

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FBI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

TABLE OF CONTENTS

SUMMARY ..... 1  
ADMINISTRATIVE DATA ..... 2  
HISTORY ..... 3  
INTERSTATE COMMERCE/ JURISDICTION ..... 3  
INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED ..... 3  
FIRM'S TRAINING PROGRAM ..... 4  
MANUFACTURING/DESIGN OPERATIONS ..... 4  
MANUFACTURING CODES ..... 5  
COMPLAINTS ..... 5  
RECALL PROCEDURES ..... 5  
OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE ..... 5  
REFUSALS ..... 5  
GENERAL DISCUSSION WITH MANAGEMENT ..... 5  
ADDITIONAL INFORMATION ..... 6  
SAMPLES COLLECTED ..... 6  
EXHIBITS COLLECTED ..... 6  
ATTACHMENTS ..... 6

**SUMMARY**

The inspection of this dietary supplement manufacturer and re-packer was conducted as a directed inspection, under FACTS assignment 962442, operation ID 3795338 and per the Domestic Food Safety Compliance Program, 7303.803.

The previous inspection was conducted on February 18<sup>th</sup>, 2003 and classified as NAI. No form FDA-483, Inspectional Observations, was issued.

The current inspection covered sanitation and verification whether or not the firm uses (b)(4) radiation during their manufacturing and repackaging of dietary supplements.

The firm was repackaging a dietary supplement called Life Enhancer during this inspection. At the conclusion of the inspection, a close out meeting was held with management. No form FDA-483, Inspectional Observations, was issued.

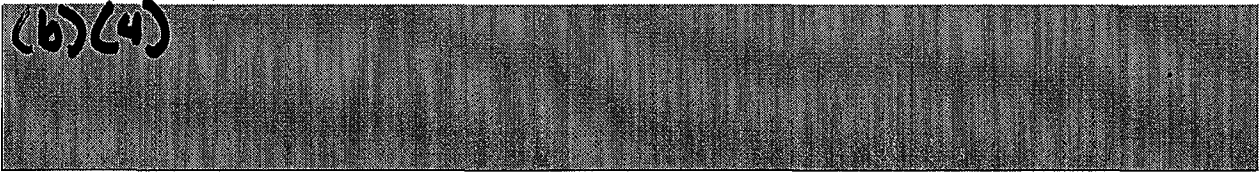
**PURGED**

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FEI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

No refusals were encountered and no samples were collected.



Post inspectional correspondence should be sent Mr. Eric Larsen, CEO, Neways International, 2089 Neways Dr., Springville, UT 84663. The FMD-145 should be addressed to Mr. Eddie Mendivil, Vice President Quality Assurance, 150 East 400 North, Salem, UT 84653.

**ADMINISTRATIVE DATA**

Inspected firm: Neways, Inc  
Location: 150 E 400 N  
Salem, UT 84653-9365  
Phone: 801-423-2800  
FAX:  
Mailing address: 150 East 400 North  
Salem, UT 84653

Dates of inspection: 8/18/2008  
Days in the facility: 1  
Participants: Becky L Bhan, Investigator

At the beginning of the inspection credentials were presented and a form FDA-482, Notice of Inspection, was issued to Mr. Eddie Mendivil, Vice President Quality Assurance.

At the conclusion of the inspection, a closeout meeting was held with Mr. Mendivil, (b)(6), PA and Ms. Payne.

There were no other inspectors or government agencies present during this inspection.

**PURGED**

## Establishment Inspection Report

Neways, Inc  
Salem, UT 84653-9365

FEI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

### HISTORY

The firm is part of Neways International. The headquarters is located at 2089 Neways Dr., Springville, UT 84663. Neways International warehouses are located throughout the world.

The firm has been in business since 1992.

The firm has approximately (b) (4) employees.

(b) (4)

(b) (4) A cleaning is conducted after each repackaging event. The firm operates (b) (4)

(b) (4)

The firm has registered under the Bio-Terrorism Act.

The firm consists of (b) (4) buildings that are approximately (b) (4) square feet.

The previous inspection was conducted on February 18<sup>th</sup>, 2003 and was classified as NAI. No form FDA-483, Inspectional Observations, was issued.

### INTERSTATE COMMERCE/ JURISDICTION

According to management, the firm ships approximately (b) (4) of their products to (b) (4) (b) (4) Products are shipped using various shipping carriers (see exhibit 1).

The firm receives bulk tablets and capsules from (b) (4) (b) (4) (see exhibit 2).

In addition to dietary supplements, the firm manufactures body soaps, shampoos, toothpaste, lotions, lipstick, and many other products. Management provided a list of all dietary supplements manufactured and repackaged at the Salem Plant (see exhibit 3).

All products are sold directly to distributors located throughout the world. Sales strategies are similar to those of (b) (4)

### INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

At the beginning of the inspection, credentials were displayed and a form FDA-482, Notice of Inspection, was issued to Mr. Eddie Mendivil, Vice President Quality Assurance. Mr. Mendivil has

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FBI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

the responsibility for all quality assurance and quality control of operations in the Salem Plant. A copy of the organizational chart is included (see exhibit 4). Mr. Mendivil reports directly to Mr. Larsen, CEO. Mr. Mendivil was present during the entire inspection and provided information related to manufacturing, storing, receiving, and distribution of products.

I also met with the following individuals during the inspection:

- Ms. Tonya Payne, Document/Regulatory Auditing Manager. Ms. Payne is responsible for all regulatory affairs and document storage. Ms. Payne reports directly to Mr. Mendivil.
- (b)(6), PA Regulatory Auditing Supervisor. (b)(6), PA is responsible for all in house audits and advises management of any deficiencies in manufacturing and maintenance at the Salem Plant. (b)(6), PA reports directly to Mr. Mendivil.

**FIRM'S TRAINING PROGRAM**

The firm has (b)(4) current good manufacturing training for all employees. Training is also conducted when there are changes in standard operating procedures.

**MANUFACTURING/DESIGN OPERATIONS**

Raw materials for mixing and bulk materials for repackaging are received in (b)(4) and placed into a quarantine area. Raw materials are then transferred to a staging area where samples are taken in a hepa filtered room and then tested for heavy metals and microorganisms. The firm does their own in-house testing (see exhibit 5). The firm does not test for irradiation of its raw materials, however documents were provided to me showing it is against company policy to accept irradiated raw materials (see exhibit 5). After test results are negative for microorganisms and heavy metals they are transported to the manufacturing areas.

(b) (4)



**PURGED**

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FEI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

During this inspection I observed bulk repackaging of a dietary supplement called Life Enhancer. This product was being manufactured for distribution (b) (4) (see exhibit 6). No products were being manufactured at the time of this inspection for distribution in the US.

The firm's pest control is managed by (b) (4) and checks are conducted every (b) (4). They use traps, lights, and external spraying. I did not observe any pest activity during this inspection.

A reconciliation exam was conducted on bulk tablets that are repackage for sale as Life Enhancement. No discrepancies were observed (see exhibit 7).

**MANUFACTURING CODES**

The lot code is embossed on the external part of the bottle. The lot code is followed by an expiration date that consists of two numeric numbers that represent the month and a slash with four numeric numbers that represent the year.

**COMPLAINTS**

Complaints are handled at the Springville Headquarters. According to management no complaints have been filed since the last inspection in 2003.

**RECALL PROCEDURES**

The firm has a recall procedure and conducts annual mock recalls. According to management no recalls have been conducted since the last inspection in 2003.

**OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE**

No objectionable conditions were observed and no form FDA-483, Notice of Inspection, was issued.

**REFUSALS**

No refusals were encountered.

**GENERAL DISCUSSION WITH MANAGEMENT**

I discussed with management two reports provided to me by the (b) (4) (see attachment 4). These reports stated that *Neways Green Qi* (lot code 575889) and *Neways Feeling Good* (lot codes 577129 & 575230) products tested positive for ionizing radiation. I stated to management their products had tested positive and they advised me they did not irradiate any of their products. They also stated it was against company policy and provide in writing to their suppliers a document stating that irradiation is not permitted. Management advised me that they were going to conduct their own investigation. I asked them if any "Green Qi" or

**PURGED**

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FEI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

"Feeling Good" product was distributed in the US and they stated that some had been distributed and they would notify the people that those products may be irradiated. No lot numbers that tested positive were distributed in the US.

A copy of the "What You Need to Know about Registration of Food Facilities" was provided to Mr. Mendivil and I briefly discussed with him food security information.

**ADDITIONAL INFORMATION**

This firm primarily repackages bulk dietary supplements that are made by third parties. During the course of the inspection I wore a (b) (4) provided by the FDA and no radiation was detected. I did not observe any devices that could irradiate products.

(b) (4)

(b) (4) to determine if these

(b) (4) Neways third party ingredient suppliers were irradiating at their facilities. Follow up trace back

investigations were conducted at (b) (4)

(b) (4)

**SAMPLES COLLECTED**

No samples were collected.

**EXHIBITS COLLECTED**

Exhibit 1, shipping carriers, dated 18AUG08 (b) (4)

Exhibit 2, third party manufacturers, dated 18AUG08 (b) (4)

Exhibit 3, dietary supplement product list, dated 18AUG08 (7pp)

Exhibit 4, Organizational Chart, dated 18AUG08 (1p)

Exhibit 5, Quality Assurance and Control documents (b) (4)

Exhibit 6, Product Labeling (b) (4)

Exhibit 7, Reconciliation Documents (b) (4)

**ATTACHMENTS**

FDA-482, Notice of Inspection, dated 18AUG08 (1p)

Attachment 2, Copy of the assignment, dated 15AUG08 (1p)

Attachment 3, (b) (4)

Attachment 4, (b) (4)

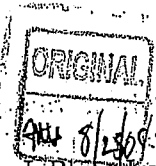
**PURGED**

**Establishment Inspection Report**

Neways, Inc  
Salem, UT 84653-9365

FEI: 1000149898  
EI Start: 08/18/2008  
EI End: 08/18/2008

---



Becky L. Bhan, Investigator

**PURGED**