

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  USFDA Chicago District Office 550 W Jackson Blvd Ste 1500 Chicago, IL 60661 phone 312-353-5863  Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 12/20/10, 12/21/10, 12/28/10, 01/06/11, 01/07/11, 01/19/11, 01/28/11
	FEI NUMBER  1000515256

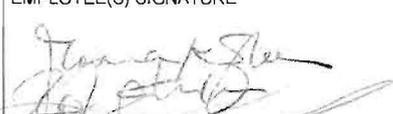
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
**TO:** William R Bagby, Jr., Owner

FIRM NAME Tiny Greens	STREET ADDRESS 2314 N. High Cross Rd
CITY, STATE AND ZIP CODE Urbana, IL 61802	TYPE OF ESTABLISHMENT INSPECTED sprout grower/manufacturer, dealer, distributor

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 (I) (WE) OBSERVED:

1. The production facility has one entrance by the loading docks, one entrance into the reception area, two entrances into the greenhouse, one entrance into the kitchen and one entrance into an office. All of the entrances are pathways for people and equipment into the production area. Employees were observed using all of the entrances.
  - a. On 12/21/10 Investigator Speer observed an employee in a red hooded sweat shirt dumping production waste into a compost pile then return to the production area via the south greenhouse entrance. The grade of the land is sloped down towards the greenhouse entrance. Run off water was observed pooling from the compost pile into drain along the walkway 11 ft from the entrance to the greenhouse. After walking through the compost pile and water, this employee returned to production wearing the same clothing and boots. This is the site of positive identification of Salmonella 4, 5, 12, i:, identified in the outbreak.
  - b. On 12/28/10 Investigator Speer observed two employees pushing a cart of trays of alfalfa sprouts from the sprouting area in production out through the south greenhouse exit. The employees entered the compost area to dump trays of sprouts. After walking and wheeling the cart through the compost pile, the employees returned to production wearing the same clothing and boots.
  - c. On 1/07/11 Investigator Speer observed micro-greens are grown in soil from the organic material decomposed outside. No kill step is monitored for the organic material decomposition. The soil is placed into sprouting trays in the greenhouse where seeds are then applied. The trays with soil are then moved into the sprouting area within 5 feet of the alfalfa sprouting trays.
  - d. On 12/21/10 Investigator Speer observed employees using the greenhouse as a break area wearing their production attire. The greenhouse contains plant material, soil and overhead irrigation. The greenhouse is connected to production facility.

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e. On 12/21/10 Investigator Speer observed employees using the east side entrance with access to the facility within 5 feet of an exterior fountain. The fountain is within 5 feet of the bird harborage area listed in observation #1g. The entrances are accesses into the greenhouse, an office and the kitchen. All entrances lead into the production facility.

f. On 12/20/10 Investigator Speer observed Amphibian/Reptile in reception area of firm. Employees were observed walking through the reception area and then entering the production area. Animals are cared for by the firms' HACCP Coordinator and owner.

g. On 12/21/10 Investigator Speer observed one sparrow like bird, nesting material and excrement within 20 feet of east entryway into facility. Employees were observed using the east side entry ways to access the greenhouse and then production areas.

h. On 1/06/11 Investigator Speer observed the foot bath by the green house empty of sanitizer solution. The <sup>(b) (4)</sup> foot baths filled with chlorine and water with only 1 foot bath recorded for sanitizer strength once per day.

2. On 1/19/11 Investigator Speer observed seed antimicrobial treatment with (b) (4) added to seeds, the drum closed and water sprayed on the seeds to sanitize. The firm has no evidence the seed sanitation is equivalent to soaking in 20,000ppm Calcium Hypochlorite. Seeds in the (b) (4) (4) of the drum with sanitizer contact time and strength undeterminable. Water is continually spraying into and draining out of each (b) (4) of the drum(s) (b) (4) Water levels within each of the drum (b) (4) was not at consistent levels from (b) (4) or drum to drum. This method of application is not the recommended method described on the product labeling. The firm did not demonstrate chlorine level verification during my visit.

3. Employee practices observed are a potentially significant source of contamination.

a. On 12/20/10 Investigator Reiber observed an employee enter the kitchen area from the production room with his apron on, then enter the rest room. The employee exited the rest room with his apron on and went back into the production area.

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b. On 01/06/11 T-J. Fu, Ph.D., Research Chemical Engineer observed an employee place a screen from the shaker table on the floor and rinse with a hose. This operation was performed within 2 feet of open trays of germinated sprouts. Water droplets from the water stream onto the floor were splashing into the trays of germinated sprouts.

c. On 12/21/10 Investigator Speer observed an employee in a red hooded sweat shirt washing his boots off in the large "grey water" fountain by the parking area. This same employee was observed working in the compost pile described in observation #1a. Water from the compost run off is pumped to this fountain.

d. On 12/20/10 Investigator Speer observed employee lunches and beverages stored on shelves in the cooler. The cooler stores finished sprouts and organic alfalfa seed. Items observed sitting on the shelf were sack lunches, a glass mason jar with clear liquid, plastic gallon milk jug with employees' name written on the jug and raw bacon in the commercial package.

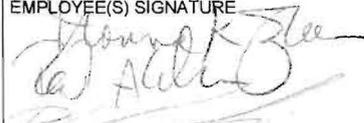
e. On 12/20/10 Investigator Alcantara observed an employee working at the washing and de-hulling line wearing a yellow apron that had duct tape on the front of the apron. The apron is a food contact surface.

f. On 12/20/10 Investigator Speer observed germination drum plexi-glass doors stored on the drum frames less than 12 inches from the floor. The drum closest to the greenhouse door had two doors stored in this manner. Water and debris from the floor was observed splashed on to the doors. The doors are not cleaned prior to installation on the germination drum.

g. On 1/06/11 Investigator Gerrity observed sprouts being unloaded from the germination drums into white perforated pails on dollies. When the dollies were rolled to the table for placing the alfalfa sprouts in trays, water from the rotating wheels on the floor was observed splashing up on the perforated pails with access to the sprouts.

h. On 1/07/11 Investigator Gerrity observed a gloved employee removing sunflower seed hulls from the sprout, use his cell phone and then return to removing seed hulls. The phone was cradled on the employees shoulder and against his ear and face. No hand sanitation was performed after handling the cell phone.

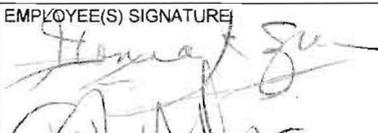
4. Design of equipment is not cleanable.

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- a. On 1/06/11 Investigator Gerrity observed sprouting trays with a plastic brace bolted to the outer front and back of the trays. Build up of biofilm-like material was around the repair on the trays.
- b. On 1/07/11 Investigator Gerrity observed rough welds, organic matter buildup and perforations on the food contact surface of a stainless steel table used to package alfalfa sprouts. Sprouts are dumped directly onto the table to be placed in packaging.
- c. On 1/07/11 Investigator Speer observed orange fencing with zip and bread type ties used to hold alfalfa sprouts for centrifuging. The fencing was observed stored on top of the centrifuge on 1/06/11 with dried up sprouts from a previous run.
- d. On 1/06/11 Investigator Gerrity observed an employee using a paddle with two bolts holding the green paddle onto the white handle. The paddle was used to scrap germinated alfalfa sprouts from the germinating drum. There was scaring and damage on the paddle and handle.
- e. On 1/07/11 Investigator Gerrity observed rotating tines with plastic tips, threaded bolts and metal hinge on the belt in the wash tank.
5. Cleaning practices are not adequate to remove residue and organic material.
- a. On 1/06/11 Investigator Gerrity observed biofilm-like buildup on the food contact surface sprouting trays. These trays had been cleaned and were ready for use.
- b. On 1/06/11 Investigator Speer observed residue buildup on the interior of the germination drums. A film build up was observed over the screen vents in the back of each of the germination drums.
- c. On 1/07/11 Investigator Speer observed mold like formations on the walls and up in the ceiling above the mung bean sprouting room. A ceiling tile was missing in the room directly above the first sprouting tank on the left as one enters the room.

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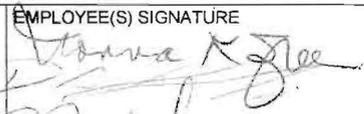
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6. Condensation dripped from the ceiling in the production areas throughout the inspection 12/20/10 - 1/18/11.

- a. On 12/20/10 Investigator Speer observed condensate from the cooling unit on the west end of the cooler dripping onto plastic containers of 4oz Alfalfa Sprouts stored under the unit.
- b. On 12/20/10 Investigator Speer observed condensate on the concrete slab ceiling above the sprouting racks with trays of sprouts. Condensate in this area was also observed 12/20/10, 12/21/10, 1/06/11, 1/07/11, 1/19/11.
- c. On 12/20/10 Investigator Speer observed condensate at the ceiling and wall junction in the packaging material warehouse. The condensate was observed pooling along the wall.
- d. On 1/06/11 and 01/07/11 Investigator Gerrity observed condensate dripping from the ceiling in the mung bean sprouting room.

7. The firm's microbiological testing is not adequate to monitor pathogen contamination.

- a. On 12/28/10 Investigator Speer observed the firm did not have a limitation standard for APC established where high levels of contamination would prompt corrective actions. The Tiny Greens Microbiological Testing Program, updated: 10/5/2010 states "The bacteria kill must exceed (b)(4)%."
- b. On 12/28/10 Investigator Speer observed the firm did not have an established protocol for sample preparation for shipment of sprouts and spent irrigation water.
- c. On 01/06/11 T-J. Fu, Ph.D., Research Chemical Engineer learned from the owner a smaller sample size of (b)(4) ml per run is used rather than the recommended of 1 liter for the spent irrigation water testing.
- d. On 01/06/11 T-J. Fu, Ph.D., Research Chemical Engineer observed the firm contracts an outside lab to test irrigation water and sprout samples. The test methodology the lab used, (b)(4), was not validated for detection of Salmonella in alfalfa sprouts or spent irrigation water. The amount of irrigation water analyzed in this method is (b)(4) ml as opposed to the two 375 ml aliquots.

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8. On 1/06/11 Investigator Speer observed the sink used for hand sanitation prior to entering production is the sink employees use in the lunch room. The sink has a hose with a valve on the end of the hose under the sink which was observed leaking water onto the floor in the foot traffic area of the lunch room.

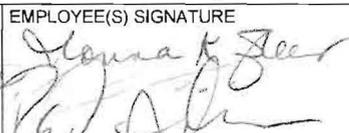
9. Contamination potential for primary well water which is the firms processing water.

a. On 12/20/10 Investigator Speer observed bio-diesel being manufactured in the well house. The manufacturing process uses (b) (4). An oil-like substance was observed on the floor of the shed and next to the gravel topped casement surrounding the primary well.

b. On 12/20/10 Investigator Speer observed an electric wire portal not sealed on the primary wellhead.

c. On 12/20/10 Investigator Speer observed cross connections at the primary well. The primary well is connected to a garden well and the bio-diesel production in the well house.

10. On 1/06/11 Investigator Alcantara observed approximately 19 insects under the micro-greens sprouting platform for trays. On 1/07/11 Investigator Speer collected a sample INV645688 of the insects for identification.

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