U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Jensen Farms 10/18/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Southwest Region
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October 18, 2011

Ref: DEN-12-01 WL

WARNING LETTER

VIA UPS Overnight Mail

Mr. Ryan D. Jensen, Co-Owner/Partner
Mr. Eric S. Jensen, Co-Owner/Partner
Jensen Farms
31 North Cline
Granada, Colorado

Dear Messrs. Jensen:

On September 10, 2011, investigators from the Food and Drug Administration (FDA) inspected your produce packing facility located at 31 North Cline, Granada, Colorado. FDA conducted this inspection under its authority in section 704 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 374] as a result of epidemiological and traceback investigations that implicated cantaloupe grown at your farm and packed at your facility with a nationwide outbreak of listeriosis.

Specifically, on September 2, 2011, the Colorado Department of Public Health and Environment (CDPHE) notified the Centers for Disease Control and Prevention (CDC) of seven cases of listeriosis reported since August 28, which was a significant increase from the average number of listeriosis cases reported in Colorado each month. By September 6, all seven Colorado patients reported eating cantaloupe in the month before illness began, and three reported eating cantaloupe marketed as "Rocky Ford," which is produced by a number of farms in the Rocky Ford region of Colorado, including Jensen Farms.

CDC has stated that this is one of the largest outbreaks of listeriosis in the history of the United States. As of October 11, 2011, 116 people from 25 states were sickened and 23 people have died. Four widely differing strains and two serotypes (1/2a and 1/2b) have been associated with the outbreak. CDC defined clusters of illnesses (clusters 1-4) based on the four strains. You may read more information about the outbreak at the following web address: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6039a5.htm?s_cid=mm6039a5_w [1].

Infection with *Listeria monocytogenes* causes a spectrum of illness, ranging from febrile gastroenteritis to invasive disease, including sepsis and meningoencephalitis. Invasive listeriosis occurs predominantly in older adults and persons with impaired immune systems. Listeriosis in pregnant women is typically a mild "flu-like" illness, but can result in fetal death, premature labor, or neonatal infection.

During the September 10 inspection, FDA sampled cantaloupes from cases on four pallets in the cold storage in your packing facility. FDA conducted laboratory analyses, including pulsed-field gel electrophoresis ("PFGE"), on these samples. Five of the ten cantaloupes FDA analyzed were positive for *Listeria monocytogenes*. The PFGE analysis determined that four of the ten cantaloupes matched the strain of *Listeria monocytogenes* representing cluster #2, and one of the cantaloupes matched the strain of *Listeria monocytogenes* representing cluster # 4. Consequently, these cantaloupes from your facility are adulterated within the meaning of Section 402(a)(1) of the Act [21 U.S.C. § 342(a)(1)] in that they bear or contain a poisonous or deleterious substance that may render them injurious to health. You can find the Act and the regulations through links in FDA's homepage at www.fda.gov [2].

During the inspection, we also collected environmental swabs from various locations and surfaces throughout your packing facility. FDA conducted laboratory analyses which determined that 13 of the 39 total environmental swabs were positive for outbreak strains of *Listeria monocytogenes*. PFGE analysis determined that eleven of the positive swabs matched the strain of *Listeria monocytogenes* represented by cluster #2, one positive swab matched the strain of *Listeria*

monocytogenes represented by cluster #4, and one positive swab matched the strain of *Listeria monocytogenes* represented by cluster #3. Further, one swab was positive for a strain of *Listeria monocytogenes* that did not match any of the outbreak strains. These positive swabs were taken from different locations throughout the washing and packing areas in your facility, all of which were either food contact surfaces or areas adjacent to food contact surfaces. This significant percentage of swabs that tested positive for outbreak strains of *Listeria monocytogenes* demonstrates widespread contamination throughout your facility and indicates poor sanitary practices in the facility.

Accordingly, the cantaloupe packed in your facility are adulterated within the meaning of Section 402(a)(4) of the Act [21 U.S.C. § 342(a)(4)] in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. A summary of the PFGE results from samples collected during this investigation that tested positive for *Listeria monocytogenes* is attached for your information.

FDA may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. Additionally, the receipt of this warning letter and any action taken to correct the violations cited in it do not preclude a subsequent criminal prosecution by the United States Department of Justice.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or other similar violations, from occurring in the future. Include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

This letter may not list all the violations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act and all applicable regulations.

FDA acknowledges receipt of the letter, dated October 17, 2011, from your counsel, Michael W. Callahan. In this letter, Jensen Farms agreed, among other things, to FDA inspection of its growing, packaging, and cold storage operations before it resumes food harvesting, packaging, or processing. Jensen Farms also agreed to correct all objectionable observations noted during said FDA inspections.

We note that, in our Draft Guidance for Industry, Guide to Minimize Microbial Food Safety Hazards of Melons, we recommend a number of practices to minimize microbial food safety hazards associated with melons throughout the entire melon supply chain. Specifically, we recommend, among others, the following postharvest practices:

- Using packing equipment designed to facilitate cleaning and sanitation of melon contact surfaces and constructed of materials that may be easily cleaned and sanitized;
- Validating and verifying that melon wetting and brushing operations are not a potential source of melon contamination or cross-contamination; and
- Cooling and cold storing melons as soon as possible after harvest because delays in cooling when melons with netted rinds (such as cantaloupe) are wet from washing operations may allow for multiplication of human pathogens on the rind surface.

Please send your reply to FDA, Attention: Carolyn A. Pinney, Compliance Officer, at the above letterhead address. If you have any questions regarding this letter, please contact Carolyn A. Pinney at (303) 236-3024.

Sincerely,
/S/
La Tonya M. Mitchell
Denver District Director

Links on this page:

1. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6039a5.htm?s_cid=mm6039a5_w
2. http://www.fda.gov/