

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER

22215 26th Ave SE Suite 210
Bothell, WA 98021
(425) 302-0340 Fax: (425) 302-0404
Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

07/15/2014 - 08/29/2014*

FEI NUMBER

3003051915

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark C. Osborne, Plant Manager

FIRM NAME

nSpired Natural Foods, Division of the
Hain Celestial Group

STREET ADDRESS

710 Jefferson Ave

CITY, STATE, ZIP CODE, COUNTRY

Ashland, OR 97520

TYPE ESTABLISHMENT INSPECTED

Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically,

Two environmental sub-samples (INV 858387) collected on 7/16/2014 within Bakery^{(b) (4)} during the manufacturing of dried pasteurized almonds lot 5461, were determined to be positive for Salmonella. The locations of the sub-samples are listed below:

1. Sub 175 Floor below cooling tower, east side, northern floor surface
2. Sub 188 Floor below cooling tower, west side, southern floor surface

OBSERVATION 2

Failure to maintain equipment in an acceptable condition through appropriate cleaning and sanitizing.

Specifically,

On 7/18/2014, food residues were on the food contact surface of the discharge hopper on Roaster^{(b) (4)} in Bakery^{(b) (4)}. The food residues were present on the equipment during the pre-operation inspection of the equipment, after the equipment was cleaned. The QC Manager confirmed the equipment was clean and ready for use.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Ian J. Thomson, Investigator
Crystal A. Harlan, Investigator
Jeffrey J. Leclair, Investigator
Leon R. Marquart, Investigator
Christopher R. Czajka, Investigator

DATE ISSUED

08/29/2014

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax:(425) 302-0404 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/15/2014 - 08/29/2014*
	FEI NUMBER 3003051915

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark C. Osborne, Plant Manager

FIRM NAME nSpired Natural Foods, Division of the Hain Celestial Group	STREET ADDRESS 710 Jefferson Ave
CITY, STATE, ZIP CODE, COUNTRY Ashland, OR 97520	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 3

Employees did not wash hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated.

Specifically,

On 7/16/2014 an employee used an electric pallet jack and then returned to transferring dried pasteurized almonds, lot 5461, from the discharge hopper to cardboard boxes using a blue plastic bucket without washing their hands between the two operations. Their hands were in direct contact with the top inside surface of the bucket, as well as, the bottom of the bucket. The bottom of the bucket is in direct contact with dried pasteurized almonds when the employees manually transfer dried pasteurized almonds from the discharge hopper to cardboard boxes for cooling.

OBSERVATION 4

Food contact surfaces are not designed to withstand the environment of their intended use.

Specifically,

On 7/21/2014 cracks in the plastic were observed on six of the buckets inside of the cooling tower attached to Roaster ^{(b) (4)}. Each crack was approximately one half inch long. On 7/22/2014 missing pieces of plastic were observed on two of the buckets inside of the cooling towers in Bakery ^{(b) (4)}. The largest missing piece of plastic was approximately two inches by one inch. The plastic buckets are in direct contact with roasted nuts when the cooling tower is in operation. The plastic buckets are used to convey nuts into the cooling tower cage from the discharge hopper and from the cooling tower cage to the super sack.

OBSERVATION 5

Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of organic matter and the opportunity for growth of microorganisms.

Specifically,

The weld on the food contact shovels for Roaster ^{(b) (4)} and Roaster ^{(b) (4)} in Bakery ^{(b) (4)} have rough welds. The weld attaches the shovel blade to the handle. The shovels were in direct contact with roasted almonds during the production of roasted almonds lot 5511. The shovels are used by employees in the transfer of roasted almonds from the discharge hopper to the cooling tower.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ian J. Thomson, Investigator Crystal A. Harlan, Investigator Jeffrey J. Leclair, Investigator Leon R. Marquart, Investigator Christopher R. Czajka, Investigator	DATE ISSUED 08/29/2014
	<i>Ian J. Thomson</i> <i>Crystal A. Harlan</i> <i>Jeffrey J. Leclair</i> <i>Leon R. Marquart</i> <i>Christopher R. Czajka</i>	

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/15/2014 - 08/29/2014*
	FEI NUMBER 3003051915

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mark C. Osborne, Plant Manager

FIRM NAME nSpired Natural Foods, Division of the Hain Celestial Group	STREET ADDRESS 710 Jefferson Ave
---	-------------------------------------

CITY, STATE, ZIP CODE, COUNTRY Ashland, OR 97520	TYPE ESTABLISHMENT INSPECTED Manufacturer
---	--

On 7/21/2014, the screw auger was observed out of the (b) (4) for cleaning. The weld on the food contact surface of the screw auger for the (b) (4) in the NA Jar Line had rough welds. The screw auger conveys nuts from the in-feed hopper on the (b) (4) into the course mill for the production of nut butters. The screw auger is in direct contact with the nuts.

The base of the cooling tower cage for Roaster^{(b) (4)} in Bakery^{(b) (4)} is frayed and missing pieces of metal. The cooling tower cage holds nuts in the cooling tower to allow for air to cool the nuts prior to transfer into a lined super sack.

OBSERVATION 6

The procedure used for sanitizing of equipment and utensils has not been shown to provide adequate sanitizing treatment. Specifically,

The (b) (4) multi-range sanitizer used to sanitize food contact surfaces label states non-immersed items must be allowed to air dry. nSpired Natural Foods Cooling Tower Cleaning Instructions state, "Pressure wash interior and exterior with sanitizer solution. Let sit for (b) (4) minutes then rinse off with hot water."

OBSERVATION 7

The plant is not constructed in such a manner as to allow floors to be adequately cleaned and kept clean. Specifically,

Throughout the facility, numerous cracks and gouges in the floor were observed. Including, but not limited to, the following:

- A. Four depressions, each approximately three inch diameter circles, in the NA Jar Line room. The circular depression appear to be aligned with the feet of the in-line metal detector.
- B. A two inch diameter circular depression in the floor of the NA Jar Line room. The circular depression appears to be aligned with the a foot of the (b) (4) filler.
- C. A three inch by three inch gouge is located in the southwest corner of the dry goods warehouse.
- D. A crack in the concrete floor in Bakery^{(b) (4)} approximately 15 feet long, parallel to the over-head door leading into the room.
- E. A crack in concrete floor in Bakery^{(b) (4)} greater than 20 feet long, perpendicular to the man-door leading into Bakery^{(b) (4)}. The crack in the floor continues from the doorway, past the front of the dish wash sink, to underneath the storage racks.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ian J. Thomson, Investigator Crystal A. Harlan, Investigator Jeffrey J. Leclair, Investigator Leon R. Marquart, Investigator Christopher R. Czajka, Investigator	DATE ISSUED 08/29/2014
		

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 22215 26th Ave SE Suite 210 Bothell, WA 98021 (425) 302-0340 Fax: (425) 302-0404 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 07/15/2014 - 08/29/2014*
	<small>FEI NUMBER</small> 3003051915

<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> To: Mark C. Osborne, Plant Manager	
<small>FIRM NAME</small> nSpired Natural Foods, Division of the Hain Celestial Group	<small>STREET ADDRESS</small> 710 Jefferson Ave
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Ashland, OR 97520	<small>TYPE ESTABLISHMENT INSPECTED</small> Manufacturer

OBSERVATION 8

Lack of backflow protection from piping systems that discharge waste water.

Specifically,

On 7/21/2014, a hose was submerged in the sink used to sanitize cleaned utensils. The sink used to sanitize cleaned utensils contained a solution of sanitizer and water. The hose was connected directly to the sink nozzle without backflow protection.

*** DATES OF INSPECTION:**
 07/15/2014(Tue), 07/16/2014(Wed), 07/17/2014(Thu), 07/18/2014(Fri), 07/21/2014(Mon), 07/22/2014(Tue), 07/23/2014(Wed),
 07/24/2014(Thu), 08/19/2014(Tue), 08/20/2014(Wed), 08/21/2014(Thu), 08/22/2014(Fri), 08/25/2014(Mon), 08/26/2014(Tue),
 08/27/2014(Wed), 08/28/2014(Thu), 08/29/2014(Fri)

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Ian J. Thomson, Investigator Crystal A. Harlan, Investigator Jeffrey J. Leclair, Investigator Leon R. Marquart, Investigator Christopher R. Czajka, Investigator	<small>DATE ISSUED</small> 08/29/2014
		