IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**No. 11-2371-STA-cgc**
	)	
AMERICAN MERCANTILE CORPORATION, a corporation, INGREDIENTS CORPORATION OF AMERICA a/k/a BARZI BRAND, a corporation, and DAMON S. ARNEY, an individual,	)	
	)	
Defendants.	)	

ORDER GRANTING IN PART, DENYING IN PART PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Before the Court is the government's Motion for Summary Judgment (D.E. # 22) filed on December 12, 2011. Defendants American Mercantile Corporation, Ingredients Corporation of America, and Damon S. Arney have filed a response in opposition to Plaintiff's Motion. The government has filed a reply, and Defendants have filed a sur-reply. For the reasons set forth below, Plaintiff's Motion is **GRANTED IN PART, DENIED IN PART**. The Court reserves ruling on the permanent injunction sought by the United States, pending a hearing on that issue.

BACKGROUND

The following facts are not in dispute for purposes of this Motion unless otherwise noted. This case involves alleged violations of the Food, Drug, and Cosmetic Act ("FDCA"). Defendant

American Mercantile Corporation ("AMC") is a Tennessee corporation, which currently lists its principal place of business as 1270 Warford Street, Memphis, Tennessee. (Compl. ¶ 3; Answer ¶ 3; Schafer Decl. ¶ 4; ex. A-1.) Until recently, AMC's principal place of business was located at 1310 Farmville Road, Memphis, Tennessee ("the Farmville Road facility"). (Compl. 3; Answer ¶ 3; Schafer Decl. ¶ 4.) Defendants add that AMC ceased all operations and any other activities at the Farmville Road facility in the spring of 2011. (Arney Decl. ¶¶ 5, 6.)

Defendant Ingredients Corporation of America a/k/a Barzi Brand ("ICA") is a Tennessee corporation and subsidiary of AMC that currently conducts its operations at 1270 Warford Street, Memphis, Tennessee. (Compl. ¶ 4; Answer ¶ 4; Schafer Decl. ¶ 5 & Ex. A-2.)[1] ICA previously conducted its operations at 676 Huron Avenue, Memphis, Tennessee ("the Huron Avenue facility"). (*Id.*) Defendants add that ICA moved its offices and primary storage facility to Warford Street in the fall of 2010. (Arney Decl. ¶¶ 8, 11.)

Defendant Damon S. Arney ("Arney") is the owner and president of AMC and ICA. (Compl. 5; Answer ¶ 5; Schafer Decl. ¶ 6.) He is responsible for overseeing all areas of operations and has the duty, power, responsibility, and authority to detect, prevent, and correct the insanitary conditions at AMC and ICA. (*Id.*; *see also* Bradley Decl., ex. B, ¶ 8.)

The parties disagree about the exact nature of each Defendant's enterprise. According to the government, both Defendants receive, process, manufacture, prepare, pack, label, hold, and distribute a wide variety of food products and ingredients, including spices, spice blends, seeds, herbs, and

[1] Defendants add that ICA owns the rights to Barzi Brand but does not do business under that name. However, the Court finds that this fact is not supported in the record Defendants cite in their briefing. Mr. Arney does not refer to the Barzi Brand name in his declaration. *See* Arney Decl. (D.E. # 35-1).

sauces. (Compl. ¶¶ 3-4; Answer ¶¶ 3-4; Schafer Decl. ¶¶ 4-5.) Defendants assert that AMC's primary business is to import and supply bulk botanical products that are then sold to large food or non-food manufacturers. (Arney Decl. ¶ 2.) AMC also sells numerous crude and semiprocessed botanicals to manufacturers that "further process" these materials in order to meet food grade requirements. (*Id.* ¶ 7.) By contrast, ICA purports to be primarily a spice manufacturer that produces goods, such as barbecue dry rubs, for sale to customers that then sell the goods in retail distribution or to customers who utilize the spice blends in their cooking or processing operations. (*Id.* ¶ 8.) It is undisputed that both corporate Defendants ship their food products and ingredients to sources located outside of the state of Tennessee. (Compl. ¶¶ 7, 11; Answer ¶¶ 7, 11; Schafer Decl. ¶¶ 4-5, 12, 15, 18, 21; exs. A-13, A-20, A-21, A-34, A-35; Bradley Decl. ¶¶ 6-7, 11,15; exs. B-5, B-8.)

According to the government, Defendants are repeat violators of the FDCA whose unsanitary practices, including the failure to exclude rodents and insects from its facilities and food, have necessitated previous action by this Court.[2] Therefore, the government seeks summary judgment on the issue of whether Defendants have violated the FDCA and whether a permanent injunction against all Defendants should issue. The injunction proposed by the United States generally would require Defendants to bring their operations into compliance with the FDCA.[3] For purposes of its analysis,

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[2] While Plaintiff contends that both Defendants are "repeat violators" (see Pl.'s Statement of Undisputed Fact ¶ 8, relying in part on the 2009 Consent Decree), Defendants counter that only AMC was party to the 2009 Consent Decree by which this Court ordered the seizure *in rem* of adulterated goods at AMC's facility. Be that as it may, the United States has adduced evidence that the FDA has found both AMC and ICA to be in violation of the FDCA on more than one occasion. The Court considers the 2009 Consent Decree more fully below.

[3] The Court reviews in more detail below all of the terms of the proposed permanent injunction submitted by the government.

the Court will review the history of FDA inspections and violations observed at each company's facilities.

I. History of Violations Observed During FDA Inspections of AMC's Farmville Road Facility

A. March 2009 Inspections

The FDA conducted an inspection of AMC's Farmville Road facility between March 10 and 13, 2009. As a result of this inspection, the FDA issued a five-item Form FDA-483, List of Inspectional Observations ("Form FDA-483"). (Schafer Decl. ¶ 13; ex. A-14.) Specifically, the FDA inspectors reported failures to comply with current good manufacturing practice ("cGMP"), including, but not limited to the following:

(a) AMC failed to take effective measures to protect against contamination of food by pests. (*Id.*; ex. A-15, pp.1-21, photos 1-40.) The Form FDA-483 noted the presence of three live rodents and eleven dead rodents on the premises. (*Id.*; ex. A-14.) Inspectors also documented rodent excreta pellets ("REPs") in all areas of the facility as well as live and dead insects in, around, and on containers holding products. (*Id.*)

(b) AMC failed to provide adequate screening against pests. (*Id.*; ex. A-15, pp.28-30, photos 53-57.) The Form FDA-483 noted multiple gaps in walls and around the rolldown door to the facility where rodents and pests could enter. (*Id.*; ex. A-14.)

(c) AMC failed to provide safety-type lighting fixtures. (*Id.*; ex. A-15, pp.30-31, photos 58-59.) An overhead light fixture in the warehouse was unshielded even though the light hung above an open container of unknown botanical products. (*Id.*; ex. A-14.)

(d) AMC failed to maintain fixtures and facilities (*Id.*; ex. A-15, p. 31, photo 60).

Specifically, the inspectors found fiberglass insulation hanging from the ceiling above open burlap bales of an unknown botanical product. (*Id.*; ex. A-14.)

On March 13, 2009, Defendant Arney addressed a letter to the FDA, stating that the firm was closing the week of March 16, 2009, to correct the violations reported from the inspection. (Schafer Decl. ¶ 13; ex. A-16.) After the voluntarily shutdown, the FDA conducted a follow-up inspection of AMC's Farmville Road facility between March 26 and 27, 2009. (*Id.*) FDA investigators issued another five-item Form FDA-483 to Defendants after the March 26 and 27, 2009 inspection, finding similar insanitary conditions despite Defendant AMC and Arney's efforts to clean the facility and promises to correct the violations. (Schafer Decl. ¶ 13; exs. A-17, A-18.)

FDA investigators collected samples during both of the March 2009 inspections of AMC's Farmville Road facility. (Schafer Decl. ¶ 14; exs. A-19, A-20, A-21, A-25). One sample collected during the second inspection was taken from an area AMC claimed to have cleaned. (*Id.*) Even so, FDA laboratory analysis confirmed the presence of filth, including rodent and insect filth, in the samples collected before and after cleaning. (Schafer Decl. ¶ 14; exs. A-22, A-23, A-24, A-26; Tucker Decl. ¶ 30.)

B. May 2009 Consent Decree

In May 2009 the U.S. Marshals Service seized adulterated food products at AMC pursuant to a Warrant In Rem issued in *United States v. 35/15 kg poly mesh bags . . .*, Civ. A. No. 09-2271-SHM/dkv (W.D. Tenn. May 1, 2009) (Consent Decree, ex. C; Schafer Decl. ¶ 7.) Thereafter, Defendant Arney, on behalf of AMC, entered into a Consent Decree of Condemnation ("the Consent Decree"), which was signed by U.S. District Judge Samuel H. Mays, Jr., on June 16, 2009. (*Id.*) Under the Consent Decree, AMC admitted and the Court adjudged that food was "held under

insanitary conditions whereby it may have been contaminated with filth." (Consent Decree ¶ 2.) AMC was required to either bring the seized food into compliance (i.e. recondition it) or destroy it. (*Id.* ¶ 10.)

AMC attempted to recondition the products; however, its efforts were insufficient. (Schafer Decl. ¶ 7.) Specifically, the FDA investigators conducted a walk through at AMC in July 2009, to determine whether pests had been excluded from the facility, as was required before reconditioning efforts could begin. (*Id.* & ex. A-3.) The FDA documented eight separate areas where live insects were present. (*Id.*)[4] After AMC undertook further cleaning and attempts at reconditioning, a verification sample collected by investigators on October 6, 2009, confirmed the continued presence of insects in the facility, including inside a product that AMC had determined was not contaminated. (*Id.*; exs. A-4, A-5, A-6.) FDA's laboratory analysis of the post-seizure verification sample (and sub-samples) confirmed the presence of, among other things: multiple examples of stored product insects; insect larval casts and empty pupal cases; parasitic wasps; and product with insect bore holes. (*Id.*; ex. A-6.) Thus, pursuant to the Consent Decree, other than a small number of goods that the FDA allowed AMC to divert to non-food use, the condemned food was ultimately destroyed. (Schafer Decl. ¶ 7; exs. A-7, A-8.) Defendants state that the value of the products AMC destroyed was approximately $800,000. (Arney Decl. ¶ 3.)

[4] Defendants add that in response to the 2009 inspection and the FDA's findings, Arney decided to change AMC's operations and discontinued storing goods at the Farmville Road location. (Arney Decl. ¶¶ 3, 4.) From that time on, AMC engaged warehouse facilities to store all of its products and used the Farmville Road facility on only a limited basis. (*Id.* ¶ 4.)

C. October 2010 Inspection

The FDA's most recent inspection of AMC's Farmville Road facility was conducted between October 12 and 22, 2010, for the purpose of assessing Defendants' current compliance with the FDCA. (Schafer Decl. ¶ 10; Bradley Decl. ¶ 9.) Defendants respond that they cannot address the FDA's reasons for conducting the October 2010 inspection. (Defs.' Resp. to Statement of Fact ¶ 13.) Defendants further emphasize that AMC no longer conducts any operations of any kind at the Farmville Road facility and stores all products at three independent warehouses: one in Memphis and two in New Jersey, all of which are registered with and regulated by the FDA. (Arney Decl. ¶ 6.)[5] The October 2010 inspection revealed that Defendants had failed to implement effective corrections and uncovered further evidence of filth, including continued, widespread insect activity. (Schafer Decl. ¶ 10; Bradley Decl. ¶¶ 9, 12; exs. B-1, B-6.) While admitting that this is what the FDA inspectors concluded, Defendants dispute the use of the phrase "further evidence" or the government's characterization of insect activity as "continued" and "widespread." In any event, at the conclusion of the October 2010 inspection of AMC's Farmville Road operation, FDA investigators issued a Form FDA-483 to Defendant Arney, specifically noting several violations.[6] (Schafer Decl. ¶ 10; Bradley Decl. ¶ 12; ex. B-6.)

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[5] The government notes in its briefing that federal regulations require facilities holding food products to register with the FDA. (Pl.'s Reply 14 n.13 (citing 21 U.S.C. § 415(a)). The government denies, though, that the FDA regulates or licenses such warehouses. (*Id.*)

[6] Defendants add that the Form FDA-483 was issued to Defendant Arney in his capacity as the company representative for AMC, not in his individual capacity. Defendants do not actually cite any support in the record for this fact. Nor is it clear to the Court that the distinction is relevant to the Court's summary judgment analysis. The Court will consider Defendant Arney's potential liability for violations of the FDCA below.

(a) AMC failed to take effective measures to protect against the contamination of foods with pests. *See* 21 C.F.R. § 110.35(c) (repeat observation) (Bradley Decl. ¶ 9(a); ex. B-1, pp.6-14, photos 10-26.) Investigators observed live and dead insects throughout the facility around products, on the exterior packaging of products, and in products. (*Id.*) For example, investigators noted insects in kola nuts and sweet orange peel powder, as well as on top of boxes containing those products. (*Id.*) Also, investigators found insects on the exterior of a tub containing slippery elm bark, on packaged graviola leaves, and on the exterior packaging of dehydrated granulated garlic grain. (*Id.*) Moths also were observed flying around products and on the exterior packaging of products, along with cobwebs and live spiders. (*Id.*)

(b) AMC failed to provide adequate screening or other protection against pests. *See* 21 C.F.R. § 110.20(b)(7) (repeat observation). (Bradley Decl. ¶ 9(b); ex. B-1, pp.15-16, photos 27-29.) For example, investigators observed a gap approximately two inches wide at the juncture between the roof and a wall leading to the exterior of the building, and a door with a gap revealing sunlight down the entire right-hand side and across the bottom. (*Id.*) Two exhaust fans in the ceiling of the manufacturing area, which led to the exterior, also were observed without screens. (*Id.*)

(c) AMC's Farmville Road facility was not constructed in a manner so as to prevent drip or condensation from contaminating food, food-contact surfaces, and food-packaging materials. *See* 21 C.F.R. § 110.20(b)(4). (Bradley Decl. ¶ 9(c); ex. B-1, pp.17-18, photos 30-32.) Investigators observed that a black substance, which AMC employees identified as roof tar, had dripped from the ceiling onto food products, food-packaging, and surfaces of the facility. (*Id.*)

(d) AMC failed to store raw materials and other ingredients in a manner that would protect against contamination. *See* 21 C.F.R. § 110.80 (repeat observation). (Bradley Decl. ¶ 9(d); Ex. B-1,

pp.18, photo 33.) For example, investigators observed slippery elm bark in a storage container on an exterior dock with the container door open during the entire time they were present on October 20 and 21, 2010. (*Id.*) Investigators also observed clover hay stored on an exterior dock during all days they were present. (*Id.*)

(e) AMC failed to operate fans and other air-blowing equipment in a manner that minimized the potential for contaminating food, food-contact surfaces, and food-packaging materials. *See* 21 C.F.R. § 110.20(b)(6). (Bradley Decl. ¶ 9(e); ex. B-1, pp.19, photo 34.) The investigators observed a large, dusty fan without a screen operating in the processing area before, during, and after the production of sassafras. (*Id.*)

(f) AMC's facility was not constructed in a manner so as to allow walls and ceilings to be adequately cleaned and kept clean. *See* 21 C.F.R. § 110.20(b)(4). (Bradley Decl. ¶ 9(f); ex. B-1, pp.19-20, photos 35-37.) The investigators saw a crack, running from the ceiling to about halfway down a wall, that was filled with foam, as well as exposed insulation in the ceiling of the front room. (*Id.*)

(g) AMC failed to provide safety-type light bulbs over exposed food. *See* 21 C.F.R. § 110.20(b)(5). (Bradley Decl. ¶ 9(g); ex. B-1, p. 21, photo 38.) The investigators saw an unshielded light bulb suspended above kola nuts that were packaged in damaged, poly-woven bags. (*Id.*)

FDA investigators collected four samples (with more than seventy sub-samples) at AMC's Farmville Road facility to document the insanitary conditions during the October 2010 inspection. (Schafer Decl. ¶ 11; Bradley Decl. ¶ 10; exs. B-2, B-3, B-4, B-5.) FDA laboratory analysis of those samples confirmed the presence of insects and other filth. (Schafer Decl. ¶ 11; exs. A-9, A-10, A-11, A-12; Tucker Decl.; ex. D, ¶ 15.)

Defendants challenge the validity of the underlying violations the FDA documented in the October 2010 inspection. Defendants contend that the products evidencing insect activity were actually received in a shipment only a few days prior to the FDA inspection. (Arney Decl. ¶ 5.) Upon receipt of the shipment and before the FDA inspection commenced, AMC employees discovered that much of the merchandise was contaminated with insects, prompting AMC to elect to destroy the products. (*Id.*) Defendants state that arrangements were made for the delivery of a dumpster where AMC could dispose of the contaminated products. (*Id.*) Due to the volume of affected goods, AMC had to have the dumpster emptied and returned several times in order to dispose of all of the products. (*Id.*) According to Defendants, the dumpster was full when the FDA inspectors arrived. (*Id.*) Importantly, Defendants maintain that the FDA inspectors took samples from the discarded products and reported the findings in their Form FDA-483. (*Id.*)

AMC claims that as a result of the contamination of these goods, AMC immediately ceased doing business with the warehouse facility where the infested shipment had originated. (*Id.*) Defendant Arney affirms that in the aftermath of the October 2010 inspection, he also reorganized the manner in which AMC conducted its business. (*Id.* ¶ 6.) According to Arney, he made the decision to discontinue any storage or processing of goods at AMC's Farmville Road facility. (*Id.* ¶ 7.) Now AMC never takes physical possession of the goods it sells or processes the goods in any way for its customers. (*Id.* ¶¶ 6, 7.) Rather, when AMC makes a sale, the goods ship to the customer from one of three independent warehouse facilities. (*Id.* ¶ 7.) Furthermore, in light of its new operations model, AMC terminated all of its employees except for one individual who was reassigned to ICA. (*Id.*)

II. History of Violations Observed During FDA Inspections of ICA's Facilities

A. May 2004 Inspection of the Huron Avenue Facility

The FDA inspected ICA's Huron Avenue facility between May 11 and 12, 2004. (Schafer Decl. ¶ 22; ex. A-39.) As a result of the May 2004 inspection, the inspectors issued a four-item Form FDA-483, noting observations of insect casings; a dead rodent; trash, debris, and spillage of raw ingredients; and poor employee practices such as an employee eating in a product testing and sampling room. (*Id.*)

B. June 2009 Inspection of the Huron Avenue Facility

The FDA returned to inspect ICA's Huron Avenue facility between June 9 and 17, 2009. (Schafer Decl. ¶ 19 & ex. A-32.) The eight-item Form FDA-483 issued to Defendants reported the following violations among others:

(a) ICA failed to take effective measure to protect against contamination of food by pests (as evidenced by numerous REPs and live and dead insects). (*Id.*; ex. A-29, pp.1-4, photos 1-7; ex. A-30, pp.1-43, photos 1-85.)

(b) ICA failed to prevent drip or condensation from contaminating food (as evidenced by food stored under a roof leak). (*Id.*; ex. A-30, pp.43-44, photos 86-88.)

(c) ICA failed to receive and store raw materials in a manner which protected against contamination (as evidenced by products with moisture-staining, mold, and holes). (*Id.*; ex. A-30, pp.43-44, 47-49, photos 86-88, 93-96.)

(d) ICA failed to provide adequate screening or other protection against pests (as evidenced by gaps under doors). (*Id.*; ex. A-30, pp.45-46, photos 89-91.)

Furthermore, investigators collected three samples (with sub-samples) at the June 2009

inspection of the Huron Avenue facility. (Schafer Decl. ¶ 20; exs. A-33, A-34, A-35). FDA laboratory analysis of these samples confirmed the presence of rodent and insect filth. (Schafer Decl. ¶ 20; exs. A-36, A-37, A-38; Tucker Decl. ¶ 40.) On January 5, 2010, the FDA issued a letter to ICA, warning that the FDA's June 2009 inspection of the Huron Avenue facility had revealed insanitary conditions that caused foods stored there to be adulterated and explaining that it was ICA's responsibility to correct those conditions. (Schafer Decl. ¶ 25; ex. A-40.)

C. November 2010 Inspection of the Warford Street Facility

Defendants highlight the fact that ICA no longer conducts operations of any kind at the Huron Avenue facility and has operated exclusively at the 1270 Warford Street facility since the fall of 2010. (Arney Decl. ¶¶ 8, 10, 12.) The FDA conducted an inspection of ICA's Warford Street facility between November 1 and 8, 2010, in follow-up to the earlier inspection of ICA's former Huron Avenue facility. (Schafer Decl. ¶ 16; Bradley Decl. ¶ 13.)[7] According to the government, the November 2010 inspection revealed widespread filth, including obvious insect and rodent activity. (Schafer Decl. ¶16; Bradley Decl. ¶¶ 13, 17; ex. B-9.) Defendants object to the United States' characterization of the conditions observed during the inspection as "widespread" and "obvious" and add that the inspection took place during the relocation of ICA's operations from Huron Avenue to Warford Street. (Arney Decl. ¶ 15.) Based on the November 2010 inspection, the FDA issued a five-item Form FDA-483 to ICA, noting the following violations. (Schafer Decl. ¶ 16; Bradley Decl. at ¶ 17; ex. B-9.)

[7] While admitting that the November 2010 inspection occurred, Defendants deny that the inspection was a follow-up to the earlier inspection conducted at the Huron Avenue facility. Defs.' Resp. to Statement of Undisputed Fact ¶ 21.) Even though Defendants have not cited any evidence in support of their denial, the Court finds that the dispute is not actually material to its summary judgment analysis.

(a) ICA failed to take effective measures to protect against contamination of food by pests. *See* 21 C.F.R. § 110.35(c) (repeat observation). (Bradley Decl. ¶ 13(a).) Investigators noted numerous live and dead insects, as well as evidence of rodent activity around products, on the exterior packaging of products, and in products. (*Id.*) For example, investigators observed REPs and rodent hairs on boxes of granulated garlic and underneath a storage rack. (*Id.*) In addition, investigators observed insects on boxes of dehydrated green bell peppers, in the inner folds and neck of a plastic bag containing ground fennel, on and in a closed plastic bag containing lemon peel powder, and on chopped onion product. (*Id.*) Investigators noted dead insects adhering to tape used to close products, including a bag of bread crumbs, a box of beet root powder, a bag of dry whey, and a box of organic tomatoes. (*Id.*) Defendants dispute that the Form FDA-483 documents any evidence of rodent activity in products. Defendants further argue that the FDA laboratory results from this inspection concluded that, aside from two insects in a Beatreme sample, no product was actually contaminated with rodent or insect filth. (Schafer Decl., ex. A-27, A-28).

(b) ICA failed to clean food-contact surfaces and equipment as frequently as necessary to protect against contamination of food. *See* 21 C.F.R. § 110.35(d)(1) & (3). (Bradley Decl. ¶ 13(b).) Specifically, investigators observed rust inside two mixers used in processing dry food products and mold on the exterior lid of a kettle used for mixing and cooking barbeque sauce. (*Id.*) Defendants dispute the FDA's findings about the presence of rust and mold on their equipment. With respect to the rust, Defendants argue that the mixer in question is an industrial capacity, stainless steel machine, approximately 4 feet by 10 feet in size and capable of mixing 1,000 pounds of material. (Pratt Decl. ¶ 14.) Defendants dispute that the substance observed on the mixer was rust and claim that it was only the size of a dime and could only have been residue left from the previous use of the

mixer**.** (*Id.*) Defendants further assert that ICA's standard operating procedure requires that each mixer be cleaned before and after each use with a food grade cleaning agent. (*Id.*; Arney Decl. ¶ 15.) Douglas Pratt, the general manager of ICA, was present during the inspection and attempted to explain the likely cause of the residue to the FDA inspector but to no avail. (Pratt Decl. ¶ 14.) As for the mold, Defendants deny that mold was present in the sauce room at the Warford Street facility. (*Id.* ¶ 15.) The discoloration observed by the FDA inspector was simply dust created by the ongoing construction in that part of the facility. (*Id.*) Defendants assert that construction workers were present in the room on the date of the inspection and that no food production had occurred in the room at that time. (*Id.*; Arney Decl. ¶ 15.)

(c) The investigators saw an employee with hair hanging outside of his hairnet, *see* 21 C.F.R. § 110.10(b)(6), as he leaned over a bulk container of garlic butter blend and hand-filled it into plastic boxes. (Bradley Decl. at ¶ 13(c).) Defendants deny that any violation occurred. Defendants identify the employee as Delaney Boone, an African-American whose hair was braided and in a hairnet at the time of the inspection. (Pratt Decl. ¶ 16.) According to Defendants, one of the employee's braids at the back of his neck came out of the hairnet while he was working, and this was the basis for the inspector's finding. (*Id.*)

During the November 2010 inspection of ICA, the FDA investigators collected two samples (with approximately 30 sub-samples). (Schafer Decl. ¶ 17; Bradley Decl. ¶ 15; exs. B-7, B-8.) FDA laboratory analysis of the samples confirmed rodent and insect activity. (Schafer Decl. ¶ 17; exs. A-27, A-28; Tucker Decl. ¶ 33.) Defendants contend that the lab results actually demonstrate that no product was contaminated with rodent feces and that no insects were found in any product, aside from two insects in the Beatreme. (Schafer Decl., ex. A-27, A-28).

III. Procedural History

The United States filed its Complaint for Permanent Injunction on May 11, 2011, seeking injunctive relief for Defendants' alleged violations of the FDCA. The parties have reported to the Court that before filing suit and even up until the summary judgment stage, they engaged in negotiations to attempt a settlement but without success. Then, on December 2, 2011, Defendants filed a motion for court-ordered mediation and an extension of deadlines (D.E. # 20), which the government opposed, and the Court ultimately denied. (*See* Order Denying Defs.' Mot. for Court-Ordered Mediation Jan. 20, 2012, D.E. # 32.) However, before the Court could take up Defendants' motion for mediation, the United States filed the instant Motion for Summary Judgment. In response Defendants filed a motion for discovery pursuant to Rule 56(d) (D.E. # 33), seeking an opportunity conduct limited discovery, which Defendants claimed was needed to respond to the Motion for Summary Judgment. While their motion for discovery was pending, Defendants filed a response in opposition to the Rule 56(a) Motion. On May 29, 2012, the Court conducted a hearing on Defendants' motion for discovery and later denied the motion, concluding that Defendants had failed to show with specificity what additional information discovery would reveal. (*See* Order Denying Defs.' Mot. for Disc. June 18, 2012, D.E. # 47.) The Court did grant Defendants an opportunity to file a sur-reply in opposition to the Motion for Summary Judgment.[8] Therefore, the United States' Motion for Summary Judgment is now ripe for disposition.

[8] The government filed a motion for extension of time to file its reply and for enlargement of the page limit (D.E. # 39) and went on to file its reply brief. The government's motion is granted. Furthermore, Defendants also filed a separate motion for permission to file a sur-reply (D.E. # 43). Because the Court has granted Defendants leave to file a sur-reply and Defendants have now done so, that motion is moot.

IV. Motion for Summary Judgment

The government now seeks judgment as a matter of law on Defendants' alleged violations of the FDCA. The United States argues that Defendants violated 21 U.S.C. § 331(a) and (k), meaning that the government has the burden to prove that (1) Defendants' products are "food" within the meaning of the Act; (2) that the food was "adulterated" as the FDCA defines that term; and (3) that the food moved in interstate commerce. According to the United States, no genuine issue of material fact exists as to any element in this case, making summary judgment proper. The government contends that the Court may take judicial notice of the fact that Defendants' products are "food," which the FDCA defines to mean "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." The government further argues that Defendants admit their products travel in interstate commerce, thereby satisfying this element. Finally, the United States claims that Defendants' food is adulterated because they prepare, pack, and hold it under insanitary conditions whereby it may have become contaminated with filth. The government relies on the numerous findings detailed in the FDA Form-483s, particularly the presence of pests and rodents on the premises of Defendants' facilities, most recently in late 2010. Based on these violations, the United States seeks a permanent injunction, arguing that violations of the FDCA have occurred and are likely to occur again. Notably, the government asserts that the Court need not consider the traditional, four-factor balancing test for granting injunctive relief. Instead the Court need only find a likelihood of future violations because the government has brought this statutory injunction action to enforce federal law. Therefore, the United States argues that summary judgment is warranted and that permanent injunctive relief should be granted.

In their response in opposition, Defendants largely focus their arguments on the likelihood of future violations of the Act, a factor Defendants claim the government has failed to prove. Defendants emphasize that since the FDA's most recent inspections, both corporations have changed the manner in which they conduct business. With respect to AMC, Defendants state that AMC no longer utilizes the Farmville Road facility for any purpose and has completely altered its operations model. Rather than storing and processing goods at its own facility, AMC now receives shipments at third-party warehouses, one in Tennessee and two in New Jersey, all of which are "FDA licensed." AMC also briefly suggests that its operations do not involve food products but rather "raw agricultural commodities," which are not covered by the FDCA. As for ICA, Defendants argue that ICA no longer operates at the Huron Avenue facility but has now completely moved all of its operations to the newly refurbished Warford Street facility. Defendants also cite a number of other remedial actions taken to correct the problems associated with ICA's operations at the former Huron Avenue facility. Defendants highlight that the Tennessee Department of Agriculture ("TDA") conducted a more recent inspection of the Warford Street facility in June 2011 and found no evidence that food was being held under insanitary conditions. According to Defendants, not only can the government not prove a likelihood of future violations, the government must also satisfy the other three factors in the traditional balancing test for injunctive relief. Defendants maintain that a court sitting in equity need only dispense with the full balancing test where Congress requires issuance of an injunction for statutory violations, as opposed to giving the court discretion to issue the injunction. Defendants argue that the FDCA merely gives the Court discretion to issue injunctive relief, and so the four-factor test should apply. For these reasons, Defendants argue that a permanent injunction is not warranted.

In its reply, the government argues that Defendants have conceded or admitted all of the facts that go to establish their violations of the FDCA. Moreover, the entire record of violations at Defendants' facilities suggests that only court oversight will ensure that Defendants achieve and maintain compliance with the Act. The government also reiterates its argument that it need only prove that violations have occurred and that without injunctive relief are likely to occur again in the future. In response to the remedial measures undertaken by Defendants, the government points out that the expert Defendants hired to address their compliance issues was retained in the spring of 2009. As the FDA's findings from October and November 2010 demonstrate, the hiring of this expert failed to address the compliance issues in Defendants' operations. Even if Defendants have completely remedied their violations and brought their operations into compliance, their past violations nevertheless justify injunctive relief. The government raises the possibility that should the Court decline to enter an injunction, Defendants will likely return to the practices which have made them repeat offenders in the eyes of the FDA.

Finally, Defendants have filed a sur-reply in which they emphasize (1) AMC's complete reorganization of its business to discontinue actual handling any foods; (2) ICA's investment in the new Warford Street facility; (3) the fact that the FDA has not returned to inspect the Warford Street facility since late 2010; and (4) the fact that ICA passed a more recent TDA inspection in June 2011.

STANDARD OF REVIEW

Federal Rule of Civil Procedure 56(a) provides that a party is entitled to summary judgment if the moving part "shows that there is no genuine dispute as to any material fact and the movant is

entitled to judgment as a matter of law."[9] In reviewing a motion for summary judgment, the evidence must be viewed in the light most favorable to the nonmoving party.[10] As a result, the "judge may not make credibility determinations or weigh the evidence."[11] When the motion is supported by documentary proof such as depositions and affidavits, the nonmoving party may not rest on his pleadings but, rather, must present some "specific facts showing that there is a genuine issue for trial."[12] It is not sufficient "simply [to] show that there is some metaphysical doubt as to the material facts."[13] These facts must be more than a scintilla of evidence and must meet the standard of whether a reasonable juror could find by a preponderance of the evidence that the nonmoving party is entitled to a verdict.[14] When determining if summary judgment is appropriate, the Court should ask "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law."[15]

Summary judgment must be entered "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will

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[9] Fed. R. Civ. P. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Canderm Pharmacal, Ltd. v. Elder Pharms, Inc.*, 862 F.2d 597, 601 (6th Cir. 1988).

[10] *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

[11] *Adams v. Metiva*, 31 F.3d 375, 379 (6th Cir. 1994).

[12] *Celotex*, 477 U.S. at 324.

[13] *Matsushita*, 475 U.S. at 586.

[14] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

[15] *Id*. at 251-52.

bear the burden of proof at trial."[16] In this Circuit, "this requires the nonmoving party to 'put up or shut up' [on] the critical issues of [her] asserted causes of action."[17]

ANALYSIS

For the reasons that follow, the Court holds that Plaintiff is entitled to judgment as a matter of law on the issue of whether Defendants have violated the FDCA. However, the Court will reserve ruling on the issue of whether permanent injunctive relief is warranted, pending a fuller hearing on that question. Therefore, Plaintiff's Motion for Summary Judgment is **GRANTED** on the question of liability.

I. The Statute

The United States alleges that Defendants have violated 21 U.S.C. § 331(a) & (k). Section 331(a) prohibits "the introduction or delivery for introduction into interstate commerce of any food . . . that is adulterated . . . ."[18] Section 331(k) prohibits "the doing of any other act with respect to, a food . . ., if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated . . . ."[19] In order to prove that Defendants have violated the FDCA, the government must show (1) the Defendants' products are "food" within the meaning of the Act; (2) the food is (or became) "adulterated" within

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[16] *Celotex*, 477 U.S. at 322.

[17] *Lord v. Saratoga Capital, Inc.*, 920 F. Supp. 840, 847 (W.D. Tenn. 1995) (citing *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1478 (6th Cir. 1989)).

[18] 21 U.S.C. § 331(a).

[19] 21 U.S.C. § 331(k).

the meaning of the Act; and (3) the food moves in interstate commerce.[20] The statute provides that "food shall be deemed to be adulterated . . . if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."[21]

II. Corporate Defendants

It is undisputed that both AMC and ICA are Tennessee corporations and that AMC is the parent corporation of ICA. Both corporations currently have their principal place of business at the same address, 1270 Warford Street, Memphis, Tennessee. Both corporations have as their owner and president Defendant Damon S. Arney. As a threshold matter, the Court must determine whether all of each corporation's past violations of the FDCA can be imputed to both corporations as a matter of law. In other words, the issue presented is whether AMC should be held liable for the violations committed by ICA (and vice versa).

A. Presumption of Corporate Separateness

Concerning the corporate Defendants, the United States makes no distinction between the two entities in the Motion for Summary Judgment. For example, the government refers to "Defendants" collectively and cites all of the prior inspections and reported violations at both businesses as proof that "Defendants" have violated the law (as well as proof of the likelihood of future violations, an issue that goes to the need for permanent injunctive relief). In effect, the government treats all of the violations as a single pattern or practice carried out by a joint enterprise.

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[20] *See United States v. Universal Mgmt. Servs., Inc., Corp.*, 191 F.3d 750, 754 (6th Cir. 1999).

[21] 21 U.S.C. § 342(a)(4).

However, the United States cites no authority for the proposition that the FDCA violations of one corporation can be imputed to another corporation, even in the parent-subsidiary context. The Supreme Court has remarked that "it is a general principle of corporate law deeply ingrained in our economic and legal systems that a parent corporation (so-called because of control through ownership of another corporation's stock) is not liable for the acts of its subsidiaries."[22] It is nevertheless true that the common law of corporations recognizes several ways in which a corporation may be held liable for the acts of another corporation. For example, under Tennessee common law, piercing the corporate veil may be appropriate to hold a parent corporation liable for the acts of its subsidiary, particularly where the corporate form "is used as a cloak or cover for fraud or illegality."[23] Similarly, common law will treat two corporations in a parent-subsidiary relationship as alter egos where "the parent corporation[] control[s] the subsidiary corporation's internal affairs or daily operations."[24] In other scenarios, two business entities may be held liable for each other's

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[22] *United States v. Bestfoods*, 524 U.S. 51, 61-64 (1998) (citing 1 W. Fletcher, *Cyclopedia of Law of Private Corporations* § 33, p. 568 (rev. ed. 1990) ("Neither does the mere fact that there exists a parent-subsidiary relationship between two corporations make the one liable for the torts of its affiliate"); Horton, *Liability of Corporation for Torts of Subsidiary*, 7 A.L.R.3d 1343, 1349 (1966) ("Ordinarily, a corporation which chooses to facilitate the operation of its business by employment of another corporation as a subsidiary will not be penalized by a judicial determination of liability for the legal obligations of the subsidiary")).

[23] *Rogers v. Louisville Land Co.*, 367 S.W.3d 196, 214 (Tenn. 2012) ("The corporate entity generally is disregarded where it is used as a cloak or cover for fraud or illegality, to work an injustice, to defend crime, or to defeat an overriding public policy, or where necessary to achieve equity."). *See also Anderson v. Abbott,* 321 U.S. 349, 362 (1944) ("Limited liability is the rule, not the exception" and "there are occasions when the limited liability sought to be obtained through the corporation will be qualified or denied.").

[24] *Gordon v. Greenview Hosp., Inc.*, 300 S.W.3d 635, 652-53 (Tenn. 2009) ("The courts have declined to disregard the presumption of corporate separateness in the absence of evidence of the parent corporation's domination of the day-to-day business decisions of the subsidiary corporation.") (other citations omitted). *See also Chicago, M. & St. P.R. Co. v. Minneapolis*

acts where the two corporations are engaged in a joint enterprise.[25] At summary judgment, the government has not argued, much less met its burden to show, how any of these exceptions recognized at common law would apply in this case.[26] Therefore, the Court concludes that the law of corporations does not require the Court to hold both AMC and ICA liable for the statutory violations of the other company, as the government's Motion implies.

Likewise, nothing in the language of the FDCA itself indicates a congressional intent to hold both parent and subsidiary liable for only one corporation's violations of the Act. The Court finds no reason to conclude that by enacting the FDCA, Congress displaced common law rules on corporate separateness. Although the Court finds no authority addressing this precise issue for purposes of the FDCA, the Supreme Court has considered the question of corporate liability in the context of the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"), another regulatory statute designed to safeguard public health. In *United States v.*

Civic & Commerce Ass'n, 247 U.S. 490, 501 (1918) (principles of corporate separateness "have been plainly and repeatedly held not applicable where stock ownership has been resorted to, not for the purpose of participating in the affairs of a corporation in the normal and usual manner, but for the purpose . . . of controlling a subsidiary company so that it may be used as a mere agency or instrumentality of the owning company").

[25] *See Fain v. O'Connell,* 909 S.W.2d 790, 792-93 (Tenn. 1995) (recognizing liability on an "enterprise theory" and holding that "elements that need to be shown to establish a joint venture among several parties are a common purpose, some manner of agreement among them, and an equal right on the part of each to control both the venture as a whole and any relevant instrumentality").

[26] *E.g. Rogers*, 367 S.W.3d at 215 ("The party seeking to pierce the corporate veil has the burden of presenting facts demonstrating that it is entitled to relief.") (listing factors to be considered to determine whether this burden is met); *Gordon*, 300 S.W.3d at 653 ("To disregard the presumption [of corporate separateness], the party seeking to do so must demonstrate (1) that the subsidiary corporation is a sham or dummy, (2) that the two corporations are, in fact, identical and indistinguishable, or (3) that the subsidiary corporation is merely an instrumentality, agent, conduit, or adjunct of the parent corporation.") (internal citations omitted).

Bestfoods, 524 U.S. 51 (1998), the Supreme Court held that one corporate entity could not be held liable for a second, related corporation's violations of CERCLA. The Court's reasoning in *Bestfoods* is illustrative. The Supreme Court began by restating the common law principle that a parent corporation cannot be held liable for the acts of its subsidiary.[27] The Court then determined that the statutory language of CERCLA itself did not directly address the question presented. As a result, the Court concluded that "the failure of the statute to speak to a matter as fundamental as the liability implications of corporate ownership demands application of the rule that in order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law."[28] Therefore, the Supreme Court held that one corporation could be liable for the statutory violations of a second corporation only where a common law doctrine such as veil piercing applied.[29]

The Court finds the Supreme Court's reasoning in *Bestfoods* persuasive and concludes that the same analysis should apply to the issue presented in the case at bar. For the reasons already discussed, the Court begins with the common law presumption that both parent and subsidiary cannot be liable for the acts of only one of the corporations in the parent-subsidiary relationship. Upon examination of the statutory text of the FDCA, there is no evidence that Congress enacted the

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[27] *Bestfoods*, 524 U.S. at 61-62 (citations omitted).

[28] *Id.* at 63-64 (holding that "when (but only when) the corporate veil may be pierced, may a parent corporation be charged with derivative CERCLA liability for its subsidiary's actions"); *see also Mickowski v. Visi-Trak Worldwide, LLC*, 415 F.3d 501, 513-15 (6th Cir. 2005) (applying the reasoning set out in *Bestfoods* to issue of corporate liability in patent law and holding that "because federal patent laws do not speak to the issue of successor liability, there is little basis to abrogate the general rule derived from state common law").

[29] *Bestfoods*, 524 U.S. at 63-64.

FDCA with the intent to alter or displace "well-settled" common law rules on corporate liability.[30] Therefore, in the absence of some basis in common law to disregard the separate corporate forms, the Court will consider each corporation's violations (and the possible remedy for those violations) separately for purposes of summary judgment.

The Court recognizes the possible argument that under the FDCA, a parent corporation might be liable for violations of the subsidiary (or vice versa) if it could be shown that the parent exercised some degree of control over the acts of the subsidiary.[31] More specifically, the Supreme Court in *United States v. Park,* 421 U.S. 658 (1975) held that a "corporate agent" might be liable under the FDCA where "by virtue of the relationship [the corporate agent] bore to the corporation, the agent had the power to prevent the act complained of."[32] If the government could prove that either AMC or ICA was a "corporate agent" for the other company and had the power to prevent the other firm's violations of the Act, then the "corporate agent" would arguably be liable for the other corporation's violations.[33] Even so, there is no evidence in the record that either AMC or ICA was the "corporate

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[30] *Id.* at 63 ("Nothing in CERCLA purports to rewrite this well-settled rule, either.").

[31] The government seems to suggest this argument in a footnote in its reply brief where Plaintiff points out that Arney is the owner and president of both companies and that ICA is a wholly-owned subsidiary of AMC. Pl.'s Reply 9 n.8 (D.E. # 40). The government goes on to conclude that "Arney and AMC have a duty to remedy similar violations at ICA." *Id.* For reasons more fully explained below, the government's point about Arney's liability is well-taken. However, the United States fails to show why, aside from the parent-subsidiary relationship of the corporate Defendants, AMC should be liable for the acts of ICA.

[32] *Park*, 421 U.S. at 671.

[33] The same showing might also support a finding that the two entities are alter egos. *See Gordon*, 300 S.W.3d at 652-53 ("The courts have declined to disregard the presumption of corporate separateness in the absence of evidence of the parent corporation's domination of the day-to-day business decisions of the subsidiary corporation.").

agent" for the other, such that one could have prevented the violations of the other. The only evidence before the Court that could possibly show such an agency relationship is the fact that Arney is the owner and president of both companies. And yet it is well-settled that "the fact that the subsidiary is wholly owned by the parent corporation or the fact that the corporations have the same directors and officers" is insufficient "to show that the two are alter egos."[34] Without more evidence to show why the Court should disregard the separate corporate forms, the Court cannot conclude that either AMC or ICA is the "corporate agent," as the Supreme Court considered the term in *Park*, of the other company. Therefore, the Court holds that the violations of each corporate Defendant must be analyzed separately.

B. Defendant AMC

Even considering all of the evidence separately as to each Defendant, the Court concludes that the government is entitled to summary judgment on AMC's violations of the Act. As previously discussed, the government must prove that AMC's products are food; the food was adulterated; and the food will move (or has moved) in interstate commerce. For purposes of summary judgment, AMC concedes the interstate element. As a result, the only elements actually in dispute are whether AMC's products are "food" and whether the "food" was "adulterated," as the FDCA defines these terms.

1. AMC's Products Are "Food"

With respect to the first issue, the Court holds that AMC's products included "food" for purposes of the Act. As previously mentioned, the FDCA defines the term "food" to mean "(1)

[34] *Gordon*, 300 S.W.3d at 652 (citing *Bestfoods*, 524 U.S. at 69-70; *Adams v. Republic Steel Corp.,* 621 F. Supp. 370, 375 (W.D. Tenn. 1985)).

articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[35] AMC suggests in its response brief (though not in its sur-reply) that some of its products are not "food" as the Act uses the term but are instead "raw agricultural commodities."[36] The Act defines "raw agricultural commodities" to mean "any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing."[37] AMC has adduced evidence that its products were "botanicals" used in non-food products.[38] The United States contends that AMC's goods do not actually meet the statutory definition of "raw agricultural commodities," and even if they did, other goods held and sold by AMC are undeniably used as "food." Therefore, AMC still has the duty to comply with the FDCA and its regulations.

The Court need not resolve the parties' arguments. AMC has admitted in its answer that its products were "foods" for purposes of the Act. The Complaint alleges at paragraph 6 that both Defendants' "products are food within the meaning of the Act, 21 U.S.C. § 321(f)."[39] In their Answer, Defendants stated in response to the allegations of paragraph 6, "Defendants admit that

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[35] 21 U.S.C. § 321(f).

[36] *See* Defs.' Mem. in Opp'n 3 (stating that one of the issues of material fact at summary judgment was "whether AMC's business operations involve food products that are subject to the FFDCA [sic] or does it involve the importation and distribution of raw agricultural commodities that is [sic] excluded from the FFDCA [sic]" and citing 21 C.F.R. § 110.19, which exempts businesses handling "raw agricultural commodities" from the regulation of the FDCA).

[37] 21 U.S.C. § 321(r).

[38] Arney Decl. ¶ 2 (D.E. # 35-1).

[39] Compl. ¶ 6 (D.E. # 1).

some of its (sic) products constitute 'food' within the meaning of 21U.S.C. § 321(f)."[40] What is more, Defendants admit in the next paragraph of their Answer that "AMC and ICA ship products, including food, outside the state of Tennessee."[41] The Court holds that AMC has admitted in its responsive pleadings that some portion of its products constitute "food." The case law is clear that such an admission in the pleadings cannot later be contradicted with evidence to the contrary at summary judgment.[42] On the basis of its Answer, the Court holds that AMC has "dispens[ed] wholly with the need for proof of the fact" that its goods are, at least in part, "food" for purposes of the FDCA.[43] Therefore, this element of the government's *prima face* case is satisfied.

2. AMC's "Food" Is "Adulterated"

The only remaining issue then is whether AMC's food is "adulterated." In order to satisfy its burden, the government must prove that AMC's food "has been prepared, packed, or held under insanitary conditions whereby it *may have become* contaminated with filth, or whereby it may have

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[40] Answer ¶ 6 (D.E. # 14).

[41] *Id.* ¶ 7. The Answer responded to the Complaint's allegation that "Defendants ship their food products to customers located outside the state of Tennessee . . . ." Compl. ¶ 7.

[42] *Cadle Co. II, Inc. v. Gasbusters Prod. I Ltd. P'ship,* 441 F. App'x 310, 312-13 (6th Cir. 2011) ("Judicial admissions . . . are formal admissions in the pleadings of a present action, which have the effect of withdrawing a fact from issue and dispensing wholly with the need for proof of the fact.") (quotation and other citations omitted); *Barnes v. Owens–Corning Fiberglas Corp.,* 201 F.3d 815, 829 (6th Cir. 2000) (quotation omitted); *see also Christian Legal Soc'y Chapter v. Martinez,* 130 S. Ct. 2971, 3005 (2010) (J. Alito, dissenting) (noting "the binding effect of a party's admissions in an answer"). Additionally, AMC entered into the 2009 Consent Decree were it admitted and the Court adjudged AMC's products to be "food" for purposes of the Act. The Court need not consider what effect (if any) the Consent Decree has on the question of whether AMC's goods are "food" covered by the Act.

[43] *Cadle Co. II,* 441 F. App'x at 312.

been rendered injurious to health."[44] Actual contamination is not required.[45] The standard simply requires that a reasonable probability of contamination exists.[46] Even so, proof of actual contamination is *prima facie* evidence that the food has been held under insanitary conditions.[47] Likewise, the existence of insanitary conditions adjacent to food will create a reasonable possibility that the food may become contaminated.[48] "Filth" is construed to have its usual and ordinary meaning.[49] The FDA has promulgated regulations setting forth criteria and definitions to "apply in determining whether a food is adulterated within the meaning of section 402(a)(4) of the act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become

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[44] 21 U.S.C. § 342(a)(4) (emphasis added). The government does not seek summary judgment on the issue of whether AMC's food may have been rendered injurious to health. *See* Comp. ¶ 13 ("The foods held by Defendants are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, and held under insanitary conditions whereby they may have been contaminated with filth."); Pl.'s Mem. in Support of Mot. Summ. J. 9-10 (arguing that Defendants' food is adulterated because they prepare, pack, and hold it under insanitary conditions whereby it may have become contaminated with filth). Therefore, the Court does not reach that question here.

[45] *United States v. Gel Spice Co.*, 773 F.2d 427, 429 (2d Cir. 1985); *United States v. King's Trading, Inc.*, 724 F.2d 631, 632 (8th Cir. 1983); *United States v. H.B. Gregory Co.,* 502 F.2d 700 (7th Cir. 1974); *United States v. Union Cheese Co.*, 902 F. Supp. 778, 786 (N.D. Ohio 1995); *United States v. 1,200 Cans. . . Pasteurized Whole Eggs*, 339 F. Supp. 778, 786 (N.D. Ga. 1972).

[46] *United States v. Wiesenfeld Warehouse Co.,* 376 U.S. 86, 90–91 (1964); *Berger v. United States*, 200 F.2d 818, 821 (8th Cir. 1952) ("The statute is designed to prevent adulterations 'in their incipiency' by condemning insanitary conditions which may result in contamination. The condition condemned by the statute, which must be proved to support a conviction, is one which would with reasonable possibility result in contamination."); *United States v. Gel Spice Co., Inc.*, 601 F. Supp. 1205, 1211 (E.D.N.Y. 1984).

[47] *Berger*, 200 F.2d at 823.

[48] *United States v. Cassaro, Inc.,* 443 F.2d 153, 157 (1st Cir. 1971).

[49] *Id.* at 156.

contaminated with filth . . . ."[50] The question of insanitary conditions is to be determined from the totality of the circumstances.[51]

Based on the results of the October 2010 inspection of AMC's Farmville Road facility, the government has proven a reasonable probability of contamination with filth as to food stored there at that time. The Form FDA-483[52] from this inspection reported the following violations: (1) live and dead insects around, on, and in products in violation of 21 C.F.R. § 110.35(c); (2) failure to provide adequate protection against pests in violation of 21 C.F.R. § 110.20(b)(7); (3) failure to prevent roof tar from dripping on food products and food-contact surfaces in violation of 21 C.F.R. § 110.20(b)(4); (4) failure to store raw materials so as protect them from contamination in violation of 21 C.F.R. § 110.80; (5) failure to operate ventilation fans with an appropriate screen in violation of 21 C.F.R. § 110.20(b)(6); (6) structural damages and exposed insulation in violation of 21 C.F.R. § 110.20(b)(4); and (7) the use of unshielded lighting over food products in violation of 21 C.F.R.

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[50] 21 C.F.R. § 110.5.

[51] *United States v. 1,500 Cases More or Less, Tomato Paste,* 236 F.2d 208 (7th Cir. 1956); *Union Cheese Co.*, 902 F. Supp. at 786.

[52] Another court has recently made the following findings about Form-483:

> The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD & C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.

City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp., 1:10-CV-520, 2012 WL 1094656, at *2 (W.D. Mich. Mar. 30, 2012) (citing FDA Form 483 Frequently Asked Questions http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm (last visited Mar. 30, 2012)); *Pub. Pension Fund Group v. KV Pharm. Co.,* 705 F. Supp. 2d 1088, 1100 (E.D. Mo. 2010)).

§ 110.20(b)(5). In addition to the Form FDA-483, the United States has also submitted a number of photographs taken during the October 2010 inspection as well as laboratory analysis confirming the presence of insect and filth in several samples.[53] At summary judgment AMC concedes most of the violations reported from the inspection.[54]

The only violation AMC actually disputes is the finding related to the presence of pests and actual contamination. AMC claims that the pests were observed in products, which were delivered a short time before the inspection and were already marked for disposal, though AMC has not adduced evidence showing which products were received in this condition.[55] Even accepting AMC's

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[53] Pl.'s Mot. Summ. J., ex. 31 (D.E. # 26-2).

[54] In their responses to the government's statement of undisputed facts, Defendants assert the following as to each reported violation from the October 2010 inspection: "For purposes of these Summary Judgment proceedings only, Defendants admit that this is what the FDA inspectors concluded. However, Defendants deny the validity of the underlying violations." *See* Defs.' Resp. to Pl.'s Statement of Undisputed Facts ¶¶ 14(a)-(g). Defendants have failed to attach any evidentiary support to demonstrate that there is a genuine dispute as to any of the reported violations, with the exception of the findings of actual pest infestation. *See* Fed. R. Civ. P. 56(c)(1)(A) ("A party asserting that a fact. . . is genuinely disputed must support the assertion by citing to particular parts of materials in the record . . . ."); Local Rule 56.1(b)(3) ("Any party opposing the motion for summary judgment must respond to each fact set forth by the movant by. . . demonstrating that the fact is disputed."). As such, the FDA's findings are deemed admitted for purposes of this Motion. Fed. R. Civ. P. 56(e)(2) ("If a party fails to properly support an assertion of fact. . ., the court may consider the fact undisputed for purposes of the motion.").

[55] The record shows that the FDA collected samples from multiple types of goods stored in different places throughout the facility. In addition to photographic evidence showing the presence of pests on and around AMC's goods, the government has attached a diagram of the warehouse, indicating where the inspectors collected the samples. Pl.'s Mot. Summ. J., ex. B-2 at pp. 8-9 (D.E. # 26-3) and B-3 at p.6 (D.E. # 26-4) (both pages appear to be identical). The various samples were taken from multiple locations on the premises over a two-day period and analyzed in two separate lots numbered as "INV 620349" and "INV 632415." *Id.*; *see also* ex. A-9 at p. 4 (D.E. # 22-12); A-10 at p. 6 (D.E. # 22-13).

Defendants have not responded with any evidence to show that all of these samples came from the goods received in the contaminated shipment(s), which AMC had received only a short

claim as true for purposes of summary judgment, AMC admits that it stored contaminated food on its premises. The Court holds that such proof of actual contamination shows that AMC held food under insanitary conditions.[56] The undisputed evidence shows that AMC held the food under insanitary conditions adjacent to otherwise uncontaminated food, thereby creating a reasonable possibility that the food may become contaminated.[57] As the relevant regulation makes clear, "No pests shall be allowed *in any area of a food plant*."[58] The same regulation goes on to charge AMC with the duty to take "[e]ffective measures. . . to exclude pests from the processing areas and to protect against the contamination of food *on the premises* by pests."[59] Construing these regulations together, AMC had a duty to exclude pests from any area of the Farmville Road facility or a part of the facility used for or in connection with the holding of human food. Based on this authority, the Court holds that the undisputed proof establishes that AMC held contaminated food on the premises in violation of the FDCA and its regulations.

Taken together with the other uncontested violations observed during the October 2010 inspection and under the totality of the circumstances, the Court holds that the government is entitled

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time before the inspection. Additionally, one of the photographs taken during the inspection depicts a product labeled as "Queen of the Meadow" and bearing the words "REJECT." *See Id.*, ex. B-1 at p. 6 (D.E. # 26-2). The date on the label is July 30, 2009, more than one year before the inspection occurred. *Id.*

[56] *Berger*, 200 F.2d at 823.

[57] *Cassaro, Inc.,* 443 F.2d at 157.

[58] 21 C.F.R. § 110.35(c) (emphasis added). The regulations elsewhere define a "plant" to mean "the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food." 21 C.F.R. § 110.3(k).

[59] § 110.35(c) (emphasis added).

to summary judgment on the issue of whether AMC adulterated food in violation of the FDCA. The reported violations give rise to a reasonable possibility of contamination at the Farmville Road facility, and Defendants have not raised any issues of material fact to dispute the evidence presented by the United States.[60] Therefore, the Motion for Summary Judgment is **GRANTED** on the issue of AMC's liability.

C. Defendant ICA

The Court next considers whether the government is entitled to judgment as a matter of law against ICA for violations reported during the November 2010 inspection of the Warford Street facility. For purposes of summary judgment, it is undisputed that ICA's products are "food" as the Act uses the term and that the food moved in interstate commerce. The only disputed issue concerns whether the food was "adulterated."

The FDA Form-483 from reported the following violations from the November 2010 inspection: (1) pest and rodent activity in and around food products in violation of 21 C.F.R. § 110.35(c); (2) suspected signs of rust and mold in food prep areas in violation of 21 C.F.R. § 110.35(d)(1) & (3); and (3) an employee with hair hanging out of his hairnet in violation of 21 C.F.R. § 110.10(b)(6). Based on these conditions, the government argues that ICA violated the Act and that summary judgment is warranted. In response ICA contests two of the three findings, the observations of rust and mold and the employee's hairnet. The Court holds that questions of fact remain about these two alleged violations, precluding judgment as a matter of law on those issues.

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[60] *H. B. Gregory Co.*, 502 F.2d at 703 (holding that evidence of rodent activity as well as "other general insanitary conditions throughout the warehouse," such as potential entryways for pests, constituted evidence beyond a reasonable doubt of adulteration in a criminal prosecution for violations of the FDCA).

Nevertheless, ICA does not seriously dispute the FDA's most damaging findings about pest and rodent activity. Therefore, the Court holds that the United States is entitled to summary judgment as to that violation.

Viewing the evidence in the light most favorable to ICA, a reasonable juror could find that the FDA has not proven all of the alleged violations observed during the November 2010 inspection. First, the investigators reported that rust was detected inside a large scale mixer and that mold was observed in a food processing room. ICA's plant manager disputed these findings at the time of the inspection, asserting that the supposed rust was actually a residue left in the mixer from the last time it was used and that the suspected mold was nothing more than construction dust. The Court notes that the government has adduced no evidence that samples of the rust or mold were taken or that analysis was conducted to verify that the substances the investigators observed were in fact rust and mold.[61] Based on this record, the Court holds that a genuine dispute of fact exists and summary judgment would not be appropriate as to these alleged violations.

As for the employee's hair, the regulation at issue requires that "plant management shall take all reasonable measures and precautions to ensure . . . cleanliness."[62] Specifically,

> All persons working in direct contact with food, food-contact surfaces, and food-packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against contamination of food. The methods for maintaining cleanliness include, but are not limited to . . . [w]earing, where appropriate, in an

[61] The Court recognizes the government's evidence showing that ICA refused to permit inspectors to take any photographs during the November 2010 inspection. Bradley Decl. ¶ 14. It is not clear whether photographic evidence would have conclusively identified the disputed substances. In any event, the fact remains that the evidence actually in the record is not "so one-sided that one party must prevail as a matter of law" on this point. *Anderson*, 477 U.S. at 251-52.

[62] 21 C.F.R. § 110.10(b).

> effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.[63]

Viewing the evidence in the light most favorable to ICA, genuine questions of fact remain about whether ICA violated this regulation. The evidence shows that the employee was wearing a hair net and that some of his hair, which was in a long braid, came out of the net. The government has not shown that the hair net was not being worn "in an effective manner" or that the hair momentarily coming out of the restraint is *ipso facto* a violation of the regulation. Without additional proof, a reasonable fact finder could conclude that no violation of 21 C.F.R. 110.10(b(6) actually occurred. Thus, the Court concludes that summary judgment would not proper for this violation.

Even though the United States is not entitled to judgment as matter of law on all of the reported violations, ICA has not challenged what are arguably the most damaging findings from the November 2010 inspection: the presence of insects and signs of rodent activity in and around products. As previously discussed, an enterprise has a duty under the regulations to exclude pests from any area on the premises where food is held or processed. ICA has not introduced any evidence to dispute that insect and rodent activity was detected during the inspection. ICA simply argues that lab analysis of samples taken during the inspection did not reveal actual contamination. This contention ignores the fact that proof of actual contamination is not required; the FDCA is violated when food becomes adulterated, meaning there is a reasonable probability of contamination. Courts have repeatedly held that the presence of insects and rodents in a food processing facility creates a

[63] § 110.10(b)(6).

reasonable probability of contamination.[64] Based on the undisputed evidence showing that pests were not being excluded from the premises of the Warford Street facility, the government has shown that a reasonable probability of contamination with filth existed and that ICA's food was "adulterated," as the FDCA uses the term. The Court concludes then that ICA has failed to create a genuine issue on this point, making summary judgment proper as to this violation. Therefore, Plaintiff's Motion is **GRANTED** on this issue.

III. Individual Liability of Defendant Arney

Having concluded as a matter of law that both AMC and ICA violated the FDCA, the Court turns to the issue of whether Defendant Arney can be held liable for his role in allowing the violations committed by these enterprises to occur. The Supreme Court has held that officers or managers of a business organization, which is found to be in violation of the FDCA, are themselves liable for the violations.[65] This is so because any "corporate agent" who "had the power to prevent" violations of the FDCA may be liable for the corporation's acts.[66] Defendant Arney does not argue to the contrary. The undisputed evidence shows that Arney is the owner and president of each

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[64] *See e.g. Union Cheese Co.*, 902 F. Supp. at 786-87 (finding that presence of flies, pupa, and maggots in and near food and other factors "adulterated" the food for purposes of the FDCA); *United States v. Union Warehouse Coop.*, 833 F.2d 172, 175-76 (9th Cir. 1987) (finding that violations occurred where wheat contained live and dead insects and REPs and defects at facility allowed pests to enter food handling areas); *H. B. Gregory Co.*, 502 F.2d at 702-703; *Cassaro, Inc.*, 443 F.2d at 156-57 (holding that even small amounts of insect and larvae fragments constituted "filth" and resulted in adulteration of food).

[65] *United States v. Dotterweich*, 320 U.S. 277, 281-84 (1943) (in violations of public health legislation like the FDCA, "[t]he offense is committed . . . by all who have a responsible share in the furtherance of the transaction which the statute outlaws."); *Park,* 421 U.S. at 672 (same).

[66] *Park*, 421 U.S. at 671.

corporation. The Court holds that by virtue of this authority, Arney "had the power to prevent" the violations committed by AMC and ICA. The Court concludes then that summary judgment is proper as to Defendant Arney for the violations of the Act committed by AMC and ICA.[67] Therefore, Plaintiff's Motion is **GRANTED** on the question of Defendant Arney's liability.

IV. Request for Injunction Relief

As the Sixth Circuit has recognized, the FDCA provides only three remedies for violations: (1) injunctive relief, 21 U.S.C. § 332; (2) criminal prosecution, 21 U.S.C. § 333; and (3) seizure, 21 U.S.C. § 334.[68] The United States has requested a permanent injunction against all Defendants and has proposed the terms of injunctive relief for Defendants' violations of the FDCA.[69] The United States seeks to have Defendants and each of their officers, agents, employees, representatives, successors, assigns, attorneys and any person in active concert with any of them enjoined from directly or indirectly receiving, processing, manufacturing, preparing, packing, labeling, holding,

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[67] In the summary judgment briefing, Defendants assert in various places that Arney was acting in his official capacity on behalf of one of his companies, and not in his individual capacity. Be that as it may, the case law is clear that a corporate officer such Mr. Arney can be liable under the Act. *See Park*, 421 U.S at 671 ("[W]here the statute under which they were prosecuted dispensed with 'consciousness of wrongdoing,' an omission or failure to act was deemed a sufficient basis for a responsible corporate agent's liability. It was enough in such cases that, by virtue of the relationship he bore to the corporation, the agent had the power to prevent the act complained of."); *United States v. Hodges X-Ray, Inc.*, 759 F.2d 557, 560-61 (6th Cir. 1985) ("[C]orporate officers could be held individually liable for violations of public health legislation," specifically the FDCA).

[68] *Universal Mgmt. Servs., Inc., Corp.*, 191 F.3d at 760–61.

[69] The government submitted a proposed order of summary judgment and permanent injunction with its Motion for Summary Judgment in December 2011. As required under Local Rules, the proposed order was emailed to chambers with a copy to counsel for Defendants. Otherwise, the proposed order does not appear on the record. Therefore, the Court's summary of the terms of the injunctive relief is based on the proposed order submitted by the United States.

and/or distributing any article of food at the Farmville Road facility or the Warford Street facility or at any other location where Defendants operate until certain conditions are met. Among these conditions are the following:

(1) Defendants must destroy at their own expense and under FDA supervision all articles of food and food ingredients in their custody, control, or possession within thirty days of the entry of the Court order.

(2) Defendants must conduct at their own expense a comprehensive cleaning and fumigation effort to rid their facilities of all pests.

(3) Defendants must retain at their own expense an expert who is qualified to develop and implement a written sanitation control program, which will ensure that Defendants comply with cGMP.

(4) Defendants must notify the FDA of the expert's name and qualifications within five days of retaining the expert.

(5) Defendants' expert must develop an effective written sanitation control program acceptable to the FDA, which will meet certain minimum requirements for food-related operations.

(6) Defendants must obtain FDA approval of the expert's plan.

(7) Upon FDA approval, Defendants must make the written program available to all employees and assign responsibility and authority for implementing the program to an employee trained in sanitation control requirements.

(8) Defendants' expert must develop a written employee training program.

(9) Defendants' expert must conduct a comprehensive inspection of Defendants' facilities to determine whether Defendants have adequately established and implemented the written sanitation

control program and brought their facilities into compliance. Defendants' expert must certify his or her conclusions in writing to the FDA. Once Defendants' expert makes this certification, the FDA would have the option to conduct its own inspection of the facilities at Defendants' expense and/or notify Defendants in writing that Defendants appear to be in compliance. Only then would Defendants be allowed to resume operations.

Going forward, Defendants would have responsibility for continuing the implementation of the sanitation control program and must obtain prior approval from the FDA for any changes or modifications to the program. Defendants would have an ongoing to duty to inform and train all of their employees on the requirements of the sanitation program as well as the provisions of the court order. Under the terms of the permanent injunction, the FDA would be permitted to inspect Defendants' facilities, without prior notice to Defendants, to ensure continuing compliance with the permanent injunction. Pursuant to the proposed injunction, this inspection authority would be apart from, and in addition to, the FDA's authority to inspect, granted by 21 U.S.C. § 374. Defendants would bear the costs of any and all of these inspections according to a schedule of hourly rates proposed in the order.

Furthermore, Defendants and any related party would be permanently enjoined from committing any act that would violate the FDCA, its implementing regulations, or the terms of the injunction itself. In the event that Defendants and/or their agents violate Section 331(a) or (k) of the FDCA, the FDA would have discretion to order Defendants to take appropriate action, including the immediate cessation of processing, preparing, packing, holding, and distributing of food. In the event that the FDA required Defendants to cease production, they would not be permitted to resume until the FDA certified that Defendants were in compliance with the terms of the injunction, FDA

regulations, and the FDCA. If the FDA deemed it necessary, Defendants would be required to recall all articles of their products, and all costs of such a recall would be borne by Defendants.

The proposed injunction provides that all decisions and determinations specified are to be vested in the discretion of the FDA and that the agency's decisions will be final, subject only to review by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). No discovery may be had by either party. In the event Defendants sought to change ownership or alter their operations in any way that would affect Defendants' compliance with the injunction, Defendants would first be required to give the FDA thirty days written notice of such changes. Finally, this Court would retain jurisdiction over this action for the purpose of enforcing or modifying the terms of the injunction.

A. Standard of Injunctive Relief Under the FDCA

The parties fundamentally disagree over the applicable standard for granting injunctive relief. The government cites the Supreme Court's decision in *United States v. W.T. Grant Co.* and argues that it only has to show that Defendants violated the statute and there exists "some cognizable danger of recurrent violation."[70] To be complete, the Supreme Court set out the following standard for injunctive relief in *W.T. Grant*, a case involving violations of the Clayton Act:

> But the moving party must satisfy the court that relief is needed. The necessary determination is that there exists some cognizable danger of recurrent violation, something more than the mere possibility which serves to keep the case alive. The chancellor's decision is based on all the circumstances; his discretion is necessarily broad and a strong showing of abuse must be made to reverse it. To be considered are the bona

[70] Pl.'s Mem. in Support 17 (quoting *United States v. W. T. Grant Co.*, 345 U.S. 629, 633 (1953)).

> fides of the expressed intent to comply, the effectiveness of the discontinuance and, in some cases, the character of the past violations.[71]

In response, Defendants contend that the government must satisfy the traditional four-factor balancing test for permanent injunctive relief, showing (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[72]

The Court holds that in order to obtain injunctive relief under the FDCA, the government need only prove that Defendants violated the Act and that there is a likelihood of future violations of the Act. Courts have held that the traditional four-factor test for permanent injunctive relief is not applicable in the FDCA context because the government is enforcing a statute to protect the public interest.[73] Specifically, the United States need not prove irreparable harm.[74]

While it has never addressed this exact issue in the FDCA context, the Sixth Circuit has held that the government need not establish all of the traditional factors to obtain an injunction pursuant

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[71] *W.T. Grant Co.*, 345 U.S. at 633.

[72] Defs.'s Resp. in Opp'n 8 (citing *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2756 (2010) (actual factors not included in Defendants' brief).

[73] *E.g. United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 27-28 (2d Cir. 1972). The Supreme Court has observed that the purpose of the FDCA is to protect the public health. *United States v. Article of Drug. . . Bacto–Unidisk,* 394 U.S. 784, 798 (1969).

[74] *Union Warehouse Coop.*, 833 F.2d at 175-76; *Diapulse Corp.*, 457 F.2d at 28; *United States v. Spectro Foods Corp.*, 544 F.2d 1175, 1181 (3d Cir. 1976); *United States v. Premo Pharm. Labs, Inc.*, 511 F. Supp. 958, 977 (D.N.J. 1981) (courts have power to enjoin present and future violations of section 331 "solely on the basis that such violations have been established"); *United States v. Nutrition Serv., Inc.,* 227 F. Supp. 375, 389 (W.D. Pa. 1964).

to federal statute where the statutory text "has replaced the traditional equitable factors with a different inquiry."[75] For example, the Sixth Circuit has concluded that the four-factor test did not apply under the Railroad Revitalization and Regulatory Reform Act of 1974.[76] That statute authorized a federal court to issue an injunction based on a showing of "reasonable cause." Based on the plain language of the statute, the Sixth Circuit held that "[i]n order to issue a preliminary injunction under [the statute], a court must determine only whether there is 'reasonable cause' to believe that a violation of [the statute] has occurred or is about to occur."[77] The Sixth Circuit rejected the argument that a district court should apply the traditional balancing test, reasoning that "Congress has expressly authorized the granting of injunctive relief to halt or prevent the violation of [the statute]."[78] In a subsequent opinion, the Sixth Circuit noted in *dicta* that the statutory

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[75] *United States v. Szoka,* 260 F.3d 516, 523-24 (6th Cir. 2001) (holding that four-factor test did not apply to injunctions for violations of the Federal Communication Act of 1934); *United States v. Miami Univ.*, 294 F.3d 797, 817 (6th Cir. 2002) (holding that the four-factor test did apply to injunctions for violations of the Family Educational Rights and Privacy Act because the statute did "not expressly authorize the granting of injunctive relief to halt or prevent a violation. . . ."); *United States v. City of Painesville*, 644 F.2d 1186, 1193-94 (6th Cir. 1981) (concluding that to enjoin violations of the Clean Air Act, courts need not consider "the presence of irreparable injury or the inadequacy of a legal remedy for violations"). *See also Sec. Exch. Comm'n v. Quinlan*, 373 F. App'x 581, 585 (6th Cir. 2010) ("The SEC may seek permanent or temporary injunction against future violations of securities laws. . ., upon showing there is a reasonable and substantial likelihood that, if not enjoined, the defendant would violate securities laws in the future."); *United States v. Universal Mgmt. Services, Inc.*, 999 F. Supp. 974, 977-78 (N.D. Ohio 1997), *aff'd sub nom. United States v. Universal Mgmt. Services, Inc., Corp.*, 191 F.3d 750 (6th Cir. 1999).

[76] *CSX Transp., Inc. v. Tenn. State Bd. of Equalization*, 964 F.2d 548, 551 (6th Cir. 1992).

[77] *Id.*

[78] *Id.*

language and the "reasonable cause" standard for injunctive relief being construed in *CSX Transportation* was "similar" to the statutory language in the FDCA.[79]

Applying the same reasoning here, the Court holds that the government is not required to meet the traditional four-factor test to enjoin violations of the FDCA. The Act grants the Court jurisdiction to issue an injunction simply "for cause shown."[80] The Court construes the Act in much the same way that the Sixth Circuit construed the statute at issue in *CSX Transportation*.[81] Therefore, the government's burden is to show that "cause" exists to issue the injunction. In other words, the government must prove that a defendant has violated the Act and that there is a likelihood of future violations.[82] The Court has held that Defendants are liable for violations of the FDCA. Therefore, in order to obtain the permanent injunction it seeks, the government must now prove a likelihood of future violations.

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[79] *Miami Univ.*, 294 F.3d at 817.

[80] 21 U.S.C. § 332.

[81] *See also Miami Univ.*, 294 F.3d at 817 (stating in *dicta* that the statutory language construed in *CSX Transportation* was "identical or similar" to the statutory language of the FDCA).

[82] *W.T. Grant*, 345 U.S. at 633 (defining the standard for permanent injunctive relief under the Clayton Act); *Diapulse Corp.*, 457 F.2d at 28-29; *United States v. Rx Depot, Inc.*, 290 F. Supp. 2d 1238, 1246 (N.D. Okla. 2003); *United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 486-87 (D.N.J. 1993); *United States v. Vital Health Prods., Ltd.*, 786 F. Supp. 761, 770 (E.D. Wis. 1992); *United States v. Baxter Healthcare Corp.*, 712 F. Supp. 1352, 1355 (N.D. Ill.1989), *aff'd,* 901 F.2d 1401 (7th Cir.1990); *United States v. 22 Rectangular & Cylindrical Finished Devices*, 714 F. Supp. 1159, 1167 (D. Utah 1989) ("Here, it is sufficient to warrant an injunction under section 332(a) if it is established that the defendants violated section 331 and that such violations likely will continue.").

B. Likelihood of Future Violations

In support of its request for a permanent injunction, the government argues that the Court should consider all of the violations committed by Defendants collectively in analyzing the issue. The government stresses Defendants' pattern of conduct, history of violations, the prior *in rem* seizure action, and the current violations at more than one facility. The government contends that without the injunction, "Defendants will almost certainly continue to operate under unsanitary conditions, just they did following the *in rem* seizure."[83] For their part Defendants cite a number of changes in the operations of AMC and ICA that have occurred since the earlier violations and the *in rem* action and even after the most recent FDA inspections.[84] For example, AMC has since ceased using the Farmville Road facility. AMC also claims that it no longer processes food in its own facility but uses an independent processing facility. On the other hand, ICA continues to process food but has relocated all operations to the Warford Street facility. Defendants claim that they have spent hundreds of thousands of dollars modernizing the facility for food processing. Defendants also claim that they have retained a expert on FDCA compliance and implemented the expert's recommendations for improvements at the Warford Street facility. Based on these changes in

[83] Pl.'s Mem. in Support 19.

[84] The Court notes that Defendants have submitted a statement of additional facts with their response to the Motion for Summary Judgment. Defs.' Counter-Statement of Disputed Facts (D.E. # 35-27). The Court finds that many of these factual contentions relate to subsequent changes in circumstances that go to the likelihood of Defendants' future violations. Because the Court does not reach that issue here, the Court does not address all of the additional facts Defendants have asserted in their briefing.

circumstances, Defendants argue that the government cannot show a likelihood of future violations and that an injunction should not issue.[85]

Just as with the issue of liability, the Court finds that separate consideration of each corporate Defendant is required at the remedies stage. As such, the Court must analyze the likelihood of AMC committing future violations as a separate and distinct issue from the likelihood of ICA committing future violations. Moreover, in the event the Court finds a likelihood of future violations as to a corporate Defendant, the Court will then need to consider what form of injunctive relief is appropriate under the circumstances as a remedy against that Defendant. The Court finds that oral argument on the likelihood of future violations and the proper scope of an injunction to prevent such violations would assist the Court in making its determination.[86] Therefore, the Court reserves ruling on the questions of whether a likelihood of future violations exists and whether permanent injunctive relief is warranted. A hearing on these remaining issues is set for Wednesday, September 12, 2012, 10:00 A.M., Courtroom 4, Memphis, Tennessee.

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[85] In addition to presenting evidence of their efforts to comply with the FDCA, Defendants also cite the fact that the AIB (undefined in the brief) conducted three audits of the Warford Street facility in the spring of 2011, all of which occurred after the FDA's last inspection and all of which found the facility to be in compliance with the FDCA. Defs.'s Resp. in Opp'n 17. Defendants also defend the thoroughness and results of the TDA's inspection in June 2011. *Id.* at 18-19.

[86] This is not an evidentiary hearing for the purpose of finding additional facts. Typically, an evidentiary hearing is required before a permanent injunction may issue unless "no factual issues remain for trial." *Wedgewood Ltd. P'ship I v. Twp. of Liberty, Ohio*, 610 F.3d 340, 349 (6th Cir. 2010). Because the Court has granted the government judgment as a matter of law on the issue of whether Defendants violated the Act, no triable issues remain. Strictly speaking then, an evidentiary hearing is not required. *Id.*; *Moltan Co. v. Eagle-Picher Indus., Inc.*, 55 F.3d 1171, 1174 (6th Cir. 2005). Therefore, the Court need not receive evidence at the motion hearing.

CONCLUSION

The government's Motion for Summary Judgment is **GRANTED** on the issue of whether Defendants have violated the FDCA. Although the Court holds that separate analysis of each Defendant's acts is appropriate, the Court concludes that no genuine issue of material fact exists as to whether Defendants violated the Act. The undisputed evidence shows that Defendant AMC failed to comply with the law by not excluding pests from the premises of its Farmville Road facility at the time of the October 2010 inspection. The undisputed evidence also shows that Defendant ICA violated the law by not excluding pests from the premises of its Warford Street facility at the time of the November 2010 inspection. Based on the record before the Court, the government is entitled to judgment as a matter of law as to each corporate Defendant's violations of the FDCA. Additionally, Defendant Arney is liable for both companies' violations insofar as Arney was a corporate agent of both companies who had the authority to prevent the violations.

As for the remedy, the Court holds that in order to obtain injunctive relief, the United States need only prove that Defendants violated the law and that there exists a likelihood of future violations. The Court expressly reserves ruling on the issue of the likelihood of future violations and the terms of possible injunctive relief against each Defendant, pending a hearing on these issues.

IT IS SO ORDERED.

s/ S. Thomas Anderson
S. THOMAS ANDERSON
UNITED STATES DISTRICT JUDGE

Date: August 24, 2012.