



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

December 4, 2009

Paul Newell  
Willamette Shelling Inc.  
14975 NE Tangen RD.  
Newberg, Oregon 97132

Dear Mr. Newell:

Thank you for your recent letter with the corrected dates, responding to our list of observations (FORM FDA 483) dated November 20, 2009.

We will review your response and, if necessary, provide you with a written reply as soon as possible. Your correspondence will be made a part of your official establishment file.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen" followed by "ADD for".

Charles M. Breen  
District Director

bcc:

. CB/EF: Willamette Shelling Inc., Newberg, OR: FEI: 3010692

DD Chron File

PJC/BKA w/copy of response ltr.

DFM/dfm:a: response - Willamette Shelling Inc., December 4, 2009

RECEIVED

DEC 04 2009

SEA-DO DD

Willamette Shelling, Inc.  
14975 NE Tangen RD.  
Newberg OR.  
97132

NOVEMBER 25, 2009 (NO)  
~~October 23, 2009~~

Charles Breen  
Food and Drug Administration  
22201 23<sup>rd</sup> Drive SE  
Bothell, WA 98021-4421

Reference # 519325-326

Dear Charles Breen

NOVEMBER 17, 2009 (NO)  
On ~~October 17, 2009~~ investigators Jinkee M. Vila-Binayug and Jeffrey J. LeClair performed our annual FDA plant sanitation inspection. This letter is to inform you of the actions that Willamette Shelling, Inc is taking.

**Observation 1**

Remove and discard all cardboard boxes in the first two rows. Sweep up REPS and mop floors. Inspect all other cardboard; discard all soiled cardboard as needed. Move cardboard 18 inches away from warehouse wall. Complete clean and mop of warehouse.

Reattach screen on left bottom, overlay new screen with smaller holes.

All metal totes to have covers

**Observation 2**

Employee meeting has taken place and the employee's have been instructed about the following: That all employees associated with the sorting room will wash hands and dipping hands before returning to sorting tables. Employees with gloves will replace gloves when returning to there work area. Employees were reminded that if you are to rub your nose that you need to rewash hands before returning to work area.

**Observation 3**

Plastic curtains to be washed and sanitized. If not able to do then the curtain will be removed.

**Observation 4**

The employees that work in the metal tote area were instructed not to use plastic stool in tote dumping spout area. Also it was noted that all metal totes were cleaned before each season but was agreed that totes need to be cleaned as needed.

**Observation 5**

Employee meeting has taken place and was noted that all jewelry would not be allowed in the sorting room area.

**Observation 6**

New plastic shields for lighting has been ordered and will be replaced as needed when material is available.

**Observation 7**

Employee meeting has taken place and was noted that all employee smocks are to be stored in the designated closet which cannot be mixed with their street clothes.

We would like to thank both investigators for their professionalism and their help in this matter. If you have any questions please feel free to call me.

Regards



Paul Newell  
Willamette Shelling, Inc.

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14975 NE Tangen RD.  
Newberg OR.  
97132

**RECEIVED**

NOV 30 2009

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