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SUMMARY

This surveillance inspection of this OTC and Rx Human and Veterinary Drug and Dietary Supplement Manufacturer was conducted per FACTS Assignment #_(b) (2)_ and CP 7321.008 (Domestic and Import Dietary Supplements). The inspection covered only CGMP inspection of Dietary Supplements per the assignment.

The previous inspection was dated 9/10/07 and was a CGMP inspection for OTC and Rx Human and Veterinary Drug products. The inspection was classified NAI. No follow-up to observations made during that inspection were covered during the current inspection.

Upon arrival, credentials were presented to and a FDA-482, issued to Jon C. Peppmuller, Interim Site Leader. Mr. Peppmuller is currently the firm's most responsible person at this site on a daily basis.

No dietary supplements were manufactured during the inspection. Included in the inspectional review were general facilities, raw material and component identity and specification testing, Master Manufacturing Records and product specification, manufacturing processes and batch control records, complaints and Adverse Experience Reporting, quality control, finished product specifications, and release criteria, and testing of finished dietary supplements.

No FDA-483, Inspectional Observations, was issued at the close of the inspection. No refusals were given and no samples collected. Management was warned of the firm's responsibility to comply with the FD&C Act and of the penalties available to the Agency for non-compliance.

ADMINISTRATIVE DATA

Inspected firm:	Novartis Consumer Health
Location:	10401 Hwy 6
	Lincoln, NE 68517-9626
Phone:	402-464-6311
FAX:	
Mailing address:	10401 Hwy 6 Box 83288
	Lincoln, NE 68517
Dates of inspection:	9/9-11/2008
Days in the facility:	3
Participants:	Jessica E. Hensley, Investigator

HISTORY

Novartis Consumer Health, Inc. (NCH) was incorporated in Delaware 12/20/1994. The company headquarters is 200 Kimball Dr., Parsippany, NJ 07054. This is the location of all officers including the President and CEO, Larry Allgaier. Other US locations include Ex-Lax, Inc, HC-01 Box 16629, Route 909, Kml. 3 Bo. Mariana, Humanao, Puerto Rico 00791-9731. Shareholders include Novartis Finance Corporation, 608 Fifth Avenue, NY, NY 10020 and Novartis Consumer Health, S.A., Route de l' Entraz, 1197 Prangins, CH-1260, Prangins/Nyon, Switzerland.

There have been no recalls since 6/25/08 for dietary supplements.

Hours of Operations include:
Office Hours are Monday through Friday 7:30 am to 4 pm.
Manufacturing Hours are (b) (4) . Manufacturing occurs on (b) (4)
Traditionally, (b) (4), (b) (4), and (b) (4) are the (b) (4) months for manufacturing.

The firm is registered under the Bioterrorism Act.

The FMD-145 letter should be addressed to Jon C. Peppmuller, Interim Site Leader.

INTERSTATE COMMERCE

NCH continues to distribute their product world wide. The two regional distribution centers located at (b) (4) and (b) (4) (b) (4) continues to be used as distribution sites for product sold and distributed in the United States. The firm's dietary supplements are shipped from this site to the warehouse in (b) (4) for US distribution. Product sent through the (b) (4) distribution center go to (b) (4).

JURISDICTION

The dietary supplements manufactured include:

Product	Flavor	Count and Form
Benefiber Plus Calcium	Wild Berry	90 Chewable Tablets
Benefiber	Orange Crème	100 Chewable Tablets
Benefiber	Orange Crème	36 Chewable Tablets
Benefiber	Assorted Fruit	100 Chewable Tablets
		Wild Berry, Lemon, and Orange Crème
Benefiber		72 Caplets
Benefiber		114 Caplets
Benefiber Plus Heart Health with Vitamins B6, B12 & Folic Acid		60 Caplets
Benefiber Plus Calcium Powder	Packaged at (b) (4)	

Packaged Products (Manufactured at Novartis-Horsham, England and Imported)

Slow FE (Slow Release Iron)	30 Tablets
Slow FE (Slow Release Iron)	60 Tablets
Slow FE (Slow Release Iron)	90 Tablets

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

A copy of the Organizational Chart is attached as Exhibit 1 for the Lincoln, NE location. A list of the Board of Directors and Officers is also attached (Exhibit 2). The most responsible person at the firm on a daily basis is Jon C. Peppmuller, Interim Site Leader. He received the FDA-482, Notice of Inspection and was present for the close-out discussion.

Mr. Peppmuller assigned the primary inspectional contact, Polly A. Harris, QA Director. She has a (b) (7)(C) and has been with Novartis Consumer Health for (b) (7)(C) Under her direction are quality assurance and quality control. Her responsibilities include but are not limited to quality assurance, documentation, technical writing, sample administration, investigations, quality systems, GMP training, auditing, and management of FDA and DEA inspections.

Also present for most of the inspection was Heidi M. Brokenicky, QA Manager. She manages product release. Her other responsibilities include managing compliant handling, quality engineering, stability administration, documentation, supplier auditing, and technical writing.

David W. Lueckenhoff, Director of Production Operations for OT Solids, was present for the walk-through. He explained production processes. He is responsible for overall operations of production and development for OT Solids (which in this facility includes the dietary supplement manufacturing). Jim J. Richard, Operations Manager Solids Business Unit, was also present for the walk through. He directs overall day-by-day operations in solids manufacturing, like assuring completion of batch records, documentation, investigations, stability studies, raw material disposition, packaging material disposition, auditing and all testing for the business unit.

MANUFACTURING/DESIGN OPERATIONS

Initial Interview

This location had _____ employees at the end of July 2008. I was told the number only fluctuates about___ at any given time.

The firm operates as a manufacturer and packager of human and veterinary drug products. These products include liquid, ointment, granule, tablet and capsule dosage forms. They also manufacture dietary supplements in tablet, caplet, and powder forms.

For a list of dietary supplements manufactured see section: JURISDICTION.

The firm does not manufacture dietary supplements with botanical ingredients. Products chosen for inspectional review include the firm's most manufactured products: Benefiber Plus Calcium Chewable Tablets (Wild Berry-flavor randomly chosen) and Benefiber Caplets. Benefiber Plus Calcium Chewable Tablets were only manufactured once since 6/25/08, and the Benefiber Caplets had not been manufactured. Also, these were not scheduled for manufacture during the inspection.

Most procedures in the firm are cross-product procedures for both drug and dietary supplement manufacture and general procedures for the firm. The firm does not treat dietary supplements differently in respect to manufacturing practices.

Personnel, Physical Plant and Equipment and Utensils

Personnel

Numerous procedures exist for preventing microbial contamination and hygienic practices for employees throughout the firm's operations.

The firm's training was reviewed. Currently, the firm is implementing (b) (4) a (b) (4) for (b) (4) and (b) (4) paths. The whole firm has not yet been entered into (b) (4), but a retraining for all procedures was performed at a (b) (4) to ensure all employees meet the basic training requirements. The employees previously kept their own training records. (b) (4).

The firm has a separate QA/QC. The Quality Assurance Director is Polly A. Harris. She has a (b) (4) and has been with Novartis Consumer Health for (b) (4). Under her direction are quality assurance and quality control. Her responsibilities include but are not limited to quality assurance, documentation, technical writing, sample administration, investigations, quality systems, GMP training, auditing, and management of FDA and DEA inspections.

QA consists of approximately (b) (4) employees in various teams whose responsibilities include stability, monograph writers, QA release group (raw materials and finished goods), document control, quality engineering (responsible for equipment qualification and process validation), and a research group. Quality Control personnel include incoming component testing, raw materials testing, microbial units, and raw materials samplers. The QC lab for solids has (b) (4) employees.

Physical Plant and Grounds

Various procedures were reviewed for equipment and facility cleaning and employee practices. No discrepancies were observed.

Water is not a component of the dietary supplements reviewed during this inspection. City water is used for equipment cleaning and USP water is used for rinsing equipment.

The firm assigned sanitation supervisor is (b) (7)(C) He was unavailable during the inspection. His responsibilities include directing, developing, coordinating, and prioritizing activities for Packaging Engineering,(b) (4) Project Engineering, Validation, and Facility & Factory Maintenance Groups. He establishes and maintains compliance with GMP's, GLP's, and SOP's within the Engineering Department and oversees the approval of validation requirements/protocols/reports, investigations, annual product reviews, procedures, and other control documents.

Equipment and Utensils

Equipment is shared, used in production of solids, both drugs and dietary supplements. Equipment qualification and process validation has been performed and is controlled by the quality engineering group.

The firm maintains change control procedures monitored by QA. The procedures were reviewed and all changes made since 6/25/08 affecting the dietary supplements covered in this inspection were reviewed.

Written procedures have been established for the calibration, cleaning, and maintenance of instruments and equipment used for raw material and component sampling and testing as well as for the manufacturing process. Calibration and maintenance of various pieces of equipment was reviewed with no discrepancies noted.

The firm does not use any raw materials in the dietary supplements that require refrigeration, freezing, or cold storage and does not perform wet processing.

Production and Process Control System

Requirements to Establish Production and Process Control System

The firm has established the following specifications in part:

Components- In addition to label specifications, the component specs include size, material, design for the bottle and cap closure, torque values are taken for the bottle cap after application, and the approved supplier.

Raw Materials- Must come from an approved supplier for the material. Depending on the status of the supplier for the material testing will be performed for identity testing and possibly assay, LOD (Loss of Drying), moisture, particle size, bulk density, lead, microbial limits and/or further testing. The suppliers are classified Approved, Qualified or Certified. All Certificates of Analysis are reviewed

In Process Materials- Weight, Hardness, Thickness, Appearance, and Friability are measured.

Labels- Shrink Sleeve label applied to bottle by supplier. Lot and Expiration is added to the bottom of the bottles and the corrugate.

Finished Products- Testing for Finished Products include Appearance, LOD, Weight Variation, and Calcium content.

Dietary Supplement Ingredients must come from an approved supplier for the material. Depending on the status of the supplier for the material testing will be performed for identity testing and possibly assay, LOD (Loss of Drying) and/or further testing. The suppliers are classified Approved, Qualified or Certified.

I reviewed the procedure for supplier qualification and reviewed the qualification of the suppliers for two ingredients in the products reviewed in this inspection. No discrepancies were observed.

No discrepancies were observed during the review of batch records for finished product testing.

Samples are taken for finished goods for reserve samples at the beginning, middle, and end of each packaging order. They are collected in finished form in the bottle. Representative samples of the labels are also kept.

Quality Control

Production and Process System

Quality Assurance reviews and approves suppliers for components and raw materials. Supplier approval procedures were reviewed. .

QA performs final lot review and release for all raw materials and finished products including dietary supplements, including returned laboratory tests and lot packaging orders.

Laboratory Operations

QA has approved all laboratory procedures related to all manufactured dietary supplements. All testing performed is reviewed by quality control prior to lot release.

Material Review and Disposition

A material review has not been necessary. One unplanned deviation has occurred with the conclusion of a defective seal and not ruling out a deformed bottle. It was determined to be an isolated event.

Equipment, Instruments and Controls

Engineering/(b) (4)Technology Group is responsible for all equipment calibration and routine maintenance.

Components, Packaging and Labeling

Upon receipt of components and raw materials the firm takes samples for specification testing. Once testing is completed QA releases passing components and raw materials.

There are no known allowances for adjustments of components or labels to make them suitable for use when they otherwise would not have been. QA ultimately has the responsibility to make disposition determination for any rejected materials.

Master Manufacturing Record, Batch Record, and Manufacturing Operations

The firm maintains change control for all manufacturing records. Change control was reviewed.

Batch records including in-processing testing is reviewed by QA prior to QA lot release. Production and process control is monitored by QA.

Packaging and Labeling

This firm does not re-pack dietary supplements.

Inclusive of Batch Record Review is Packaging Review prior to lot release.

The firm does have procedures for re-packing or re-labeling product. A product was relabeled for distribution to (b) (4) and (b) (4) labels were applied as described in a Planned Deviation report which was reviewed with no deviations observed.

Returned Dietary Supplements

Return procedures define a return versus a refusal and conditions for returning the product to inventory. The procedure determines under what circumstances an investigation would be conducted. QA makes the determination to conduct investigations.

The firm does not rework returns or salvage any returns.

Reprocesses are not conducted.

Product Complaints

QA personnel perform investigations of consumer complaints per procedure. All complaints were reviewed during the inspection including investigations. No discrepancies were observed.

Components, Packaging and Labeling

(b) (4) uses the (b) (4) relates it to the (b) (4) from the supplier and delivers a unique identifier for Novartis for components and raw materials. These numbers can be used for tracking all components and war materials used in the manufacture of all dietary supplements. Samples are collected per the sampling schedule and testing is performed per specifications. Once testing is complete QA will release the components and raw materials for use.

The firm does not re-pack.

The firm maintains procedures, receiving records, and documentation for components and their QA release.

Master Manufacturing Record

The Master Manufacturing Records for the Benefiber Plus Calcium Chewable Tablets (Mixed Berry flavor) and the Benefiber Caplets were reviewed with no discrepancies noted.

The Master Manufacturing Record (MMR) was reviewed as well as Batch Records were reviewed for Benefiber Chewable Tablets (Orange Crème) lots (b) (4) (manufactured (b) (4)), (b) (4) (manufactured (b) (4)), and (b) (4) (manufactured (b) (4) and Benefiber Plus Calcium Chewable Tablets (Wild Berry Flavor) lot (b) (4) (manufactured (b) (4)). Specifications for each point, step and stage in the manufacturing process is established including packaging.

The MMR includes all steps in the manufacture and packaging of the dietary supplements.

Batch Production Record

The firm maintains batch records.

The products chosen for review during this inspection are the firm's (b) (4) products in terms of (b) (4) manufactured. However, since the 6/25/08 date for implementation for the new dietary supplement regulations the firm has only produced (b) (4) batch of the mixed berry Benefiber Plus Calcium Chewable Tablets and batches of the Benefiber caplets. In addition to the (b) (4) batch of mixed berry flavor, I additionally reviewed the only (b) (4) batches of Orange Crème flavor for a better representation of the batch records for the firm's dietary supplements.

Laboratory Operations

The firm maintains the same set of procedures for raw materials and component testing for both drugs and dietary supplements, each of which has a set of specifications and testing procedures for testing the specs. Examples were reviewed.

Manufacturing Operations

The firm has not discriminated between drug products and dietary supplements in the development of manufacturing procedures. Most equipment and manufacturing line are shared amongst all solids forms of products. While no manufacturing was conducted during my inspection, the procedures were reviewed for manufacture as well and the batch records. No discrepancies were noted.

During the firm walk-through and by review of procedures including those for cleaning, I determined the firm has established appropriate precautions against raw material, component and fished dietary supplement contamination.

(b) (4) , (b) (4) (b) (4) and (b) (4)

Packaging and Labeling Operations

Procedures for examination and release, issuance and reconciliation of components were reviewed. Procedures to ensure components are not contaminated during packaging were reviewed.

(b) (4) These numbers are shared with the Ex-Lax, Inc. facility in Puerto Rico; as such (b) (4) (b) (4) Procedures for batch number retrieval were reviewed.

Procedures exist for lot tracking through component, and raw material receipt through distribution of finished goods.

Holding and Distributing

The (b) (4) site is not monitored by Novartis for environmental controls like temperature and humidity. The firm is audited (b) (4) every (b) (4) years. (b) (4) monitors environmental controls like temperature and humidity and the records are reviewed by Novartis routinely.

(b) (4) keeps the (b) (4) and (b) (4) The distribution site maintains its own system for tracking inventory and distribution. This firm also maintains Bills of Lading, Packing Lists, Commercial Invoices, and Purchase Orders for distribution tracking.

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Product Complaints and Returns

Returned Dietary Supplements

The procedure for returns was reviewed. Investigations are completed per the procedure, but no returns have been completed for the dietary supplements reviewed since 6/25/08.

The firm only performs reworks like a labeling change or repackaging but no manufacturing steps are repeated.

Product Complaints

The procedure for complaint handling was reviewed. This is the same procedure used for the drug products complaint handling. No discrepancies were observed.

Only (b) (4) complaints were received for products manufactured since 6/25/08. These complaints were all reviewed. (b) (4) of the complaints were closed and (b) (4) remain open. Complete investigations were performed for the closed complaints.

Other Elements of Operations Covered

The firm's corporate office is responsible for all Adverse Event Reporting. I provided the firm with the link to the industry guidance for the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

Labels were reviewed for contact information for adverse event reporting.

An attachment C for CP 7321.008 was completed. The firm does not manufacture or import products containing ruminant tissue or tissue-derived materials. The firm is attached.

MANUFACTURING CODES

(b) (4). These numbers are shared with the Ex-Lax, Inc. facility in Puerto Rico; as such (b) (4) (b) (4) Procedures for batch number retrieval were reviewed.

COMPLAINTS

The firm provided me with all (b) (4) complaints for the reviewed products since 6/25/08. (b) (4) were complete reports with conclusions. The (b) (4) most recent (8/30/08 and 9/3/08) were incomplete and were only made available for the complaint description. No discrepancies were noted.

RECALL PROCEDURES

The firm maintains the same recall procedures for dietary supplements as for drug products. Recall procedures were reviewed. No recalls have been performed for dietary supplements.

REFUSALS

None.

GENERAL DISCUSSION WITH MANAGEMENT

At the close-put discussion with management the following people were present:
Jon C. Peppmuller, Interim Site Leader
Mark D. Kurtenbach, Director Strategic Sourcing
Thomas L. Frantz, Site Controller
Terry L. Maynard, Director Liquids Business Unit
David W. Lueckenhoff, Director Solids Business Unit
Joseph J. Kolar, II, Director, ExPO
Joseph T. Delaney, Head, Global QA for OTC Manufacturing Sites
Polly A. Harris, Director QA and Compliance
Holly M. Little, Associate Director Health, Safety and Environment
(b) (7)(C) Executive Assistant

No FDA-483 was issued at the close of this inspection. Firm management was warned of its responsibility to comply with the FD&C Act and of the penalties available to the Agency for non-compliance.

SAMPLES COLLECTED

None.

EXHIBITS COLLECTED

1 Organizational Chart for the Lincoln, NE plant.
2 NCH Board of Directors and Officers

ATTACHMENTS

FDA-482, Notice of Inspection, dated 9/9/08, issued to Jon Peppmuller, Interim Site Leader.
Attachment C to CP 7321.008, dated 9/9-11/08.

Jessica E. Hensley, Investigator