

IN THE IOWA DISTRICT COURT FOR POLK COUNTY, IOWA

<p>ERICK JOHNSON, Plaintiff, vs. JIMMY JOHN'S FRANCHISE, LLC AND JIMMY JOHN'S GOURMET SANDWICHES Defendants.</p>	<p>LAW NO. ORIGINAL NOTICE</p>
--	--

TO THE ABOVE-NAMED DEFENDANTS:

You are notified that a Petition has been filed in the Office of the Clerk of this Court, naming you as a Defendant in this action. A copy of the Petition (and any documents filed with it) are attached to this Notice. The name and address of Petitioner's attorney is Terry M. Kurt of Hammer Law Firm, PLC, 590 Iowa Street, Suite 2, Dubuque, IA 52001. The attorney's phone number is (563)582-1560 and facsimile number (866)921-6143.

You must serve a motion or answer within twenty (20) days after service of this Original Notice upon you, and within a reasonable time thereafter, file your motion or answer with the Clerk of Court for Polk County, at the County Courthouse in Des Moines, Iowa. If you do not, judgment by default may be rendered against you for the relief demanded in the Petition.

This case has been filed in a county that uses electronic filing. You must register to efile through the Iowa Judicial Branch website at <http://iowacourts.state.ia.us/eFile> and obtain a log in and password for filing and viewing documents in your case and for receiving service and notices from the court.

For general rules and information on electronic filing, refer to the Iowa Court Rules Chapter 16 Pertaining to the Use of Electronic Document Management System, available on the Iowa Judicial Branch website. For court rules on the Protection of Personal Privacy in court filings, refer to Division VI of the Iowa Court Rules Chapter 16. If you are unable to proceed electronically, you must receive permission from the court to file in paper. Contact the clerk of court in the county where the petition was filed for more information on being excused from electronic filing.

If you require assistance of auxiliary aides or services to participate in court due to a disability, immediately call your District ADA Coordinator at (515) 286-3394. Persons who are hearing or speech impaired may call Relay Iowa TTY (1-800-735-2942). **Disability coordinators cannot provide legal advice.**

IMPORTANT:

YOU ARE ADVISED TO SEEK LEGAL ADVICE AT ONCE TO PROTECT YOUR INTERESTS.

STATE OF IOWA JUDICIARY

Case No. LACL148324

County Polk

Case Title ERICK JOHNSON VS JIMMY JOHNS FRANCHISE LLC ET AL

THIS CASE HAS BEEN FILED IN A COUNTY THAT USES ELECTRONIC FILING.

Therefore, unless the attached Petition and Original Notice contains a hearing date for your appearance, or unless you obtain an exemption from the court, you must file your Appearance and Answer electronically.

You must register through the Iowa Judicial Branch website at <http://www.iowacourts.state.ia.us/Efile> and obtain a log in and password for the purposes of filing and viewing documents on your case and of receiving service and notices from the court.

FOR GENERAL RULES AND INFORMATION ON ELECTRONIC FILING, REFER TO THE IOWA COURT RULES CHAPTER 16 PERTAINING TO THE USE OF THE ELECTRONIC DOCUMENT MANAGEMENT SYSTEM:

<http://www.iowacourts.state.ia.us/Efile>

FOR COURT RULES ON PROTECTION OF PERSONAL PRIVACY IN COURT FILINGS, REFER TO DIVISION VI OF IOWA COURT RULES CHAPTER 16: <http://www.iowacourts.state.ia.us/Efile>

Scheduled Hearing:

[Empty box for scheduled hearing details]

If you require the assistance of auxiliary aids or services to participate in court because of a disability, immediately call your district ADA coordinator at (515) 286-3394 . (If you are hearing impaired, call Relay Iowa TTY at 1-800-735-2942.)

Date Issued 07/21/2020 03:01:38 PM



District Clerk of Polk

County

/s/ Jennifer Ewers

IN THE IOWA DISTRICT COURT FOR POLK COUNTY, IOWA

<p>ERICK JOHNSON, Plaintiff, vs. JIMMY JOHN'S FRANCHISE, LLC AND JIMMY JOHN'S GOURMET SANDWICHES Defendants.</p>	<p>LAW NO. PETITION AT LAW AND JURY DEMAND</p>
--	--

COME NOW, the Plaintiff, ERICK JOHNSON, by and through his attorney, **Ron Simon, of Ron Simon & Associates** and **Terry M. Kurt, of Hammer Law Firm, PLC**, and for his Petition at Law, state to the Court as follows:

COUNT I

PARTIES

1. Plaintiff Erick Johnson is an adult and resident of Jefferson, Iowa in Greene County.
2. Defendant Jimmy John's Franchise, LLC is an Illinois corporation. It may be served through its registered agent, Brian A. Smith, 311 S. Wacker Drive, Suite 3000, Chicago, IL 60606.
3. Defendant Jimmy John's Gourmet Sandwiches is an Iowa corporation.

JURISDICTION AND VENUE

4. This Court has jurisdiction and venue over Defendants because Defendants sell and distribute products in Polk County, Iowa, and because the actions forming the basis of this lawsuit took place in Polk County, Iowa.

GENERAL ALLEGATIONS

About E. coli

5. E. coli: Escherichia coli is the name of a common family of bacteria that includes both Shiga toxin-producing E. coli (a specific sub-group of this family that can cause bloody diarrhea, or hemorrhagic colitis) in humans, and enteropathogenic E. coli bacteria, which also causes severe stomach cramps, diarrhea that is often

bloody, vomiting and sometimes a low-grade fever, according to health officials.

6. After ingestion, E. coli bacteria travel to the lumen of the small intestines, then penetrate the epithelium, multiply, and enter the blood. This infection process – also referred to as the incubation period – usually takes 6 to 72 hours for the onset of symptoms. As few as 15-20 cells of E. coli bacteria can cause infection.
7. After a susceptible individual is exposed to and ingests E. coli, the bacteria attaches to the inside surface of the large intestine and initiates an inflammatory reaction of the intestine.
8. The mean incubation period (time from ingestion to the onset of symptoms) of E. coli is estimated to be two to four days (range, 1-21 days).
9. Typically, a patient with an acute E. coli bacterial infection presents with abdominal cramps, bloody diarrhea, and vomiting. E. coli bacteria can produce a wide spectrum of disease from mild, non-bloody diarrhea, to severe bloody diarrhea accompanied by excruciating abdominal pain to life-threatening complications.

E. coli O103 Outbreak Linked to Food Served at Jimmy John's Stores

10. The Iowa Department of Public Health has reported that, as of January 7, 2020, a total of 22 people from Iowa have been infected with the outbreak strain of E. coli O103. Twenty of the 22 case individuals were interviewed by the Iowa Department of Public Health, with 100 % reporting they purchased and consumed food at one or more of 15 Jimmy John's restaurants in Iowa.
11. Those interviewed reported eating sprouts at one or more Jimmy John's restaurants in the week before their illness.
12. The Iowa Department of Inspections and Appeals concluded that Jimmy John's restaurants were the outbreak vehicle, and identified samples of sprouts and sprout irrigation water, collected by the firm that supplied the sprouts to Jimmy John's restaurants, as positive for the strain of E. coli O103 that was related to the outbreak strain by whole genome sequencing, a state-of-the-art genetic subtyping method.

Defendants' Wanton and Willful Disregard of the Known Risk Posed by Sprouts

13. At all times relevant thereto, Defendants operated their restaurants with intentional disregard for the potential contamination of their sprouts with bacterial pathogens including, but not limited to, E. coli.
14. Furthermore, Defendants have an extensive record of wanton and willful behavior showing intentional disregard for the rights and safety of those who eat at their restaurants. Since 2008, sprouts from Jimmy John's have repeatedly been linked

to outbreaks of Salmonella and E. coli illnesses. According to CDC reports, these outbreaks include:

- a. In 2008, 28 people were sickened in an outbreak of E. coli O157:NM(H-) in which consumption of alfalfa sprouts at Jimmy John's was deemed a risk factor for illness.
 - b. In 2009, 256 people were sickened in a Salmonella outbreak linked to consumption of sprouts. Many of the illnesses in this outbreak occurred from consumption of Jimmy John's sandwiches.
 - c. In 2010, 140 people were sickened in Illinois in a Salmonella serotype I4,[5],12:i:-, outbreak linked to sprouts at numerous Jimmy John's restaurant outlets. A simultaneous outbreak of Salmonella Newport occurred in Washington with seven people sickened, also linked to sprouts served at Jimmy John's.
 - d. In 2012, 29 people were sickened in an outbreak of E. coli O26 linked to consumption of sprouts at Jimmy John's.
 - e. A 2013 outbreak of eight people from Colorado who were infected with the outbreak strain of E. coli O157:H7. Of the eight persons interviewed by Colorado Department of Public Health and Environment, 100% report eating a sandwich with raw cucumbers at one of three Jimmy John's restaurants in the Denver metro area.
 - f. In 2014, 19 people were sickened in an outbreak of E. coli O121 linked to consumption of sprouts at several restaurants, including Jimmy John's.
 - g. A 2018, 10 people were sickened in an outbreak of Salmonella serotype *Montevideo* in Illinois (2), Minnesota (2), and Wisconsin (6). The victims reported eating raw sprouts on sandwiches from Jimmy John's in Illinois and Wisconsin.
15. As a result of these numerous sprout outbreaks spanning over a decade, the FDA sent a *Warning Letter* to James North, President of Jimmy John's Franchise, LLC.
 16. The FDA Warning Letter states: "*In May 2012, a meeting was held with FDA at your request. During that meeting, you expressed that you would offer only clover sprouts, and to only source clover sprouts from (b)(4) suppliers. Since that corrective action, your firm has been implicated in three additional sprout-related outbreaks. Documents from traceback investigations conducted by FDA, states and local partners demonstrate that in addition to (b)(4) sprouts, Jimmy John's restaurants are using multiple other sources of sprouts.*" See Exhibit A, attached.
 17. Defendants have long been aware of the danger of their sprouts being contaminated with bacterial pathogens like E. coli and Salmonella. They have

also long been aware of the severe harm such contamination can cause and has caused to consumers, yet they have repeatedly, willfully, and wantonly refused to take appropriate action to address this recurring problem.

Plaintiff's Illness

18. On December 9, 2019, Plaintiff purchased and consumed a sandwich from the Jimmy John's located at 5950 NW 86th Street #102, Johnston, Iowa 50131.
19. Within a few days, he began experiencing symptoms consistent with E. coli poisoning, including bloody stool, nausea, and diarrhea.
20. On December 13th, Plaintiff presented to the emergency room at Boone County Hospital and was thereafter hospitalized for E. coli poisoning.
21. Shortly thereafter, Plaintiff was interviewed by the Greene County Health Department who confirmed he was part of the E. coli outbreak.

FIRST CAUSE OF ACTION
(Strict Products Liability)

22. At all times, Defendants were in the business of producing, manufacturing, preparing, marketing and serving clover sprouts (hereinafter "the product") to the public.
23. There was a manufacturing defect in the product when it left Defendants' possession and control. The product was defective because it contained E. coli. The presence of E. coli was a condition of the product that rendered it unreasonably dangerous.
24. There was a marketing defect in the product when it left Defendants' possession and control. The product was defective because it contained E. coli and Defendants failed to give adequate warnings of the product's dangers that were known or by the application of reasonably developed human skill and foresight should have been known. Defendants also failed to give adequate warnings and instructions to avoid such dangers. Defendants' failure to provide such warnings and instructions rendered the product unreasonably dangerous.
25. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages set forth below.
26. Defendants are therefore strictly liable for importing, manufacturing, distributing, marketing, and selling defective and unreasonably dangerous product and introducing it into the stream of commerce.

SECOND CAUSE OF ACTION
(Negligence)

27. Defendants owed Plaintiff a duty of ordinary care in the manufacture, preparation, testing, packaging, marketing, distribution, and selling of the product. Further, Defendants owed Plaintiff the duty of warning or instructing Plaintiff of potentially hazardous or life-threatening conditions with respect to the product.
28. Defendants breached their duties in one or more of at least the following ways:
 - a. negligently growing, harvesting, manufacturing, distributing, and marketing the product;
 - b. failing to properly test the product before placing it into the stream of commerce;
 - c. failing to prevent human and/or animal feces from coming into contact with the product;
 - d. failing to adequately monitor the safety and sanitary conditions of their premises;
 - e. failing to apply their own policies and procedures to ensure the safety and sanitary conditions of their premises;
 - f. failing to adopt and/or follow FDA recommended good manufacturing practices;
 - g. failing to take reasonable measures to prevent the transmission of E. coli and related filth and adulteration from their premises;
 - h. failing to properly train and supervise their employees and agents to prevent the transmission of E. coli and related filth and adulteration from their premises;
 - i. failing to warn Plaintiff and the general public of the dangerous propensities of the product, particularly that it was contaminated with E. coli, despite knowing or having reason to know of such dangers; and
 - j. failing to timely disclose post-sale information concerning the dangers associated with the product.
29. Furthermore, Defendants had a duty to comply with all applicable health regulations, including the *FDA's Good Manufacturing Practices Regulations*, 21 C.F.R. part 110, subparts (A)-(G), and all statutory and regulatory provisions that applied to the import, manufacture, distribution, storage, and/or sale of the product or product ingredients, including but not limited to, the *Federal Food, Drug, and Cosmetics Act*, § 402(a), as codified at 21 U.S.C. § 342(a), which bans the manufacture, sale and distribution of any "adulterated" food and the *Iowa Administrative Code*, Rule 481-31.3, which contains a similar ban.

30. Under both federal and applicable state law, food is adulterated if it contains a poisonous or deleterious substance which may render it injurious to health. *Federal Food, Drug, and Cosmetics Act*, § 402(a)(1); *Iowa Adulteration of Foods*, §190.3.
31. The product was adulterated because it contained E. coli. Thus, by the import, manufacture, distribution, delivery, storage, receipt, sale, and/or offering for sale of the product and/or the product's ingredients, Defendants breached their statutory and regulatory duties.
32. Plaintiff was a member of the classes sought to be protected by the regulations and statutes identified above.
33. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages set forth below.
34. All dangers associated with the product were reasonably foreseeable and/or scientifically discoverable by Defendants at the time Defendants placed the product into the stream of commerce.

THIRD CAUSE OF ACTION
(Breach of Warranties)

35. Defendants are merchants who manufacture, import, produce, distribute, sell, and market the product.
36. Plaintiff is a consumer.
37. By offering food for sale to the general public, Defendants expressly warranted that such food was safe to eat, that it was not adulterated with a deadly pathogen, and that the food had been prepared under sanitary conditions.
38. Defendants breached the express and implied warranties of merchantability by impliedly warranting that the product was of merchantable quality and fit for human consumption when it was not due to the presence of E. coli. Plaintiff reasonably relied upon Defendants' skill and judgment as to whether the product was of merchantable quality and fit for human consumption.
39. Defendants breached the implied warranty of fitness for a particular purpose by holding out unreasonably dangerous product (i.e. product containing E. coli) to the public as being safe when they knew or had reason to know that the product was not safe and that the public would consume the product.
40. Defendants did not disclaim these implied warranties.
41. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages set forth below.

DAMAGES

42. Defendants' conduct was a direct, proximate, and producing cause of Plaintiff's injuries and damages, including but not limited to damages in the past and future for the following: pain and suffering, mental anguish, physical impairment, physical disfigurement, loss of enjoyment of life, medical and pharmaceutical expenses, travel and travel-related expenses, emotional distress, lost wages, lost earning capacity, loss of consortium, attorneys' fees (to the extent recoverable) and other general, special, ordinary, incidental and consequential damages as would be anticipated to arise under the circumstances.
43. WHEREFORE, Plaintiff prays for judgment against Defendants as follows:
- a. Past and future economic and non-economic damages;
 - b. Court costs;
 - c. Pre- and post-judgment interest at the highest rate allowed by law; and
 - d. For such other relief as the Court deems just and proper.

JURY DEMAND

COMES NOW Plaintiff, ERICK JOHNSON, and hereby requests trial by jury of the above captioned matter.

Dated: July 21, 2020

ERICK JOHNSON, PLAINTIFF

By: 
Terry M. Kurt AT0012091
of
HAMMER LAW FIRM, P.L.C.
590 Iowa Street, Suite 2
Dubuque, IA 52001
Telephone: (563) 582-1560
Fax: (866) 921-6143
Email: terry@hammerlawoffices.com

RON SIMON & ASSOCIATES
Ron Simon (*pending admission pro hac vice*)
820 Gessner, Suite 1455
Houston, Texas 77024

Telephone: (713) 335-4900

Fax: (713) 335-4949

ron@rsaalaw.com

ATTORNEYS FOR PLAINTIFF

EXHIBIT A

WARNING LETTER

Jimmy John's Franchise, LLC

MARCS-CMS 599962 – FEBRUARY 21, 2020

Delivery Method:

Certified Mail

Product:

Food & Beverages

Recipient:

James North

President

Jimmy John's Franchise, LLC

2212 Fox Drive

Champaign, IL 61820

United States

Issuing Office:

Division of Human and Animal Food Operations East VI

United States

WARNING LETTER

FY2020-HAFE6-01

Dear Mr. North:

The U.S. Food and Drug Administration (FDA), along with the Centers for Disease Control and Prevention (CDC), and state and local partners, have collaboratively investigated several outbreaks linked to Jimmy John's restaurants. In this letter we detail evidence from five outbreaks, including the most recent outbreak in the state of Iowa during December 2019 of human infections with *Escherichia coli* O103. The evidence demonstrates that your corporation, through your franchised Jimmy John's restaurants, engaged in a pattern of receiving and offering for sale adulterated fresh produce, specifically clover sprouts and cucumbers.

The pathogens associated with these outbreaks are Shiga toxin producing *Escherichia coli* (STECs) and *Salmonella enterica*. STECs can cause serious illness in humans, including diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called hemolytic uremic syndrome (HUS). HUS is most likely to occur in young children and the elderly. This condition can lead to serious kidney damage and death. *Salmonella* is a

pathogenic bacterium that can cause serious, sometimes fatal, infections. These infections can be especially serious in young children, the elderly, and others with weakened immune systems. Healthy individuals may suffer short-term symptoms such as severe diarrhea, bloody diarrhea, fever, chills, abdominal discomfort, and vomiting. The presence of these pathogens in your food, as evidenced by links to foodborne outbreaks, causes your products to be adulterated within the meaning of section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act)[21 U.S.C. § 342(a)(1)] in that they bear or contain an added poisonous or deleterious substance which may render them injurious to health. The introduction or delivery for introduction into interstate commerce of food that is adulterated is a prohibited act under section 301(a) of the Act [21 U.S.C. 331(a)]. Further, receipt in interstate commerce of adulterated food is a prohibited act under section 301(c) of the Act [21 U.S.C. § 331(c)]. You can find the Act and its implementing regulations through links on FDA's home page at <https://www.fda.gov>.

Human Illness Outbreaks

1. November to December 2019; outbreak of human infections with *E. coli* O103 (STEC)

Iowa Department of Public Health reported that as of January 7, 2020, a total of 22 people from Iowa were infected with the outbreak strain of *E. coli* O103. Twenty of the 22 case individuals were interviewed by the Iowa Department of Public Health. Of the case individuals interviewed, 100 % reported eating at one or more of 15 Jimmy John's restaurants. Of the 20 interviewed, 45% (9) reporting eating sprouts in the week before their illness. Iowa Department of Public Health states this proportion is significantly higher than results from a survey of healthy people in which 3.3% reported eating sprouts in the seven days before being interviewed.

Iowa Department of Inspections and Appeals ascertained that (b)(4) of the 15 Jimmy John's restaurants received clover sprouts from (b)(4) clover sprouts during the period of interest. As further confirmation that sprouts served at your restaurants were the outbreak vehicle, samples of sprouts and sprout irrigation water collected by the firm that supplied the (b)(4) Jimmy John's restaurants yielded a strain of *E. coli* O103 that was highly related to the outbreak strain by whole genome sequencing, a state-of-the-art genetic subtyping method. The analytical work was done by (b)(4).

2. Outbreak of human infections with *Salmonella* Montevideo

The CDC reported that as of February 28, 2018, ten people were infected with the outbreak strains of *Salmonella* Montevideo in Illinois (2), Minnesota (2), and Wisconsin (6). Eight (80%) of these ten people ate meals at Jimmy John's restaurants in Illinois and Wisconsin the week before becoming sick. All eight people reported eating raw sprouts on sandwiches from Jimmy John's in Illinois and Wisconsin. One ill person in this outbreak reported eating raw sprouts purchased from a grocery store in Minnesota. All the *Salmonella* Montevideo isolates were closely related by whole genome sequencing.

The evidence supports that (b)(4) sprouts for the implicated Jimmy John's restaurants. (b)(4) shown in invoices collected by State and local partners, including the Illinois Department of Public Health, Minnesota Department of Health, the Minnesota Department of Agriculture, the Wisconsin Department of Agriculture, Trade and Consumer Protection, and the Wisconsin Department of Health Services, from various Jimmy John's locations the Minnesota grocery store and/or distributors.

3. Outbreak of human infections with *E. coli* O102 (STEC)

The CDC reported that as of August 1, 2014, 19 people were infected with the outbreak strain of *E. coli* O121 in Idaho, Montana, Michigan, Utah, California, and Washington. In interviews, 13 (81%) of 16 ill persons reported eating raw clover sprouts in the week before becoming ill. This proportion is significantly higher than results from a survey of healthy persons in which no more than 8% reported eating raw clover sprouts in the week before they were interviewed.

FDA's traceback investigation for 11 of the 19 case individuals identified seven points of service [POS] as the likely or most likely locations of their sprout exposures. Five (5) of seven (7) POS were identified as Jimmy John's restaurants. Clover sprouts served at each POC were sourced from the same sprout grower.


4. Outbreak of human infections with *E. coli* O157:H7 (STEC)

CDC reported that as of the end of October 2013, eight people from Colorado were infected with the outbreak strain of *E. coli* O157:H7. Of the eight persons interviewed by Colorado Department of Public Health and Environment, 100% report eating a sandwich with raw cucumbers at one of three Jimmy John's restaurants in the Denver metro area. No other ingredient exposure was as significant as cucumbers. FDA's traceback investigation identified that all three Jimmy John's restaurants involved in the outbreak received cucumbers from the same source during the period of interest.

5. Outbreak of human infections with *E. coli* O26

CDC reported that as of April 5, 2012, a total of 29 people from eleven states were infected with an outbreak strain of *E. coli* O26. Of the 27 persons interviewed, 85% (23) report eating sprouts at one of six Jimmy John's restaurant in the seven days preceding their illness. Though traceback investigation, FDA identified a single lot of seed grown and distributed by multiple sprouting firms including (b)(4) sprout operations that supplied the six Jimmy John's restaurants implicated in the outbreak.

Taken together, these outbreaks, which spanned over the past seven years and impacted no fewer than seventeen states demonstrate the corporate-wide supplier control mechanisms you have in place for receiving fresh produce are inadequate.

We acknowledge your parent company's, Inspire Brands, decision in December 2019 to destroy sprouts on hand in all of your Iowa Jimmy John's restaurants, and to implement an additional, one-time cleaning and sanitation at Iowa based Jimmy John's restaurants; however, neither you nor your parent company proposed any corrective actions to prevent these, or other Jimmy John's restaurants, from receiving adulterated produce, specifically sprouts. According to your website, www.ownajimmyjohns.com (<http://www.ownajimmyjohns.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), you have franchised approximately 2,800 Jimmy John's restaurants in 43 states. In your response to this letter, please describe and document steps you have or will take to prevent the receipt and sale of adulterated food at each of the approximately 2,800 Jimmy John's restaurants.

In May 2012, a meeting was held with FDA at your request. During that meeting, you expressed that you would offer only clover sprouts, and to only source clover sprouts from (b)(4) suppliers. Since that corrective action, your firm has been implicated in three additional sprout-related outbreaks. Documents from traceback investigations conducted by FDA, states and local partners demonstrate that in addition to (b)(4) sprouts, Jimmy John's restaurants are using multiple other sources of sprouts.

Although you stated that corrective actions were implemented following the 2019 and 2012 outbreaks, you have not provided FDA with any information demonstrating long-term, sustainable corrections have been implemented throughout your organization to prevent this violation from recurring in the future. For example, providing FDA with documentation of policies and practices demonstrating that you have made a corporate commitment to ensure produce covered by the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule), Title 21 Code of Federal Regulations, Part 112 (21 CFR Part 112), specifically sprouts, and sourced by any Jimmy John's restaurant will be procured from a farm or firm operating in compliance with the Produce Safety Rule, the Act, and, as applicable, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods (PC Rule), 21 CFR Part 117.

The above violations are not intended to be an all-inclusive list of violations that exist in connection with the food you receive and offer for sale at your restaurants. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure your firm

complies with all requirements of federal law and implementing regulations. You should take prompt action to correct all violations noted in this letter. Failure to promptly correct these violations may result in enforcement action by FDA without further notice, including seizure and/or injunction.

Next Steps

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include the specific things you are doing to address this violation. You should include in your response documentation and information that would assist us in evaluating your corrections. If you believe you have complied with the Act, include your reasoning and any supportive information for our consideration. If you cannot complete all corrections within 15 days, you should explain the reason for your delay and state when you will correct any remaining violations.

Please send your reply to Food and Drug Administration, Attention: Lauren Crivellone Compliance Officer, Office of Human and Animal Foods Operations, Division East Six, Compliance Branch, 550 West Jackson Boulevard, Suite 1500, Chicago, Illinois 60661. If you have any questions regarding this letter, you may contact Compliance Officer Crivellone via email at Lauren.Crivellone@fda.hhs.gov (<mailto:Lauren.Crivellone@fda.hhs.gov>). Please reference CMS # 599962 on any documents or records you provide to us and/or within the subject line of any email correspondence you send to us.

Sincerely,

/S/

William R. Weissinger, Program Division Director
Office of Human and Animal Foods
Division East 6

cc:

Paul J. Brown, Chief Executive Officer
Inspire Brands, Inc.
Three Glenlake Parkway NE
Atlanta, Georgia 30328

Paul J. Brown, Chief Executive Officer
Inspire Brands, Inc.
1155 Perimeter Center West, 12th Floor
Sandy Springs, Georgia 30338

Paul D. Ginsberg, President
Roark Capital Group
540 Madison Avenue Ste 37
New York, New York 10022

Paul D. Ginsberg, President
Roark Capital Group
1180 Peachtree Street NE, Suite 2500
Atlanta, Georgia 30309

[More Warning Letters \(/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters\)](#)