IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ALABAMA

UNITED STATES OF AMERICA, Plaintiff, v. BEK CATERING, LLC, d/b/a FLOPPERS FOODS, a limited liability company, and BILLY B. STEMBRIDGE, JR. and KYLE D. HUXEN, individuals Defendants.	)	Civil No._____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin BEK Catering, LLC, doing business as Floppers Foods, a limited liability company, and Billy B. Stembridge, Jr., and Kyle D. Huxen, individuals (collectively, "Defendants") from:

A. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

B. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343.

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

Defendants

4. Defendant BEK Catering, LLC ("BEK Catering"), doing business as Floppers Foods, is an Alabama company that processes seafood products. BEK Catering does business at 28396 Highway 181, Suite A, Daphne, Alabama 36526, within the jurisdiction of this court.

5. Defendant Billy B. Stembridge, Jr., is a co-owner of BEK Catering and refers to himself as the firm's "Managing Partner." Mr. Stembridge is the most responsible person at the firm. He has ultimate authority over all of the firm's operations, including major financial expenditures, production processes, product distribution, and employee supervision. Defendant Stembridge performs his duties at 28396 Highway 181, Suite A, Daphne, Alabama 36526, within the jurisdiction of this court.

6. Defendant Kyle D. Huxen is a co-owner of BEK Catering. Mr. Huxen is responsible for the BEK Catering's compliance with FDA's seafood processing regulations and training new employees. He shares responsibility with Defendant Stembridge for the firm's operations. Defendant Huxen performs his duties at 28396 Highway 181, Suite A, Daphne, Alabama 36526, within the jurisdiction of this court.

7. Defendants prepare, process, pack, hold, and distribute ready-to-eat seafood products, namely seafood soups sold under the names Shrimp Locksley and Mama's Gumbo.

8. Defendants' products are processed from seafood they purchase from a local supplier that receives seafood from locations outside the state of Alabama, including Florida.

Food Safety

9. *Clostridium botulinum* ("*C. botulinum*") is a bacterium that forms spores capable of producing a potent neurotoxin in food. All people are susceptible to *C. botulinum*'s neurotoxin, and ingestion of even a small amount of the neurotoxin can cause botulism. Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if treatment is not prompt and appropriate.

10. *C. botulinum* is widely distributed in nature and can be found in any raw fish or fishery product. Because its spores are heat-resistant, *C. botulinum* can survive cooking. *C. botulinum* can also survive in food that has been incorrectly or minimally processed. Certain strains of *C. botulinum*, called proteolytic strains, produce offensive odors and tastes in food products, and can grow at temperatures as low as 50°F. In contrast, non-proteolytic strains of *C. botulinum* do not produce the same sensory signals. These non-proteolytic strains are particularly dangerous because they can grow and produce toxin at refrigeration temperatures (as low as 38°F), rendering a food toxic without any signs of spoilage. In foods that rely on refrigeration to inhibit the growth of *C. botulinum*, seafood processors must employ appropriately rapid cooling processes after cooking to prevent pathogen growth and toxin formation.

11. Like *C. botulinum*, *Clostridium perfringens* ("*C. perfringens*") is a bacterium that causes foodborne illness. High doses of this bacterium can form a toxin in the digestive tract that results in illness. All people can be sickened by *C. perfringens*' toxin, which causes diarrhea and abdominal cramps and can produce more severe symptoms in the young and elderly.

12. *C. perfringens* is ubiquitous in nature and can be found in various foods including raw vegetables and spices. *C. perfringens* spores are heat-resistant and can survive cooking, and

then grow when food is cooled and held at temperatures between 54°F-140°F. These bacteria reproduce quickly at temperatures between 109°F-117°F and can reach high numbers in a relatively short period of time. As a result, food products that are prepared in large quantities and then held warm before serving are particularly susceptible to the growth of *C. perfringens*. To inhibit *C. perfringens* growth, seafood processors must employ appropriately rapid cooling processes after cooking to prevent pathogen growth.

13. *Listeria monocytogenes* ("*L. mono.*") is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and people with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage, or a life-threatening infection in the newborn.

14. *L. mono.* can grow at refrigeration temperatures and can also survive and multiply under other adverse conditions, such as high salt or high acid conditions. *L. mono* can colonize on moist surfaces such as floors, floor drains, wet areas, and processing equipment, which can be a potential route of introduction into food. To protect food against contamination with *L. mono.*, seafood processors must engage in proper processing activities that, for example, may include the use of a cooking step that is scientifically validated to control the number of bacteria.

15. Food allergens pose another type of food safety concern. Food allergens are proteins found in various foods, including Crustacean shellfish and other ingredients in Defendants' seafood soups such as wheat and milk that induce allergic responses in certain sensitive people. Symptoms of a food allergy include: a dry itchy throat and tongue; itchy skin or rash (hives); swelling of the lips, tongue, and throat; vomiting and diarrhea; wheezing and

shortness of breath; and anaphylaxis, which can include a drop in blood pressure and unconsciousness that can lead to death in minutes without immediate medical attention. There is no cure for food allergies. Consumers with food allergies need to avoid food allergens to prevent harmful reactions from food allergen exposures. To alert susceptible consumers, food processors must declare food allergens on product labels.

16. Other ingredients, including certain food and color additives, can cause hypersensitivity reactions in some consumers. For example, sulfiting agents, which are additives typically used during handling of shrimp on fishing vessels to prevent discoloration, can cause reactions ranging from mild to life-threatening in people with a sensitivity to these ingredients. Food processors must use product labels that list ingredients, including sulfiting agents, to alert consumers and enable them to avoid consuming foods that may cause hypersensitivity reactions.

17. The Act and its implementing regulations require a seafood processor to control the risk of C. botulinum, C. perfringens, and L. mono. formation if the bacteria are reasonably likely to grow in the processor's seafood products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. § 123.6(a)-(c).

18. The Act and its implementing regulations also require a seafood processor to control the risk of other food safety hazards such as those posed by major food allergens (including Crustacean shellfish) and other ingredients that may cause hypersensitivity reactions in susceptible consumers, if such ingredients are found in their products. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. § 123.6(a)-(c); *see* Chapter 19, Fish and Fishery Products Hazards and Controls Guidance, Office of Food Safety, Center for Food Safety and Applied Nutrition, FDA (4th ed. 2011); see also 21 U.S.C. § 343(w) (deeming food to be misbranded under the Act if it

is, or it contains, an ingredient that bears or contains a major food allergen, unless the name of the food source from which the major food allergen is derived is declared on the product label).

Regulatory Framework

Food Processing

19. Defendants' ready-to-eat fish and fishery products are food within the meaning of the Act. *See* 21 U.S.C. § 321(f).

20. Food is adulterated within the meaning of the Act "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 U.S.C. § 342(a)(4).

21. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. 21 U.S.C. § 342(a)(4); 21 C.F.R. § 123.6(g).

22. Food is also adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with Current Good Manufacturing Practice ("cGMP") requirements for food. *See* 21 C.F.R. § 110.5(a).

23. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur" during the processing of each kind of fish or fishery product that it produces. 21 C.F.R. § 123.6(a).

24. Whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur during processing of seafood, the processor must develop and

implement an adequate HACCP plan to control the identified food safety hazards. 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must include:

A. A list of the food safety hazards that are reasonably likely to occur and thus must be controlled for each fish and fishery product, as required by 21 C.F.R. § 123.6(c)(1);

B. Critical control points ("CCPs"), which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to an acceptable level a food safety hazard, as required by 21 C.F.R. §§ 123.3(b), 123.6(c)(2); and

C. Critical limits at each CCP, which are the maximum or minimum values within which a physical, biological, or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s), as required by 21 C.F.R. §§ 123.3(c), 123.6(c)(3).

25. A seafood processor must also:

A. Have adequate corrective action plans and take corrective action whenever a deviation from a critical limit occurs, as required by 21 C.F.R. § 123.7;

B. Verify that its HACCP plan is adequate to control food safety hazards reasonably likely to occur and that the plan is being effectively implemented, as required by 21 C.F.R. § 123.8(a);

C. Monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that they conform with the food cGMP requirements specified at 21 C.F.R. Part 110 and 21 C.F.R. § 123.11(b); and

D. Record its sanitation activities, as required by 21 C.F.R. § 123.11(c), and maintain appropriate records, such as documentation of CCPs and corrective actions taken, and HACCP plan verification records, as required by 21 C.F.R. §§ 123.6-123.9.

26. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product," as defined at 21 C.F.R. § 123.3(d) and (e).

27. Defendants must also comply with cGMP regulations for foods, 21 C.F.R. Part 110, which require, among other things, food processing to be conducted under conditions and controls necessary to protect food against contamination by microorganisms. *See* 21 C.F.R. § 110.80(b)(2).

28. It is a violation of the Act, 21 U.S.C. § 331(k), to cause articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

Food Labeling

29. The Act requires food (except for a raw agricultural commodity) that contains a major food allergen to declare the presence of the major food allergen on its label. *See* 21 U.S.C. § 343(w). The Act identifies eight major food allergens or food groups: milk, eggs, fish, Crustacean shellfish (e.g., crab or shrimp), tree nuts, wheat, peanuts, and soybeans. 21 U.S.C. § 321(qq). A food that contains a major food allergen that is not declared on the product label is deemed misbranded. 21 U.S.C. § 343(w).

30. A food is also misbranded within the meaning of the Act if:

A. It is fabricated from two or more ingredients and its label fails to bear the common or usual name of each ingredient (*see* 21 U.S.C. § 343(i)(2); *see also* 21 C.F.R. § 101.4);

B. Its labeling fails to bear nutrition information in the manner required by regulation (*see* 21 U.S.C. § 343(q)(1), (2)(A); *see also* 21 C.F.R. § 101.9(2)(2)(ii) (requiring a declaration of trans fat content));

C. Its label fails to bear the common or usual name of the food (*see* 21 U.S.C. § 343(i)(1); *see also* 21 C.F.R. § 101.3 (requiring identity labeling of food in packaged form)); and

D. The food is in package form and its label fails to contain the place of business (city, state, ZIP) of the manufacturer, packer, or distributor (*see* 21 U.S.C. § 343(e)(1)).

31. It is a violation of the Act, 21 U.S.C. § 331(k), to cause articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343.

Defendants' Violations

Adulteration

32. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated under 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

33. Based on inspectional evidence gathered by FDA, as described more fully below in paragraphs 36-39, the insanitary conditions at Defendants' facilities include non-compliance with seafood HACCP regulations (21 C.F.R. Part 123) and food cGMP regulations (21 C.F.R. Part 110) by, among other things, the:

A. Failure to have adequate control over the risk of *C. botulinum* and *C. perfringens* growth and toxin formation;

B. Failure to have adequate control over the risk of *L. mono.* growth;

C. Failure to have adequate control over the hazards posed by major food allergens and food additives; and

D. Failure to maintain sanitation control records to ensure compliance with 21 C.F.R. Part 110.

Misbranding

34. Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded under 21 U.S.C. § 343.

35. FDA evaluated evidence collected by an FDA investigator during an inspection of Defendants' facilities between February 26 and April 3, 2015, and a follow-up investigation conducted on July 29 and August 3, 2015, and determined that Defendants cause their products, including Shrimp Locksley and Mama's Gumbo, to be misbranded within the meaning of the Act as follows:

A. Defendants' product labels fail to declare major food allergens, in violation of 21 U.S.C. § 343(w). The label for Mama's Gumbo does not declare wheat (from wheat flour) and soy (from "Worcestershire Sauce"). The Shrimp Locksley label does not declare soy (from "Worcestershire Sauce" and "Cream Soup Base");

B. Defendants product labels fail to list all of the ingredients in the products, in violation of 21 U.S.C. § 343(i)(2) and 21 C.F.R. § 101.4. The label for Mama's Gumbo does not list all ingredients, such as flour, salt, "Worcestershire Sauce," "Cajun Seasoning," and

"Tiger Sauce," and sub-ingredients of multi-component ingredients, such as "Worcestershire Sauce," "Tiger Sauce," "Tomato Sauce," and "Chicken Broth." The Shrimp Lockley label does not list all ingredients, such as salt, "Worcestershire Sauce," "Cajun Seasoning," and "Tiger Sauce," and sub-ingredients of multi-component ingredients, such as "Worcestershire Sauce," "Tiger Sauce," "Cream Soup Base," and "Culinary Cream";

C. Defendants' product labels for Shrimp Locksley and Mama's Gumbo fail to bear nutrition information that provides a declaration of trans fat content in accordance with 21 C.F.R. § 101.9(2)(2)(ii), in violation of 21 U.S.C. § 343(q);

D. Defendants' product label for Shrimp Locksley fails to bear the common or usual name of the seafood in accordance with 21 C.F.R. § 101.3, in violation of 21 U.S.C. § 343(i)(1); and

E. Defendants' product labels for Shrimp Locksley and Mama's Gumbo fail to list the place of business of the manufacturer, packer, or distributor, in violation of 21 U.S.C. § 343(e)(1) and 21 C.F.R. § 101.5. Instead, the product labels bear the firm's previous address.

History of Defendants' Violations

36. FDA inspected Defendants' facilities five times since September 2011. During this inspection period the FDA investigator found similar types of insanitary conditions and repeated violations of seafood HACCP and cGMP regulations.

37. During FDA's inspection of Defendants' facilities between February 26 and April 3, 2015, an FDA investigator documented significant HACCP and cGMP deficiencies, including but not limited to the following:

A. Failure to process food under conditions and controls necessary to minimize the potential for microorganism growth, in violation of 21 C.F.R. § 110.80(b)(2). For

example, the FDA investigator observed that Defendants placed 102 thirty-ounce containers of seafood gumbo (at 110° F to 138° F) in the freezer without ensuring that the product cooled quickly enough to prevent the growth of *C. botulinum* and *C. perfringens*;

B. Failure to have a written HACCP plan that includes all CCPs that are necessary to control the growth of pathogenic bacteria and toxin formation, in violation of 21 C.F.R. § 123.6(c)(2). For example, Defendants' HACCP plans for Shrimp Locksley and Mama's Gumbo do not include the CCP of cooling of cooked product to control the hazards posed by *C. botulinum* and *C. perfringens*. In addition, Defendants' HACCP plan for Mama's Gumbo does not include the CCP of thawing of pasteurized crabmeat to control the hazard posed by *C. botulinum*;

C. Failure to verify that the time and temperatures listed at the cook CCP are adequate to control the hazard posed by *L. mono.*, in violation of 21 C.F.R. §§ 123.6(c)(3) and 123.8(a). Specifically, Defendants did not verify, by scientific methods, that the heat treatment (cooking time and temperature) specified in their HACCP plans for Shrimp Locksley and Mama's Gumbo will achieve a sufficient reduction of *L. mono.*, the target pathogen;

D. Failure to have a written HACCP plan that lists all of the food safety hazards that are reasonably likely to occur, in violation of 21 C.F.R. § 123.6(c)(1). Specifically, Defendants' HACCP plans for Shrimp Locksley and Mama's Gumbo do not list all of the allergen hazards in their products: for example, Crustacean shellfish (shrimp and/or crab) in Shrimp Locksley and Mama's Gumbo, milk in Shrimp Locksley, and wheat in Mama's Gumbo;

E. Failure to have a written HACCP plan that includes procedures that are adequate to monitor each of the CCPs to ensure compliance with their critical limits, in violation of 21 C.F.R. § 123.6(c)(4). For example, the refrigeration CCP in Defendants' HACCP plans for

Shrimp Locksley and Mama's Gumbo for monitoring the temperature of the cooler used to store raw materials and finished products fails to require use of a continuous time and temperature recording device;

F. Failure to implement the monitoring and recordkeeping procedures in the written HACCP plans to control food safety hazards, in violation of 21 C.F.R. § 123.6(b). Specifically, Defendants are not following the procedures in their HACCP plans for Shrimp Locksley and Mama's Gumbo for documenting the review of the finished product labeling at the finished product packing/labeling CCP to ensure that ingredients, namely sulfiting agents, are declared on product labels; and

G. Failure to maintain sanitation control records to ensure compliance with the conditions and practices specified in 21 C.F.R. Part 110, in violation of 21 C.F.R. § 123.11(c). Specifically, Defendants do not maintain sanitation control records to document the monitoring of: the condition and cleanliness of food-contact surfaces; prevention of cross-contamination from insanitary objects; maintenance of hand-washing, hand-sanitizing, and toilet facilities; protection of food, food-packaging material, and food-contact surfaces from adulteration; proper labeling, storage and use of toxic chemicals; control of employee health conditions; and exclusion of pests.

38. FDA inspected Defendants' facilities on four previous occasions: twice in 2014 (between February 7 and March 5, 2014, and between January 9 and 21, 2014), when the firm was located at 19270 Scenic Highway 98, Fairhope, Alabama 36532); and in 2012 (between December 5 and 14, 2012) and 2011 (September 28 and 29, 2011), when the firm was located at 13045 County Road, Loxley, Alabama 36551.

39. During the February-March 2014 inspection, an FDA investigator documented significant HACCP and cGMP deficiencies, including but not limited to the following:

A. Failure to have a written HACCP plan that includes all CCPs that are necessary to control the growth of pathogenic bacteria and toxin formation, in violation of 21 C.F.R. § 123.6(c)(2). This deficiency was also documented during FDA's inspections at Defendants' facilities in January 2014 and December 2012. In addition, Defendants' failure to have a written HACCP plan for each of their fish and fishery products was documented during FDA's inspections at Defendants' facilities in December 2012 and September 2011;

B. Failure to verify that the time and temperatures critical limits at the cook CCP are adequate to control the hazard posed by *L. mono.*, in violation of 21 CFR § 123.6(c)(3) and § 123.8(a). This deficiency was also documented during FDA's inspection at Defendants' facilities in December 2012;

C. Failure to have a written HACCP plan that lists all of the food safety hazards, specifically allergen hazards, that are reasonably likely to occur, in violation of 21 CFR § 123.6(c)(1);

D. Failure to implement the monitoring and recordkeeping procedures in the written HACCP plans to control food safety hazards, in violation of 21 CFR § 123.6(b). Specifically, Defendants are not following the procedures in their HACCP plans for Shrimp Locksley and Mama's Gumbo for documenting the review of the finished product labeling to ensure that ingredients, namely sulfiting agents, are declared on product labels. This deficiency was also documented during FDA's inspection at Defendants' facilities in January 2014; and

E. Failure to maintain sanitation control records, in violation of 21 CFR § 123.11(c). This deficiency was also documented during all previous FDA inspections at Defendants' facilities.

Warnings

40. Defendants have been warned repeatedly about their ongoing violations. At the close of each inspection between 2011 and 2015, an FDA investigator issued a List of Inspectional Observations ("Form FDA-483") to Defendant Stembridge (in 2014 and 2015) or Defendant Huxen (in 2011 and 2012), and discussed with him each of the observed HACCP and cGMP deviations. During the inspections in 2015 and February-March 2014, the FDA investigator also discussed with Defendant Stembridge the need for product labels to bear allergen declarations.

41. FDA issued a Warning Letter, dated May 20, 2014, notifying Defendants that they were in violation of seafood HACCP regulations, causing their products to be adulterated under the Act. The Warning Letter also noted the deficiencies in Defendants' corrective actions proposed in their responses, received by FDA on February 14 and April 1, 2014, to the Forms FDA-483 issued to them at the close of the 2014 inspections. The Warning Letter cautioned Defendants that, if they failed to promptly correct their violations, FDA may pursue further regulatory action, including an injunction. FDA did not receive a response from Defendants to the Warning Letter. As evidenced by the repetitive violations observed during FDA's 2015 inspection, Defendants have failed to take effective measures to bring their food processing operations into compliance with the law.

42. FDA issued a previous Warning Letter, dated January 6, 2012, addressed to Defendant Huxen, informing him that the firm's failures to have seafood HACCP plans for their

fishery products and sanitation control records to ensure compliance with cGMP regulations were serious violations of the Act that caused their products to be adulterated. As described in the letter, Defendants were warned that they may be subject to legal action, including an injunction, for failure to take prompt action to correct the violations.

43. In a letter dated April 24, 2012, FDA notified Defendant Huxen that his written response received on January 20, 2012, to the January 2012 Warning Letter was inadequate and incomplete.

44. On April 29, 2013, FDA held a regulatory meeting with Defendant Stembridge to discuss his recurring seafood HACCP deficiencies and the need for him to take effective steps to correct his noncompliance.

45. Defendants Huxen and Stembridge have promised corrective actions, but they have consistently failed to achieve compliance with the law. Defendants' most recent promise of corrective action, submitted by letter dated April 3, 2015, in response to the Form FDA-483 issued at the close of FDA's 2015 inspection, failed to adequately address several significant HACCP deficiencies observed during that inspection. Those HACCP deficiencies were the same or similar to the deviations that FDA brought to Defendants' attention on numerous occasions in the past: during four earlier inspections; at a regulatory meeting; and in two Warning Letters.

46. Based on the foregoing, Plaintiff believes that, unless restrained by this Court, Defendants will continue to violate the Act in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, cease receiving, preparing, processing, packing,

labeling, holding, or distributing articles of food unless and until Defendants bring their receiving, preparing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. Order that Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

B. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 343;

III. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receiving, preparing, processing, packing, labeling, holding, and distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Order that Plaintiff be awarded costs incurred in pursuing this action, including the costs of investigation to date, and such other equitable relief as the Court deems just and proper.

DATED this 1st day of July, 2016.

Respectfully submitted,

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