Notice of Inspection was issued to Dennis P. Callaway, Assistant Manager, NBTY Inc. dba Rexall Sundown, 1111 SW 30th Avenue, Deerfield Beach, FL 33442 (Raw Material Warehouse / Quarantine / Packaging).

On 9/5/08, FDA-483, Inspectional Observations, was issued to Raymond (NMI) Stadnick, Vice President, Quality Compliance.

This report was written by Mary F. Bodick, Investigator.

HISTORY

According to Mr. Stadnick, Rexall was acquired by NBTY on July 23, 2003. Mr. Stadnick provided a list of all NBTY Divisions and Brands located throughout the U.S. **(Exhibit #1)**. Included in the list are divisions: Rexall Sundown, Nature's Bounty, Puritan's Pride and Vitamin World. Brands include Metrx, CarbSolutions, Disney, Osteo Bi-Flex, Sundown, Naturalist and Puritan's Pride. Mr. Stadnick also provided a list of NBTY locations that includes manufacturing, packaging, distribution, and offices **(Exhibit #2, 2 pages)**. It was reported by Mr. Stadnick that NBTY Inc. is the official name for the Boca Raton, Florida facility.

The firm's corporate filing information and annual reports are on the attached printouts from Florida Department of State website, www.sunbiz.org **(Attachment #1, 16 pages)**. The firm has four active filings:

- NBTY Acquisition, LLC, filed 06/26/2008, state of Delaware, mailing address 2100 Smithtown Avenue, Ronkonkoma, NY 11779, no annual report, no officers listed. (pages 1-7)
- NBTY Manufacturing, LLC, filed 08/19/2003, state of Delaware, mailing address 2100 Smithtown Avenue, Ronkonkoma, NY 11779, annual report dated 3/5/2008, officers: Joseph Looney (P), Hans Lindgren (SMGR), Harvey Kamil (MGRM). (pages 8-10)
- Rexall, Inc., filed 01/13/2003, state of Florida, mailing address 2100 Smithtown Avenue, Ronkonkoma, NY 11779, annual report dated 3/11/2008, officers: Hans Lindgren (SD), Harvey Kamil (PD). (pages 11-13)
- Rexall Sundown, Inc. filed 07/11/2003, state of Florida, mailing address 2100 Smithtown Avenue, Ronkonkoma, NY 11779, annual report dated 3/5/2008, officers: Harvey Kamil (PD), Hans Lindgren (SVD), Joseph Looney (VAS). (pages 14-16)

Mr. Stadnick provided a copy of the firm's Florida operations Organizational Charts, **Exhibit #3, 8 pages.**

The three firm locations (Building 901, manufacturing; Building 1111, raw material/packaging; Building 1297, distribution/returned goods) are each registered in accordance with The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Hours of Operation:

- 901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528: Manufacturing, three shifts, Monday-Friday, 7:00 a.m. – 3:30 p.m.; 3:00 p.m. – 11:30 p.m.; 11:00 p.m. – 7:30 a.m.; Sunday shift 11:00 p.m. – 7:30 a.m. (Monday); Friday last shift ends at 11:30 p.m. The laboratory works 1st shift, Monday-Friday, and on Saturday (hours determined by analysis requirements).

- 1111 SW 30th Avenue, Deerfield Beach, FL 33442: Packaging, two shifts, Monday-Friday, 7:00 a.m. – 3:30 p.m.; 3:30 p.m. – midnight.

- 1297 Clint Moore Road, Boca Raton, FL 33487: Distribution, two shifts, Monday-Friday, 7:00 a.m. – 3:00 p.m.; 3:00 p.m. – 11:30 p.m.

Correspondence should be addressed to: Raymond Stadnick, Vice President, Quality Compliance, NBTY Inc. dba NBTY Rexall Sundown, 901 Broken Sound Parkway NW, Boca Raton, FL 33487-3528. A copy of any correspondence should also be sent to: Hans Lindgren, Senior Vice President/Director of Operations, NBTY Manufacturing LLC, 2100 Smithtown Avenue, Ronkonkoma, NY 11779.

INTERSTATE COMMERCE

According to Mr. Stadnick, the firm distributes [redacted] of its products in interstate and sells all products in the wholesale market. Examples of customers include [redacted] (b)(4) branded products.

JURISDICTION

Mr. Stadnick stated that in addition to the firm's own-label products, it contract manufactures and repacks dietary supplements and applies customer labels on the products. Mr. Stadnick stated that all labels/labeling are approved and provided by the corporate office in New York. The following labels were collected (list includes quotes from the labels):

Exhibit #4, 10 pages:

Page 1 and Page 2: Naturalist Milk Thistle Complex "***Promotes Healthy Liver Function***Milk Thistle Extract 240 mg*** (Silybum marianum) (seed) (Standardized to contain 80% Silymarin, 192 mg)"

Note: the firm had two versions of this label, page 1 is the "old" version reading "Manufactured by

Rexall Sundown, Inc. Boca Raton, FL 33487 USA"; and page 2 is the "new" version that adds "1-88-VITAHELP (848-2435)" to the address. I verified that the firm is listed in the Yellow Pages for Boca Raton, FL so the first version complies with label requirements.

Page 3: Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength "***Glucosamine Chondroitin + MSM*** Proud sponsor of the ARTHRITIS FOUNDATION***"

Page 4: Osteo Bi-Flex Joint Shield Formula with 5-Loxin MSM Advanced with Hyaluronic Acid "***Proud sponsor of the ARTHRITIS FOUNDATION***"

Page 5: Spring Valley Natural Whole Herb Cascara Sagrada "***DIGESTIVE/COLON HEALTH***"

Page 6: Rexall Naturals Sublingual Dots B-12 500 MCG "***Place tablet under tongue for 30 seconds before swallowing***Vitamin B-12 500 mcg (as Cyanocobalmic) *** 240 Micro-Lozenges"

Page 7: Serpent with Super Goat Weed "***MALE PERFORMANCE*** Yohimbe 2% Extract (bark) (Pausinystalia yohimbe) 100 mg***"

Page 8: Sundown Naturals St. John's Wort "***Promotes A Positive Mood***"

Page 9: Sundown Naturals Super Potency Sublingual B-12 6000 MCG "***Quick Dissolving*** PLACE TABLET UNDER TONGUE FOR 30 SECONDS BEFORE SWALLOWING*** Boosts Energy Metabolism***"

Page 10: Marvel The Amazing Spider-man Complete Children's Multiple Vitamin and Mineral Supplement "***With DHA*** DHA (Docosahexaenoic Acid) (From Fish Oil)"

A list of products provided by Mr. Stadnick is **Exhibit #5, 10 pages.**

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

See Organizational Charts, **Exhibit #3, 8 pages**.

901 Broken Sound Parkway, Boca Raton, FL 33487

Raymond (NMI) Stadnick, Vice President, Quality Compliance. Mr. Stadnick stated that he was responsible for quality assurance and quality control compliance for all three NBTY Florida locations. He was present on the first and last day of the inspection. He stated that he had to travel on company business for the other inspectional days, but directed Robert S. Feldman to be our

contact and provide information as needed. Mr. Stadnick reports to Hans Lindgren, Senior Vice President/Director of Operations. Mr. Lindgren's office is at NBTY Inc, New York.

Robert S. Feldman, Manager, Quality Assurance. Mr. Feldman was our primary contact 8/26-8/29/08. He stated that he was responsible for quality assurance compliance including complaint follow up. He provided information, documents, and arranged tours of the three NBTY/Rexall operating facilities. Mr. Feldman reports to Raymond Stadnick.

Alfred Shoemaker, Manager, Quality Control. Mr. Shoemaker stated that he was responsible for quality control compliance. Mr. Shoemaker reports to Raymond Stadnick.

Gentry E. Ellis, Manufacturing Manager. Mr. Ellis said that he was responsible for the manufacturing operations for dietary supplements. He accepted the FDA-482, Notice of Inspection, as the most responsible individual present at the 901 Broken Sound Parkway NW, Boca Raton, FL location of NBTY/Rexall. He accompanied us during tour of the manufacturing plant and provided information and documents regarding manufacturing and equipment maintenance cleaning operations. Mr. Ellis reports to Dan Parkhideh, Senior Vice President Manufacturing, NBTY, Inc. New York.

Lynn Boland, GMP Trainer. Ms. Boland stated that she is responsible for all employee training activities regarding good manufacturing practices and OSHA compliance. She said she also assists Mr. Feldman in complaint follow-ups if they are related to illness or injury. Ms. Boland provided SOPs and training records for employees when requested by the inspectional team. She said that she works out of Building 901 and Building 1111. Ms. Boland reports to Robert Feldman.

[redacted] stated that one of her duties is to follow up on consumer complaints with Ms. Boland. [redacted] provided the firm's consumer complaint log and documents regarding consumer complaint follow-ups for review, and copies of complaint documents we requested. She reports to Raymond Stadnick. (b)(6)

Robert Demings, Supervisor, Blending. Mr. Demings was present and was observed supervising staff (Paul Nieves and Roger Ridley) when Blending Room operations were observed. According to the Organizational Chart, Mr. Demings reports to Gentry Ellis.

Raymond Brown, Supervisor, Weigh Room. Mr. Brown was present and was observed supervising staff (Vanna Jeffries, Marta Romeiro, and Charlie Johnson) when Weigh Room operations were observed. According to the Organizational Chart, Mr. Brown reports to Gentry Ellis.

Curtis Brown, Supervisor, Coating. Mr. Brown was present and was observed supervising coating operations when coating solution mixing was observed, and equipment cleaning logs were reviewed. Mr. Brown reports to Gentry Ellis.

Earl Semper, Supervisor, Tableting. Mr. Semper was present and was observed supervising compression/tableting operations staff (Robert Deane) when tableting operations were observed. Mr. Semper reports to Gentry Ellis.

[redacted] stated that he was responsible for equipment maintenance, and training operators on how to operate the machines (e.g. tableting, encapsulating machines). He provided and explained procedures regarding equipment maintenance during the inspection. [redacted] reports to Will Kiselak. (b)(6)

[redacted] said he was acting for Richard Evans, Plant Engineer/Facilities Manager, while Mr. Evans was on vacation. [redacted] provided a tour and explanation of the firm's water systems, including the Deionized (DI) Water system. [redacted] reports to Sean Parkhideh, Director, Engineering. (b)(6)

Viviana Brazofsky, Manager, Microbiology Laboratory/Quality Control. Ms. Brazofsky provided a tour of the microbiology laboratory and explained microbiological testing procedures of raw materials prior to Quality Control acceptance for use. Ms. Brazofsky was only present on 8/27/08. Ms. Brazofsky reports to Raymond Stadnick.

[redacted] provided copies of SOPs and information regarding quality control microbiology testing activities during the inspection. [redacted] reports to Ms. Brazofsky. (b)(6)

John Fox, Supervisor, Quality Control/Chemistry Laboratory. Mr. Fox stated that he was the second shift quality control supervisor. He provided information through Mr. Shoemaker regarding quality control activities during the inspection. Mr. Fox reports to Alfred Shoemaker.

Manoj Brahmbhatt, Supervisor, Senior Scientist, Quality Control/ Chemistry Laboratory. Mr. Brahmbhatt stated that he was the quality control laboratory supervisor. Mr. Brahmbhatt provided information regarding quality control analysis performed on products through Mr. Shoemaker. Mr. Brahmbhatt reports to Alfred Shoemaker.

[redacted] We observed [redacted] performing an assay of Glucosamine HCL during the inspection. [redacted] reports to John Fox. (b)(6)

[redacted] demonstrated how the firm uses the [redacted] identification system for pure organic compounds to determine the identification of botanicals used in dietary supplements manufactured by the firm. [redacted] also demonstrated how to challenge the system. [redacted] reports to Menoj Brahmbhatt.

(b)(6)

(b)(4)

(b)(6)

[redacted] explained the way lot numbers are computer generated by the [redacted] Computer Program System used by the firm. (b)(4)

1297 Clint Moore Road, Boca Raton, FL 33487

Michael E. Ollry, Distribution Manager. Mr. Ollry accepted the FDA-482, Notice of Inspection for the Distribution Warehouse. He said he was responsible for the distribution of finished products and disposition of returned goods. He provided a tour of the facility and documents and information requested by the inspectional team. Mr. Ollry reports to Tony Camerlengo, Vice President Warehousing & Distribution, NBTY, Inc. New York.

Michael A. LaMere, Supervisor, Receiving. Mr. LaMere explained the flow of operations at the Distribution Warehouse. Mr. LaMere reports to Michael E. Ollry.

[redacted] explained the quality control procedures for products returned to the Distribution Warehouse. [redacted] reports to Mr. Feldman. (b)(6)

1111 SW 30th Avenue, Deerfield Beach, FL 33442

[redacted] accepted the FDA-482, Notice of Inspection for the Packaging facility. He said he was the most responsible individual present during the inspection because his supervisor, Neville Campbell, Manager, Packaging, was at another plant location. [redacted] said that he was responsible for packaging operations in the absence of Mr. Campbell. He provided a tour of the packaging facility and documents and information requested by the inspectional team. [redacted] reports to Mr. Campbell. (b)(6)

Adjodha Singh, Warehouse Manager. Mr. Singh said he was responsible for overseeing warehouse operations, including receiving raw materials. He explained the receiving operations. Mr. Singh reports to Neville Campbell.

[redacted] said he was responsible for following SOPs for receiving raw materials and demonstrated by walking us through the receiving procedures for an imported product, [redacted] reports to one of the warehouse supervisors, who in turn report to Adjodha Singh. (b)(6) (b)(4)

[redacted] and [redacted] demonstrated raw material inspection and sample collection for quality control analysis prior to acceptance. (b)(6)

Elsa Tavara, QA Packaging and Receiving Supervisor. Ms. Tavara explained raw material receipt as it regarded quality assurance sampling. She also accompanied us when we observed packaging operations and explained the quality assurance activities. Ms. Tavara reports to Robert Feldman.

[redacted] Label Room Technician. [redacted] explained how labels are maintained and reconciled. He provided us with examples of labels. (b)(6)

Regine F. Prehn, Supervisor, Packaging. Ms. Prehn accompanied us while we observed packaging operations and provided information regarding the flow of operations. Ms. Prehn reports to Neville Campbell.

Raymond M. O'Donoghue, Maintenance Supervisor. Mr. O'Donoghue was present during our tour of packaging operations and provided information regarding the equipment used and the maintenance schedules. Mr. O'Donoghue reports to Neville Campbell.

FIRM'S TRAINING PROGRAM

The firm's training program is handled by Lynn Boland. Ms. Boland provided copies of training records for review that coincide with procedures for Good Manufacturing Practices, Data Integrity & Proper Documentation, OSHA, and HACCP. Ms. Boland stated that she provides initial training to new employees, continuing education, and administers tests for each section of training conducted. She maintains records of employee training. Specific job related training is provided on the job by supervisors.

MANUFACTURING/DESIGN OPERATIONS

NBTY Rexall operates out of three locations in South Florida as previously described under the header, ADMINISTRATIVE DATA. Mr. Ellis provided plant diagrams for Building 901 (Manufacturing) and Building 1111 (Raw Material Warehouse/Quarantine/ Finished Product Packaging), **Exhibit #6, 3 pages)**. Building 1297 operates as a finished product distribution warehouse and receives and stores returned goods.

NBTY Rexall is a manufacturer of dietary supplement products in capsule and tablet forms. Mr. Stadnick stated that since June 25, 2008, the firm produced [redacted] lots of Osteo Bi-flex Joint Shield Formula with 5-Loxin Advanced Triple Strength; [redacted] of Naturalist Milk Thistle Complex. (b)(4)

Flow of operations (See copy of firm's flow chart, Exhibit #7, 2 pages):

- Raw materials are received at Building 1111, all raw materials are sampled by QC for analysis in Building 901 laboratory; and held in quarantine until accepted. All movement of raw materials, laboratory analysis, in process, manufacturing, packaging, and distribution activities are entered into and tracked via the firm's [redacted] computer system. (Quality Assurance verifies the [redacted] system per SOP COQA-013, [redacted] Verification (**Exhibit #8, 3 pages**)

(b)(4)

- After release by QC, raw materials are stored in Building 1111 until a work order is issued. Work orders are generated by the NBTY in New York via the [redacted] computer system. (b)(4)
- After receipt of a work order, raw materials are pulled from stock in Building 1111 and transferred to Building 901 for manufacturing operations. Raw materials are weighed by Pharmacy according to the work order requirements, and staged for blending. Verification of acceptability is performed by Quality Assurance before the raw materials are blended.
- Blending – intermediate stage
- Dosage: After blending the bulk product is either made into capsules or tablets, inspected by QC.
    - Tablets are coated, inspected by QC
- After QC release, bulk capsules/tablets are transferred to Building 1111 for packaging
- Final packaging is performed with QA verification / sampling
- Finished product is transported to Building 1297 for storage and distribution

Initial Interview

According to Mr. Stadnick, the firm has [redacted] full time equivalent employees at the three locations visited during this inspection. NBTY Inc. has [redacted] full time equivalent employees nationwide. Mr. Stadnick verified that the other corporate facilities are owned by the same corporate entity, NBTY Inc, 2100 Smithtown Avenue, Ronkonkoma, NY 11779. (b)(4)

The firm manufactures finished dietary supplements in the form of tablets and capsules.

Products we selected to inspect and to review manufacturing records: Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength, and Naturalist Milk Thistle Complex with Dandelion, Fennel & Licorice.

Personnel, Physical Plant and Equipment and Utensils

Personnel

The firm has written procedures for preventing microbial contamination, and hygienic practices for employees (See "G" series SOPs listed on **Exhibit #9, 7 pages**, Rexall Sundown Standard

Operating Procedure Index, 7/31/2008). Observations made during the inspection revealed that SOP G-04 issued 11/01/07, Personal Hygiene Responsibilities (**Exhibit #10, pages 1-5**), was not being followed (**FDA-483 Observation #3**).

I reviewed training documentation and verified that records include date of training and type of training. Ms. Lynn Boland provided these records for review.

Mr. Raymond (NMI) Stadnick, Vice President, Quality Compliance, stated that he was responsible for overseeing quality control operations. Quality control operations are conducted by Alfred Shoemaker, Manoj Brzahmbhatt, John Fox, Robert S. Feldman, Viviana Brozofsky, [redacted] Elsa Tavara, [redacted] and [redacted] Review of their training records verified that they were qualified for their work.

(b)(6)

Physical Plant and Grounds

The firm has written procedures for cleaning the physical plant and pest control. I reviewed SOPs* M-74, M-92, M-95, MT-01, MT-03, P-02, WH-50, WH-64, and G-06 for cleaning (see **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index, 7/31/2008).

Water (potable and Deionized) is used as a component in manufacturing coating solutions and in cleaning equipment. I reviewed the SOPs for water, COQA-010, COQA-012, M-83 and MT-04, and I reviewed four (4) water testing records "Raw Material Specification and Evaluation Report" dated August 6, 2008. I found no deficiencies during record review.

According to Mr. Stadnick, the assigned sanitation supervisors are Mr. Richard Evans, Plant Engineer for Buildings 901 and 1297, and Raymond M. O'Donoghue for Building 1111.

Equipment and Utensils

The firm has SOPs (See Quality Control-QC, Research & Development/Technical-RD, Manufacturing-M series listed on **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index, 7/31/2008) in place to verify automated, mechanical and electronic equipment used in manufacturing, packaging, etc., is capable of operating satisfactorily within the operating limits required by the processes.

QC personnel are required to sign/initial batch records ensuring that equipment/equipment changes in manufacturing were approved before finished product can be released for distribution.

The firm has SOPs* in place to ensure that equipment is calibrated and maintained, and inspection/sign off is required by supervisors and QC.

The firm has SOPs* in place to ensure that equipment is calibrated and maintained. Review of records since June 25, 2008 revealed that the SOPs were followed.

The firm has written procedures for cleaning, sanitizing, and maintenance of all equipment and utensils and contact surfaces ("M" series SOPs*) and for maintaining cleaning logs (**Exhibit #11, pages 1-3,** M-86 Use & Maintenance of Log Books dated 12/7/2006). During the inspection we observed that the cleaning log for Solution Prep Room was not current. The last date entered for cleaning was 7/26/2008, but production was routinely performed after that date. **See FDA-483 Observation #1.** As corrective actions, the firm re-trained personnel **(Exhibit #11, pages 4-7, training records)** and modified SOP M-86 **(Exhibit #11, pages 8-10).**

The firm does not use freezers, refrigerators, or other cold storage to store components or finished dietary supplements. No temperature recording devices are needed.

The firm does not use wet processing.

Production and Process Controls Systems

Requirements to Establish Production and Process Control System

The firm has specifications identified in SOPs* (that include Corporate Quality Assurance SOPs that begin with "CO") established for qualifying suppliers of and testing components, in process materials, labels, packaging components, and finished products. We observed receiving raw materials components (Building 1111: [redacted] product #10602, RM #192558, imported from France), in process manufacturing operations (Building 901: [redacted] with [redacted] Product ID 31-16014), packaging components (Building 901: weighing and staging/packaging components for blending of [redacted] premix for Lot #238195/Product 31-16014; and bulk packaging of tablets after tableting); labeling and finished product packaging (Building 1111: packaging operations for Echinacea capsules, Product #44651), and Warehouse/Distribution (Building 1297, various products) during the inspection. QC approval activities (identified in SOPs*) were observed and records reviewed.

(b)(4)

Mr. Feldman said that suppliers of dietary ingredients are qualified in accordance with the requirements of COQA-003, Corporate Supplier Qualification Program (copy of this SOP is **Exhibit #12, 3 pages).** He stated that the firm performs audits of vendors under COQA-002, Corporate Vendor Audit, and provided a copy (faxed from NBTY corporate office) of an example of a "Manufacturing Facility Audit" dated 11/15/05 for a vendor who supplies botanicals to NBTY

* See **Exhibit #9**, Rexall Sundown Standard Operating Procedure Index and NBTY Corporate quality Procedures Index (7 pages)

(**Exhibit #13, 13 pages:** copy of COQA-002, 11/15/05 vendor audit, and 8/28/08 NBTY corporate fax coversheet).

Mr. Shoemaker stated that the firm conducts identification tests on each dietary ingredient and maintains examples of each botanical to assist in identification. See **Exhibit #14, 6 pages** Chemistry Method Index/TLC Identification Index. Mr. Shoemaker stated that the reference library for the [redacted] test) is maintained at the corporate office in New York. (b)(4)

On 8/28/2008, we observed a demonstration of an [redacted] identity test performed by [redacted] for Silymarin (Milk Thistle). See **Exhibit #15, page 1** showing the results of "Routine Analysis Details", and SOP QP No: NIR-001, **Exhibit #15, pages 2-3.** [redacted] also demonstrated this identity test for [redacted] **(Exhibit #15, page 4).** He then performed a challenge to the [redacted] system at our request using [redacted] to see if the system would reject it for [redacted] The [redacted] printout results "Routine Analysis Details" showing "FAIL" are included as **Exhibit #15, page 5.** (b)(6) (b)(4)

On 8/27/2008, we observed [redacted] Assay performed by [redacted] in accordance with QP Number: 3.6001, Assay for [redacted] and [redacted] 2KC1 [redacted] Method), **Exhibit #16, 9 pages**. Test results are **Exhibit #17, 24 pages.** (b)(4)

We reviewed and collected copies of the firm's SOPs for raw material receiving, and certificates of analysis for dietary ingredients in the products selected to inspect: [redacted] **Exhibit #18, 19 pages:** SOPs WH-23 Receiving of Raw Materials and Bulk Products, WH-62 Sampling of Bulk Product, and WH-63 Raw Material and Bulk (Purchased and Intra-Company) Receipt and Sampling; **Exhibit #19, 3 pages:** Certificates of Analysis for [redacted] [supplier's Batch No F28/42/A8], and [redacted] [supplier's Lot #183709], and a Certificate of Analysis for [redacted] We observed a shipment of [redacted] received on 8/29/2008 at Building 1111, a copy of the pick ticket and NBTY raw Material Specification Report for [redacted] are **Exhibit #20, 6 pages**. (b)(4)

Review of the firm's in-process specifications and finished product specifications revealed that the product's specifications have the appropriate identity, purity, strength and composition.

Review of batch records found that the firm is conducting appropriate testing for dietary ingredients in the finished batches on a rotation basis. The firm tests all raw material dietary ingredients and have in process controls in place to ensure that finished batch product specifications are met.

We observed the firm's associates in the Pharmacy weighing components to prior to blending. They did not record partial weights or the identity of the scales used. Review of the firm's documentation (Raw Material Dispensing Sheet) that specifications were met revealed that batch records routinely

did not contain partial weights of components or the identity of the scales used to measure the weights. (**Exhibit #21,** copy of Raw Material Dispensing Sheet dated 8/25/08, **See FDA-483 Observation #2.)**

The firm does not exempt product specifications from the verification requirements.

The firm collects representative and reserve samples.

Quality Control

The firm has written procedures for quality control operations, SOP COQA-004, Responsibilities of the Quality Unit, **3 , pages**; and several additional SOPs covering specific quality control operations. See list, **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index and NBTY Corporate quality Procedures Index.

Production and Process System

QC personnel reviewed and approved all documentation required by the regulation and in accordance with their SOP COQA-004 Responsibilities of the Quality Unit.

QC personnel determine that all manufacturing specifications as specified in the master manufacturing records (**Exhibit #24, 3 pages,** COGN-018, Master Batch Record Approval) were met (**Exhibit #25, 11 pages,** QC-12 Procedure for In-Process Inspection, Final Quality Assurance Inspection, Sampling, Approval and Release of Manufactured Tablets/Capsules; **Exhibit #26, 5 pages,** QC-06 Quality Assurance Procedures for In-Process Inspections, Sampling, Master Job Packet Review, Final Releases of Finished Packaged Products and Filing), and in accordance with their SOP COQA-004 Responsibilities of the Quality Unit.

Laboratory Operations

Review of laboratory procedures revealed that they contain QC approval on all procedures in accordance with their SOP COQA-004 Responsibilities of the Quality Unit.

Review of laboratory records of analyses revealed QC approval on test results in accordance with their SOP COQA-004 Responsibilities of the Quality Unit.

Material Review and Disposition

Review of material reviews and disposition determinations revealed that a finished dietary supplement tablet (Product #31-16014, Lot 235626) was rejected for low assay by QC. The tablets were re-milled later used as a component in two lots of finished products (Product #31-16014, Lots 2387888 and 237736). QC followed existing SOP protocol to rework the material (**Exhibit #27, 4 pages,** QC-36 Disposition of Non-Conforming Material). Review of records of returned dietary supplements revealed that QC made appropriate disposition of the products (**Exhibit #28, 1-4 pages,**

SOP QC-15, Returned Nutritional Supplement Products; **Exhibit #28, 5-15 pages,** COWH-003, RGA (Returned Goods Authorization) Process for Wholesale Customers). These responsibilities are also listed in SOP COQA-004 Responsibilities of the Quality Unit.

Equipment, Instruments and Controls

QC review and approve processes for calibrating instruments and review calibration records in accordance with **Exhibit #29, 5 pages,** QC-52 Calibration Requirements for Certain Equipment in Manufacturing, Packaging, Warehouse; and COQA-004, Responsibilities of the Quality Unit.

Components, Packaging and Labeling

Receipt of components and packaging are not released for until after QC samples, tests to ensure conformance with specifications, and releases for use in accordance with written SOPs. These include COPK-002 Receipt and Release of Product Labeling;COQA-011 Primary Packaging Component Evaluation and Release; and WH-63 Raw Material and Bulk (Purchased and Intra-Company) Receipt and Sampling (copies of these procedures not collected). Mr. Feldman said that labeling is approved by Quality Control at the corporate level and provided to the plant for use. These responsibilities are also listed in SOP COQA-004 Responsibilities of the Quality Unit. Control of labeling at the Florida location is covered under **Exhibit #22, 11 pages,** SOP M-32, Labeling of Containers of Raw Materials, Blends, and Final Products.

QC approval is required for any rejection, and in-process adjustments of components, packaging or labels (corporate level) prior to use in the manufacture of the firm's dietary supplements, and disposition of rejected materials. This responsibility is listed in COQA-004, Responsibilities of the Quality Unit).

QC approval is required for release from quarantine all components, packaging and labels before they are used. This responsibility is listed in COQA-004, Responsibilities of the Quality Unit.

Master Manufacturing Record, Batch Record and Manufacturing Operations

Master Manufacturing Records for Naturalist Milk Thistle Complex (Product ID 31-44770), and Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength (Product ID 31-16014) were reviewed. QC approval was noted on these records (including modifications).

Batch production related records for Naturalist Milk Thistle Complex (Lot #237736), and Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength (Lot #237888 and Lot #238076) were reviewed. The records contained QC review/approval signatures. Each step in the manufacturing and packaging process of the firm's dietary supplements contained signatures of approval by QC that established specifications were met.

Each step in the manufacturing process from receipt of raw materials to disposition of finished product is electronically entered into the [redacted] computer system.

(b)(4)

Packaging and Labeling

The firm receives bulk dietary supplements for packaging and labeling.

QC approves all records for packaging and labeling operations and determines whether finished packaged and labeled dietary supplements conform to specifications. SOPs covering these responsibilities are listed on **Exhibit #9, 7 pages,** Rexall Sundown Standard Operating Procedure Index and NBTY Corporate Quality Procedures Index; and QC responsibilities are listed on **Exhibit #22, 3 pages,** COQA-004 Responsibilities of the Quality Unit.

QC's determination of non-conforming products through material review is covered under SOPs during monitoring of manufacturing and packaging processes. During this inspection, I did not find any instances of QC approval for release or rejection of re-labeled or repackaged dietary supplements since June 25, 2008.

Returned Dietary Supplements

Returned dietary supplements are quarantined on receipt, sampled by QC and determination made regarding disposition in accordance with QC-15, Returned Nutritional Supplement Products. No reprocessing is performed.

Product Complaints

Complaints are handled by the corporate call centers, initially. The complaints are reviewed by the corporate Consumer Complaint Group and forwarded to the affected NBTY location for follow-up. QC personnel review and approve decisions regarding the follow-up activity for each complaint. Mr. Feldman stated that he was responsible for complaint follow up at this location. The firm's SOPs covering complaints are SOP QC-42 Consumer Complaints Investigations **(Exhibit #30, 13 pages),** and SOP QC-48 Handling of NBTY Manufacturing Florida Technical Complaint Inquiries **(Exhibit #31, 3 pages)**. See the header "COMPLAINTS" below for additional information.

Components, Packaging and Labeling

The firm has procedures covering examination, quarantine, collection of representative samples, QC review and approval and use of identifiers (for traceback) for incoming components of dietary supplements. Each incoming dietary supplement is assigned a unique raw material lot number (assigned by [redacted] computer system). The raw material lot number follows the component throughout the manufacturing process electronically, and is noted on the batch records. The firm receives bulk dietary supplements for packaging and labeling (repackaging). Records and written procedures are maintained. We reviewed test records for all raw material components for Lot #237736 / Product # 31-44770, [redacted] and Lot #237888 / Product #31-16014, [redacted]

(b)(4)

Master Manufacturing Record

Master Manufacturing Records (MMR) for Naturalist Milk Thistle Complex (Product ID 31-44770), and Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength (Product ID 31-16014) were reviewed. The MMR's contained specifications for each step in the manufacturing process but **did not include examples of the product labels**. This was discussed during the inspection and at the closing discussion with management.

Batch Production Record

Batch production records for Naturalist Milk Thistle Complex (Lot #237736), and Osteo Bi-Flex Joint Shield Formula with 5-Loxin Advanced Triple Strength (Lot #237888 and Lot #238076) were reviewed. The records contained all required information.

Laboratory Operations

The firm maintains written procedures for raw materials and finished product testing. It has laboratory control procedures established and observation of laboratory analysis activities during the inspection revealed that the procedures were followed. We confirmed that valid laboratory methods were used by the laboratory and are covered by the firm's SOPs. For example, **Exhibit #32, 6 pages, SOP C-214, Assay of** [redacted] **and Exhibit #33, 7 pages,** SOP 3.6008, Assay of [redacted] or [redacted] A list of laboratory equipment is **Exhibit #34, 2 pages.**

(b)(4)

Manufacturing Operations

The firm has established written procedures for manufacturing operations, they are listed under "M" series in **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index and NBTY Corporate Quality Procedures Index. Observations made during the inspection revealed that personnel did not take appropriate precautions to prevent contamination when performing the raw material weighing and blending steps, **See FDA-483 Observation #3.**

We observed that the firm clearly identifies, and holds under quarantine all incoming components, and returned products awaiting disposition decisions by QC personnel.

Packaging and Labeling Operations

The firm has written procedures required by regulation for packaging and labeling operations. They are listed under "P", "M", "SC" series in **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index and NBTY Corporate Quality Procedures Index. Observations made during the inspection revealed that the firm's procedures were followed by the associates responsible for packaging and labeling.

Holding and Distributing

The firm has written procedures required by regulation for holding and distributing operations. They are listed under "WH" and "COWH" series in **Exhibit #9, 7 pages**, Rexall Sundown Standard Operating Procedure Index and NBTY Corporate Quality Procedures Index. Observations made

during the inspection revealed that the firm's procedures were followed by the associates responsible for holding and distributing products. The firm maintains records of distribution electronically through the [redacted] Computer System. Reserve samples were maintained appropriately to prevent deterioration and in the same containers, labels, etc., as the finished products. (b)(4)

Product Complaints and Returns

Returned Dietary Supplements

The firm has written procedures for returned dietary supplements (e.g., **Exhibit 27, 4 pages,** QC-15, Returned Nutritional Supplement Products, and **Exhibit #28, 11 pages,** COWH-003, RGA [Returned Goods Authorization] Process for Wholesale Customers). The firm maintains records of as required by their written SOPs of material reviews and disposition decisions. The firm does not reprocess returned dietary supplements.

Product Complaints

The firm has written procedures for complaint follow-up (e.g., SOP QC-42 Consumer Complaints Investigations **(Exhibit #30, 13 pages),** and SOP QC-48 Handling of NBTY Manufacturing Florida Technical Complaint Inquiries **(Exhibit #31, 3 pages).** Review of the firm's complaint follow-up records revealed that if sufficient information was received (i.e., product lot numbers) the firm investigated to see if the affected product failed product specifications and the batch records were reviewed.

MANUFACTURING CODES

Mr. Cheng Wing stated that raw materials are assigned codes on receipt by [redacted] computer system that follow them through the manufacturing process and are recorded in the batch records. Finished product 6-digit lot numbers are randomly assigned by the [redacted] computer system. Mr. Wing stated that only finished product codes starting with "2" series are manufactured at this plant, e.g. 210232. (b)(4)

Product codes entered in the batch records for dietary supplements manufactured at this location contain "31" before the product number. For example, Naturalist Milk Thistle Complex, (Product ID 31-44770. "31" is the plant identification number, "44770" is the product number for Milk Thistle Complex.

COMPLAINTS

Mr. Feldman said that all complaints were received by the corporate call centers in New York and Illinois. He said that information was logged in and forwarded electronically to the Consumer Complaint Group in corporate headquarters. Adverse Event evaluation and follow-up is also handled by NBTY New York. He said that the Consumer Complaint Group is responsible for assigning complaint numbers and determining which NBTY location would be responsible for the complaint follow-up investigation. He said that hardcopies of complaints and any products accompanying them were received at NBTY Rexall Florida location on Mondays. Mr. Feldman

stated that he reviewed and approved all complaint follow-ups, but that actual follow-up activities were performed by Lynn Boland and Johanna J. Rubio.

A copy of the firm's SOPs were collected [SOP QC-42 Consumer Complaints Investigations **(Exhibit #30, 13 pages),** and SOP QC-48 Handling of NBTY Manufacturing Florida Technical Complaint Inquiries **(Exhibit #31, 3 pages)]**. SOP QC-42 has a section that addresses "CFSAN Adverse Events Reporting System".

I reviewed the firm's complaint log to see if there were any complaints received that were subject to Serious Adverse Event Reporting requirements effective December 22, 2007. Record review and interviews with Mr. Feldman, Ms. Boland, and [redacted] revealed no consumer complaints that required adverse event reporting since the effective date of the reporting requirements June 25, 2008. Review of the firm's complaint file found their investigation of complaints was conducted appropriately. (b)(6)

I followed up on all complaints listed in the FACTS Assignment. The table below indicates "N/A" if the firm did not have a record of the FDA complaint or a similar complaint for the same lot number of product on file:

FDA Complaint	Date	Product	Lot #	Comments	Firm's comments
2490	2/28/01	Osteo Bi-Flex Glucosamine Chondroitin 70 Tablet bottle	1687-07D/KJJ Lavender colored tablets	4 clear capsules w/white powder in bottle	N/A
4575	6/8/01	Spring Valley Natural acidophilus 60 Gelcaps bottle	63608 0402	Tiny gray wire sticking out of one half of a caplet	N/A
5788	7/11/01	Spring Valley Glucosamine Chondroitin 120/1.5 g tablets	164489	Difficulty breathing	N/A
9342	1/7/02	Sun Down Herbals Cascara Sagrada tablets bottle	044060501, 1656-10 DJH UPC 3076801189	Abdominal pain, vomiting onset one hour; 3-4 times after taking the tablets in this bottle	N/A
11196	4/4/02	Pokemon Children's Complete Chewable 60 tablets bottle	1996-06DBZZ2577	Staple in one vitamin	N/A
11950	5/22/02	Valerian root	354560	Gastrointestinal 2 times	N/A
15003	10/25/02	Sundown E400 IU	831568 12 04	Softgels, not uniform: cloudy, clear, partially cloudy	N/A
18261	4/21/03	Osteo-Flex GC TS	478624 120 caplets	Bottle displayed red and yellow smooth caps; bottle contained 133 white round	N/A

				tablets with no markings, no cotton. No seal on bottle it was glued shut. Consumer purchased 2nd bottle that contained red & yellow caplets, bottle had safety seal and cotton.	
21430	10/15/03	Sundown Calcium 1200 Plus D 60 count bottle	794167 exp 3/06	Unknown capsule – hard capsule in w/softgel caps	N/A
23258	2/4/04	Sundown fish oil gelcaps	383010 10 06	10-12 gelcaps had what appeared to be cotton in them.	N/A
24042	3/13/04	Sundown Natural Vitamins B12; 60 capsules bottle	361518 exp 0904 and 361537 exp 0905	2 bottles purchased vitamins looked different in each bottle.	N/A
24713	4/20/04	Carb Solutions Bar Chocolate Caramel Candy Bar 1.06 ounces		Gastrointestinal; no allergen label. Allergic to Malitol	N/A
26258	7/28/04	Osteo Bi Flex TX Caplets 120 bottle	B44955A2D	Caplets in bottom of bottle stuck together with brownish material; consumer experienced weakness	N/A
26965	9/8/04	Spring Valley GC; 160 capsules bottle	339737 0607, UPC 681131742290	Outer seal not normal, quickly broke; cap seal was broken.	N/A
27369	9/28/04	Rexall Bilberry Extract 1000 milligram bottle	78103221 278469	2 different colored soft gels (beige) in bottle with black ones.	N/A
32449	5/9/05	Carb Solutions high protein bar; 60 grams packet		Foreign object: ¼" wide, ¼" long tan color	N/A
36192	4/20/06	Sundown High Potency Pure Vitamin C 500 mg 150 caplets	210232 exp 04/07; UPC 30768 45068	Contents were tablets not caplets and were not coated as labeled.	N/A
39204	11/14/06	Osteo Bile 180 tablets bottle	0709 6485703 Bar code: 3076845703	2 bottles purchased; one contained hard capsules and not gel caps; both had same code	N/A
40066	1/18/07	Members Mark Vitamin D Tablets 800 IU 400 count bottle	22825101 2009	4 tablets different: white, rectangular; no markings.	N/A
52894	6/12/07	Spring Valley High Potency Vitamin D	VA 15606W00A exp 10/09	7 foreign tablets in bottle; white rectangular with no	N/A

		200 count bottle		markings.	
54186	5/18/07	Osteo Bi-flex Advanced TS GC 80 caplets bottle	23145401 exp 11/09; UPC 030768031213	Bottle labeled as gelcaps actually contained capsules.	N/A
57170	11/27/07	**Rexall premium Royal Jelly 60 capsules**	**365497-01 exp 08-2010**	**Allergic reaction, eye irritation, hives; allergic to Mexican Ragweed.**	**Firm followed up with consumer. Copy of Complaint follow-up #07-1848 collected (Exhibit #43, 14 pages)**
57613	12/20/07	Sundown Liquid Filled Calcium 60 tablets bottle	03 1036460602 exp March 2010; UPC 003076800967	Bottle only contained 53 tablets	N/A

RECALL PROCEDURES

Mr. Feldman explained that the firm's recall activities are handled initially by the corporate office (**Exhibit #35, 7 pages,** SOP COGN-007, Recall Procedure). Mr. Feldman had his staff perform a traceback exercise to demonstrate the firm's ability to query the [redacted] computer system to collect and print documentation to conduct an effective recall. The mock traceback was performed on Lot #23466901, Osteo Bi-flex MSM w/Joint Shield Advanced Triple Strength. A copy of the traceback is **Exhibit #36, 21 pages.**

(b)(4)

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

FDA-483 was issued to Raymond (NMI) Stadnick, Vice President, Quality Compliance. Also present during the close out meeting were [redacted] Mr. Ellis, Mr. Feldman, [redacted] and Mr. Singh. Mr. Shoemaker was attended via conference call.

(b)(6)

OBSERVATION #1

You did not make and keep documentation of the date of use, cleaning and sanitizing of the equipment used to prepare coating solutions for dietary supplement tablets.

Specifically, the last entry by the operator on the cleaning log for the Solution Prep Room was dated 7/26/2008. Coating solutions were prepared routinely in this room after 7/26/2008, for example as recent as 8/27/2008 (for Lot #239609).

Exhibit #37, 2 pages: Copy of cover and page and from Solution Prep Room cleaning log book
Exhibit #38, 6 pages: batch records for Lot #239609
Exhibit #11, pages 1-3, M-86 Use & Maintenance of Log Books dated 12/7/2006

Exhibit #11, pages 8-10: SOP M-86, Use & Maintenance of Log Books, Revision 5, dated 9/2/2008 (correction to FDA-483 Observation #1)

Exhibit #11, pages 4-7: Training records "M-86 Use & Maintenance of Log Books Rev 5" 8/29-9/5/2008 (correction to FDA-483 Observation #1)

Mr. Stadnick concurred with this observation and said that when this deficiency was pointed out during the inspection, corrections were immediately made. SOP M-86 was modified on 9/2/2008 to more effectively address record keeping requirements on the log books. Ms. Boland provided training records to verify that employee training on the SOP was conducted.

OBSERVATION #2

Your batch production records did not include the actual results obtained during a monitoring operation.

Specifically, records for monitoring raw materials ("Raw Material Dispensing Sheet") in the Weigh Room do not include each partial raw material weight and the identification of the equipment used.

Exhibit #21: Raw Material Dispensing Sheet dated 8/25/08. Example showing "Partials" instead of actual values of each raw material weighed and no identification recorded for the equipment (scale) used.

Exhibit #39, 4 pages: SOP M-05 dated 9/4/2008, Scales Set-Up and Operation (correction to Observation #2).

Exhibit #40, 3 pages: Training records "Scales Set-Up & Operations (M-05) Rev 11" 9/3-9/4/2008 (correction to FDA-483 Observation #2)

Mr. Stadnick concurred with this observation and said that when this deficiency was pointed out during the inspection, corrections were immediately made. SOP M-05 was modified on 9/4/2008 to add recording partial weights and equipment identification. Ms. Boland provided training records to verify that employee training on the SOP was conducted.

OBSERVATION #3

Your personnel did not use hygienic practices to the extent necessary to protect against contamination of dietary supplement ingredients.

Specifically,

a) Your personnel did not wear outer garments in a manner that protects against contamination of dietary supplement ingredients.

Blending Room: On 8/26/2008 during your blending process of product ID 31-61621 associates touched drums, outer bags, and box cutters then filled the hopper touching raw material without refreshing gloves. An associate knelt down onto the raw material (without wearing protective clothing) and reached into the charge screen to push raw material through it into the hopper exposing the raw material to his bare arm and shirt sleeve (no sleeve protectors were worn).

Weighing Room: On 8/26/2008 an associate staging raw material for blending did not wear sleeve protectors while scooping bulk product RM 239550 into a container. Her shirt sleeve and arm came into direct contact with the raw material.

b) Your personnel used gloves that were not clean or stored in a sanitary condition.

Blending Room: Gloves used by the associates were stored loose and unprotected on a table covered with raw material dust.

Exhibit #41: Photos of blending operation showing associate kneeling on raw material powder on blending platform, and associate reaching into screen to push powder through hopper exposing raw material powder to contamination (8 photos on one page).

Exhibit #10, pages 1-5: G-04 Personal Hygiene Responsibilities issued 11/01/07

Exhibit #10, pages 6-10: SOP G-04 Personal Hygiene Responsibilities, dated 8/27/2008 (correction to FDA-483 Observation #1)

Exhibit #42, 22 pages: Training records "G-04 Personal Hygiene Rev 16" 9/2-9/3/2008 (correction to FDA-483 Observation #1)

Mr. Stadnick concurred with this observation and said that when the deficiencies were pointed out during the inspection, corrections were immediately instituted. SOP G-04 was modified on 8/27/2008 to ensure employee practices include wearing and maintaining protective clothing to prevent contamination of the dietary supplement ingredients. Ms. Boland provided training records to verify that employee training on the SOP was conducted.

GENERAL DISCUSSION WITH MANAGEMENT

Discussion Items not listed on the FDA-483:

The firm's batch records do not contain required documentation of cleaning performed or a cross reference to the cleaning logs. Mr. Stadnick stated that he would add a cross reference to the batch records to comply with this requirement.

The firm's Raw Material Specification and Evaluation Report for [redacted] Component #10623 shows the method of identification testing as [redacted] **(Exhibit #44, page 1)**, but the firm actually uses [redacted] test. Mr. Stadnick had the form changed to reflect the actual method **(Exhibit #44, page 2)**. He said that the firm planned to switch to [redacted] when they obtain the appropriate standard. (b)(4)

The MMR's contained specifications for each step in the manufacturing process but **did not include examples of the product labels**. Mr. Stadnick stated that an example of product labels would be included in the MMR's.

At the end of the close out discussion I advised Mr. Stadnick that the items listed on the FDA-483 were inspectional observations and do not represent a final Agency determination. I stated that the FDA-483, and my report would pass through several levels of review and the agency could choose to impose sanctions including sending a Warning Letter (which would require a response from the firm as to corrective actions), seizure, injunction, regulatory meeting, civil penalties, and criminal prosecution. I stated that I would include his comments to the FDA-483 observations in my written report, but that he may choose to respond to them in writing to the Florida District Director, 555 Winderly Place, #200, Maitland, FL 32751.

REFUSALS
There were no refusals.

SAMPLES COLLECTED
No samples were collected.

VOLUNTARY CORRECTIONS
The firm voluntarily corrected all FDA-483 Observations prior to the close out of the inspection.

EXHIBITS COLLECTED

Exhibit #1	List of NBTY Divisions and Brands located throughout the U.S.
Exhibit #2	List of NBTY locations that includes manufacturing, packaging, distribution, and offices, 2 pages
Exhibit #3	Organizational Charts, 8 pages
Exhibit #4	Labels, 10 pages
Exhibit #5	List of products, 10 pages
Exhibit #6	Plant Diagrams, 3 pages
Exhibit #7	Flow Chart of Operations, 2 pages
Exhibit #8	COQA-013, [redacted] Verification, 3 pages

(b)(4)

Exhibit #9	Rexall Sundown Standard Operating Procedure Index, 7/31/2008, 7 pages
Exhibit #10	G-04 issued 11/01/07, Personal Hygiene Responsibilities, pages 1-5 G-04 Personal Hygiene Responsibilities, dated 8/27/2008 (correction to FDA-483 Observation #1), pages 6-10
Exhibit #11	M-86 Use & Maintenance of Log Books dated 12/7/2006, pages 1-3 Training records, pages 4-7 M-86 Use & Maintenance of Log Books dated 9/2/2008 (correction to FDA-483 Observation #2), pages 8-10
Exhibit #12	COQA-003, Corporate Supplier Qualification Program, 3 pages
Exhibit #13	COQA-002, Corporate Vendor Audit, copy of an example of a "Manufacturing Facility Audit" dated 11/15/05 for a vendor who supplies botanicals to NBTY, and 8/28/08 NBTY corporate fax coversheet, 13 pages
Exhibit #14	Chemistry Method Index/TLC Identification Index, 6 pages
Exhibit #15	QP No: NIR-001 [redacted] Analysis; NIR test results for identity, 5 pages
Exhibit #16	QP Number: 3.6001, Assay for [redacted] and [redacted] Method), 9 pages
Exhibit #17	Test results are Assay for [redacted] 24 pages (b)(4)
Exhibit #18	WH-23 Receiving of Raw Materials and Bulk Products, WH-62 Sampling of Bulk Product, and WH-63 Raw Material and Bulk (Purchased and Intra-Company) Receipt and Sampling, 19 pages
Exhibit #19	Certificates of Analysis for [redacted] [supplier's Batch No F28/42/A8], and [redacted] [supplier's Lot #183709], and a Certificate of Analysis for [redacted] 3 pages
Exhibit #20	Pick ticket and NBTY raw Material Specification Report for [redacted], 6 pages
Exhibit #21	Raw Material Dispensing Sheet dated 8/25/08
Exhibit #22	COQA-004, Responsibilities of the Quality Unit, 3 pages
Exhibit #23	M-32, Labeling of Containers of Raw Materials, Blends, and Final Products, 11 pages
Exhibit #24	COGN-018, Master Batch Record Approval, 3 pages
Exhibit #25	QC-12 Procedure for In-Process Inspection, Final Quality Assurance Inspection, Sampling, Approval and Release of Manufactured Tablets/Capsules, 11 pages
Exhibit #26	QC-06 Quality Assurance Procedures for In-Process Inspections, Sampling, Master Job Packet Review, Final Releases of Finished Packaged Products and Filing, 5 pages
Exhibit #27	QC-36 Disposition of Non-Conforming Material, 4 pages
Exhibit #28	QC-15, Returned Nutritional Supplement Products, pages 1-4 COWH-003, RGA (Returned Goods Authorization) Process for Wholesale Customers, pages 5-15

Exhibit #29	QC-52 Calibration Requirements for Certain Equipment in Manufacturing, Packaging, Warehouse, 5 pages
Exhibit #30	QC-42 Consumer Complaints Investigations, 13 pages
Exhibit #31	QC-48 Handling of NBTY Manufacturing Florida Technical Complaint Inquiries, 3 pages
Exhibit #32	SOP C-214, Assay of [redacted], 6 pages
Exhibit #33	SOP 3.6008, Assay of [redacted] or [redacted] Method), 7 pages. (b)(4)
Exhibit #34	List of laboratory equipment, 2 pages
Exhibit #35	SOP COGN-007, Recall Procedure, 7 pages
Exhibit #36	Mock traceback performed on Lot #23466901, Osteo Bi-flex MSM w/Joint Shield Advanced Triple Strength, 21 pages
Exhibit #37	Copy of cover and page and from Solution Prep Room cleaning log book, 2 pages
Exhibit #38	Batch records for Lot #239609, 6 pages
Exhibit #39	M-05 dated 9/4/2008, Scales Set-Up and Operation, 4 pages
Exhibit #40	Training records "Scales Set-Up & Operations (M-05) Rev 11" 9/3-9/4/2008, 3 pages
Exhibit #41	Photos of blending operation
Exhibit #42	Training records "G-04 Personal Hygiene Rev 16" 9/2-9/3/2008, 22 pages
Exhibit #43	NBTY Complaint #07-1848 follow-up (FDA Complaint 57170), 14 pages
Exhibit #44	Raw Material Specification and Evaluation Report for [redacted] Component #10623 showing [redacted] and corrected form showing [redacted] 2 pages
Exhibit #45	Photo CD (officially sealed and labeled to be stored away from magnetic fields)

(b)(4)

ATTACHMENTS

FDA-482 dated 8/25/08 issued to Gentry E. Ellis, Manufacturing Manager, Building 901
FDA-482 dated 8/28/08 issued to Michael E. Ollry, Distribution Manager, Building 1297
FDA-482 dated 8/29/08, issued to Dennis P. Callaway, Assistant Manager, Building 1111
FDA-483 dated 9/5/08 issued to Raymond (NMI) Stadnick, Vice President, Quality Compliance
FACTS Assignment 951846 and Assignment Memo dated 6/30/08 (20 pages)
Complaint #57170 (NBTY Complaint #07-1848)

Attachment #1:	NBTY corporate filing information and annual reports from Florida Department of State website, www.sunbiz.org, 16 pages

Mary F. Bodick, Investigator

Susan M. Turcovski, Supervisory Investigator