

Establishment Inspection Report

R.R. Importaciones Inc.
Passaic, NJ 07055-7618

FEI: **3003005612**
EI Start: 03/25/2013
EI End: 04/19/2013

TABLE OF CONTENTS

Summary of findings 1
 Additional Information 3
 Exhibits Collected 4
 Attachments 4

Inspected firm: R.R. Importaciones Inc.
 Location: 141-143 3rd St
 Passaic, NJ 07055-7618
 Phone: 973-261-2837
 FAX:
 Mailing address: 141 3rd St 143
 Passaic, NJ 07055-7618

Dates of inspection: 3/25/2013, 4/12/2013, 4/19/2013
 Days in the facility: 3
 Participants: Miguel G. Manzano Maldonado, Investigator

SUMMARY OF FINDINGS

This inspection of a warehouse of imported food products (Mexican Products) was conducted as result of a New Jersey Department of Health & Senior Services water sample analysis, which revealed high levels of arsenic in imported mineral water ((b) (4)). GMP inspection was also conducted in conjunction, and reported in FACTS Assignment # 1505703 and OP ID # 6678842. Inspectional guidance was afforded under CP 7303.803, Domestic Food Safety Program Inspections.

The previous inspection was conducted on 03/14/2011 by NJDH&SS representative under FDA Contract Agreement # 09-90. The inspection was classified NAI with deficiencies including several pallets of product stored against the walls.

The current inspection revealed that the firm was able to provide some information regarding who supplied the mineral water; however, documentation was not able to be linked with the lot numbers of the products collected and tested by NJDH&SS in January and March 2013.

On 03/25/2013, I, Investigator Miguel G. Manzano Maldonado, presented my credentials and issued an **FDA 482**, Notice of Inspection to Mr. Rogelio Martinez, President, who indicated he was the most responsible person at the firm. I explained the purpose of the inspection which was to follow up on the imported product ((b) (4)) that was collected by NJDH&SS on 01/29/13, 03/07 & 14/2013, voluntarily destroyed, and witnessed on 03/14/13 as result of high levels of arsenic in the product. I also provided Mr.

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Martinez with FDA Reportable Food Registry (RFR) information and the 2012 FSMA Fee Schedule, and discussed the contents of these documents.

On **04/12/2013**, I, Investigator Miguel G. Manzano Maldonado, issued a second **FDA 482**, Notice of Inspection to Mr. Martinez, President, due to the time interval since the previous inspection date.

On **04/19/2013**, I, Investigator Miguel G. Manzano Maldonado, issued a third **FDA 482**, Notice of Inspection to Mr. Martinez, President of RR Importaciones Corp. I explained the purpose of the visit which was to follow up a possible Class III Food Recall and/or possible sample collection of (b) (4) placed in (b) (4) related with possible high levels of lead in the product. Please refer to Memo **FACTS Assignment # 1505703; OPID # 6729817** for details.

All FDA correspondence should be sent to: **Mr. Rogelio Martinez, President, RR Importaciones Corp., 141-143 3rd Street, Passaic, NJ 07055**

Mr. Martinez stated that the firm was established in Newark, New Jersey, approximately twelve (12) years ago and has been in the current location since then. The firm operates as a warehouse of imported products (edible and not edible) such as vegetables, fruits, candies, and home accessories from (b) (4). A product list from one of the firm's major supplier was provided and is attached as **Exhibit #1**. The firm's facility is approximately (b) (4) square feet, operates (b) (4) the firm is closed. The firm employs (b) (4) full time and (b) (4) employees. Mr. Martinez stated that all sales are made in New Jersey and no distribution is conducted at the firm, all products are picked up by his customers. Mr. Martinez stated that he does not know the annual sales of the firm. The firm's suppliers include; (b) (4) (b) (4). Mr. Martinez stated that he has a broker located in (b) (4) who distributes part of his products to different states such as (b) (4) in addition, Mr. Martinez stated that some products are also distributed to (b) (4). Mr. Martinez stated that the firm has approximately (b) (4) customers, which include: (b) (4), (b) (4).

During the first day of inspection on 03/25/2013, I informed Mr. Martinez that (b) (4) (**Exhibit #2**, one bottle observed in the firm's office, lot #(b) (4)) was tested by the New Jersey Department of Health and resulted in high levels of arsenic (NJDH&SS lab test results and product pictures are **attached**). Mr. Martinez understood and provided me with a copy of the NJD&SS Voluntary Destruction Certification (**Exhibit #3**). I asked Mr. Martinez when was this product received/purchased, he stated that the product was received around November 2012 and that was purchased for a personal activity, with no plans to sell the product. I asked Mr. Martinez for evidence of purchasing and interstate documentation of the mentioned product to trace it back to the manufacturer, Mr. Martinez stated that he does not have any documentation and that he does not keep and/or store those documents. I provided Mr. Martinez with three different lot numbers of the product ((b) (4) (b) (4)), which were collected by the state, so he could provide that information to his broker to obtain documents such as invoices and/or bill of ladings. On 03/26/2013 Mr. Martinez sent me via fax an invoice dated 2102-12-04 (**Exhibit #4**), however, the document provided has no relation with the sample collected by the state. On 04/12/2013, I returned to the firm to collect an invoice (**Exhibit #5** dated 2012-10-12) which Mr. Martinez stated was related with the products and lots that were collected and tested by NJDH&SS. During the review of this document, it was noted that the numerical value (b) (4) and the written amount in letters (b) (4) (b) (4) (b) (4) was not the same. On 04/19/2013, Mr. Martinez provided me with the corrected invoice (**Exhibit #6** dated 2012-10-12).

Establishment Inspection Report

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No link could be made with the documents provided by Mr. Martinez to the lots of water sampled by NJDH&SS.

Mr. Martinez stated that products come all the way from (b) (4) with labels and that he does not do any additional processing to the products received and only warehouses them. Mr. Martinez stated that the involved product (b) (4) is manufactured in (b) (4) and is warehoused in (b) (4), where is then purchased by Mr. Martinez, who also stated that he will not purchase anymore the (b) (4).

General discussion with management

During the inspection various deficiencies were observed. Several pallets were placed against the walls. I informed to Mr. Martinez that this was observed during the last inspection. I explained that the pallets against the wall can prevent adequate view of the floor-wall juncture, and potentially create a harborage environment for rodents and/or insects. Mr. Martinez agreed and promised to make corrections. In addition, an approximately one inch gap was observed at the bottom of the warehouse bay door. I explained to Mr. Martinez that the door has to fit tight to the floor to prevent possible entrance of rodents. Mr. Martinez agreed and promised corrections.

The firm uses a pest control company (no name provided) every (b) (4). During the inspection of the facility, no evidence of any rodent, avian, or insect activity was noted. In addition the firm garbage disposal is conducted by (b) (4).

Mr. Martinez stated that no complaints have been conducted. Also there were no complaints for the firm found in the FDA database since the last inspection.

This inspection revealed no objectionable conditions listed on a FDA 483, Inspectional Observations. No physical or documentary samples were collected. (b) (3) (A)

ADDITIONAL INFORMATION

On 04/12/2013 Mr. Martinez stated that (b) (4) is his broker located in (b) (4), (b) (4). On 04/17/2013 an entry number documentation (b) (4) **Exhibit #7** was sent to me via email (email **attached**) but the document could not be attached/ linked to the sample collected by NJDH&SS. During the inspection on 04/19/2013, Mr. Martinez provided me with entry number documentation sent via fax by the broker; product Import Entry number (b) (4) dated 10/08/2012 (**Exhibit #8**), and Entry (b) (4) dated 11/26/2012 (**Exhibit #9**) were provided, however, documents could not be linked/attached to the sample collected by NJDH&SS.

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EXHIBITS COLLECTED

1. Firm's products list (1 page)
2. Digital photos of (b) (4) Water (2 pages)
3. Copy of NJDH&SS voluntary destruction certification (1 page)
4. Invoice (b) (4), dated 2012-12-04 (1 page)
5. Invoice (b) (4), dated 2012-10-12 (1 page)
6. Invoice (b) (4), dated 2012-10-12 (1 page)
7. Entry number documentation, (b) (4) dated 03/25/2013 (4 pages)
8. (b) (4) copy of Entry Number (b) (4), dated 10/18/2012 (3 pages)
9. (b) (4) Custom Broker, Entry Number (b) (4), dated 11/26/2012, (2 pages)

ATTACHMENTS

- FDA 482, Notice of Inspection, issued to Mr. Rogelio Martinez, dated 03/25/13 (3 pages)
- FDA 482, Notice of Inspection, issued to Mr. Rogelio Martinez, dated 04/12/2013 (3 pages)
- FDA 482, Notice of Inspection, issued to Mr. Rogelio Martinez, dated 04/19/2013 (3 pages)
- Emails dated 03/19, 21, 24, 25/2013, 04, 01, 03, 05, 13, and 18/2013 (29 pages)
- NJDH&SS Environmental and Chemical Laboratory Services results (19 pages)
- Digital pictures taken by NJDH&SS (4 pages)



Miguel G. Manzano Maldonado, Investigator