IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. THOMAS L. CROFUT and JUDITH H. CROFUT, individuals d/b/a GOOD FLOW HONEY AND JUICE CO., Defendants.	Civil No. A07CA 996SS COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, 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), and the inherent authority of this Court, to enjoin and restrain Thomas L. Crofut and Judith H. Crofut, (collectively, "Defendants"), individuals doing business as Good Flow Honey and Juice Co. ("Good Flow"), from violating 21 U.S.C. § 331(k) by causing any food that is held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345. Venue in this district is proper under 28 U.S.C. §§ 1391(b).

THE DEFENDANTS

3. Defendants Judith H. Crofut and Thomas L. Crofut are co-owners of Good Flow, an unincorporated proprietorship. Defendants receive, process, prepare, pack, hold, and distribute unpasteurized fresh-squeezed fruit and vegetable juices and juice blends ("juice") at their juice production facility at 2601 East Cesar Chavez Street, Austin, Texas. Defendants' juice is "food" within the meaning of 21 U.S.C. § 321(f).

4. Defendants conduct juicing operations six days per week and employ eight to ten people, depending on daily demand. Defendants' juices are made from a variety of fruits that are shipped in interstate commerce. For example, Defendants receive lemons and oranges from a supplier in California, apples from a supplier in Washington, and limes that are imported from Mexico. Additionally, Defendants' finished juices are packaged in plastic bottles made in Venezuela using bottle closures from Kentucky.

5. Defendant Judith H. Crofut is responsible for the day-to-day management of Good Flow's juice production facility, including the supervision and training of employees. She has represented Good Flow during inspections by the Food and Drug Administration ("FDA") of the firm's juice production facility, and has corresponded with FDA both orally and in writing following such inspections. Her signature also appears on the

firm's Operations Manual and Hazard Analysis and Critical Control Point ("HACCP") Plan.

6. Defendant Thomas L. Crofut makes all operational decisions concerning Good Flow jointly with Defendant Judith H. Crofut. He helped draft and signed the firm's Operations Manual and HACCP Plan. He has also signed several letters to FDA following FDA inspections of Good Flow's juicing operations.

UNPASTEURIZED JUICE SAFETY

7. Unpasteurized, fresh-squeezed juice is a high-risk food that has been shown to be a source of *Salmonella* and other bacterial pathogens. Exposure to *Salmonella* can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Otherwise healthy individuals may suffer short-term symptoms such as high fever, severe headache, vomiting, nausea, abdominal pain, and diarrhea. Long-term complications can include severe arthritis.

8. The production of juice without proper monitoring and sanitation controls creates optimal conditions for the proliferation of *Salmonella* and other pathogenic microorganisms.

REGULATORY FRAMEWORK

9. In order to minimize potential contamination hazards known to occur during the juice manufacturing process, producers

must follow the juice HACCP regulations found in 21 C.F.R. Part 120.

10. Under the HACCP regulations, every processor of juice must conduct, or have conducted for it, a hazard analysis to determine whether there are any food safety hazards that are reasonably likely to occur during the processing of each kind of juice that it produces. 21 C.F.R. § 120.7(a). Whenever a hazard analysis identifies one or more food safety hazards that are reasonably likely to occur, such processor must, pursuant to 21 C.F.R. § 120.8(a), have and implement an adequate written HACCP plan to control the identified food safety hazard(s).

11. A HACCP plan must identify critical control points, which are points, steps, or procedures in a food manufacturing process at which controls can be applied to prevent, eliminate, or reduce to acceptable levels, a food safety hazard. 21 C.F.R. §§ 120.3(d), 120.7(a)(5).

12. At each critical control point, a HACCP plan must also identify critical limits, which are the maximum or minimum values to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food safety hazard(s). 21 C.F.R. §§ 120.3(e), 120.8(b)(3).

13. The HACCP regulations specifically require processors of unpasteurized juice to include control measures in their HACCP

plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganism of public health significance likely to occur in the juice. 21 C.F.R. § 120.24(a).

14. To achieve the 5-log reduction, juice processors are required to use a treatment process that is applied directly to the juice. 21 C.F.R. § 120.24(b). However, citrus juice processors may use a 5-log reduction process that is applied to the surface of the fruit as opposed to the juice. Id. If a 5-log reduction process is used that does not come into contact with all parts of the juice, the processor must analyze the finished juice for biotype I *Escherichia coli* ("*E. coli*"). See 21 C.F.R. § 120.25. The presence of *E. coli* in processed juice is an indicator of possible *Salmonella* contamination. *E. coli* is also a potential human health risk in its own right because certain strains of the bacteria are pathogenic and can cause diarrhea, vomiting, and even death, especially in young children, frail or elderly people, and others with weakened immune systems.

15. The HACCP regulations further require that juice processors monitor and record sanitation conditions and practices during juice processing to ensure conformance with current Good Manufacturing Practices ("CGMP"). 21 C.F.R. §§ 120.5-.6.

16. Each juice processor must verify that its HACCP plan is adequate to control food safety hazards that are reasonably

likely to occur, and that the plan is being effectively implemented. 21 C.F.R. § 120.11(a)-(b).

17. Juice products that are processed without adhering to the requirements of 21 C.F.R. Part 120 are adulterated under 21 U.S.C. § 342(a)(4). 21 C.F.R. § 120.9.

DEFENDANTS' CONDUCT AND VIOLATIONS

18. Defendants violate 21 U.S.C. § 331(k) by causing juice to become adulterated after shipment in interstate commerce.

19. Defendants' juice is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, processed, packed, and held under insanitary conditions whereby it may have been rendered injurious to health.

20. Defendants have failed to, and continue to fail to:

(a) include control measures in their HACCP plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganism of public health significance likely to occur in unpasteurized, fresh-squeezed citrus juice, 21 C.F.R. § 120.24(a);

(b) monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP, 21 C.F.R. § 120.6(b);

(c) maintain records that, at a minimum, document their monitoring and correction of sanitation conditions and practices, 21 C.F.R. S 120.6(c); and

(d) prepare, process, pack and hold their juice under appropriate conditions to avoid the adulteration of their products.

DEFENDANTS' HISTORY OF VIOLATIONS

March 2007 Inspection

21. FDA has inspected Defendants' plant on three occasions. During an inspection from March 12-21, 2007, FDA observed serious deficiencies in Defendants' HACCP plan, their implementation and verification of that plan, and their sanitation practices. Many of these deficiencies had been observed during previous inspections. The most significant repeated deficiencies include, but are not limited to, the following:

(a) Defendants failed to include control measures in their HACCP plan that will consistently produce, at a minimum, a 5-log reduction in the most resistant microorganisms of public health significance that are likely to occur in their juices. See 21 C.F.R. § 120.24. For example, although the pathogens *E. coli*, *Cryptosporidium parvum*, and *Listeria monocytogenes* ("*L. mono.*") are associated with apple juice, *Clostridium botulinum* and *E. coli* are associated with carrot juice, and *Salmonella*, *L. mono.* and *E. coli* are associated with strawberry and orange juices, Defendants' HACCP plan does not include control measures to consistently produce a 5-log reduction in any of these

pathogens. This was a repeat violation that FDA had observed in previous inspections.

(b) Defendants failed to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP. See 21 C.F.R. § 120.6(b). Specifically, defendants failed to monitor with sufficient frequency the prevention of cross-contamination from insanitary objects, as evidenced by instances where: (1) unwashed fruit, including moldy fruit, was sliced and placed into tubs of water before being juiced, a practice that exposes the flesh of the fruit, and subsequently the juice, to potential contaminants that may be present on the fruit's peel; (2) an employee wore gloves while handling and discarding moldy fruit, and then cut fruit used to make juice while wearing the same gloves; and (3) a spray nozzle soiled with fruit pulp and other debris was placed into a tub containing water and cut fruit that was subsequently processed into juice. See 21 C.F.R. § 120.6(a)(3). Defendants also failed to monitor with sufficient frequency the condition and cleanliness of food contact surfaces, as evidenced by defendants' use of a discolored and scored cutting board, soiled plastic shovel, gloves that had been in contact with soiled plastic door flaps, and a knife whose handle was wrapped with a soiled white bandage tape. See 21 C.F.R. § 120.6(a)(2).

(c) Defendants failed to maintain records that, at a

minimum, document their monitoring and correction of sanitation conditions and practices. See 21 C.F.R. S 120.6(c). Specifically, the firm's "Daily Log" with respect to sanitation practices was not filled in during several days when juice was being produced.

August/September 2006 Inspection

22. FDA conducted a previous inspection of Defendants' operations between August 28 and September 7, 2006. During this inspection, FDA investigators observed numerous HACCP violations, nearly all of which were noted again in the March 2007 inspection. The inspection found, for example, that Defendants' HACCP plan was insufficient to obtain the required 5-log reduction in the pathogens associated with the various juices manufactured by the firm; Defendants failed to monitor sanitation conditions and practices with sufficient frequency during juice processing to ensure conformance with CGMP; and Defendants failed to maintain records that, at a minimum, document their monitoring and correction of SSOP conditions and practices. This inspection resulted in a Warning Letter being issued to Defendants on January 24, 2007.

September 2003 Inspection

23. A previous inspection conducted by FDA on September 18, 2003 found, among other things, that Defendants had failed to develop a written hazard analysis to determine whether there are

food hazards that are likely to occur; Defendants had no written HACCP plan for the processing of juice; and Defendants had no records documenting their monitoring and correction of sanitation practices conditions and practices. This inspection resulted in the FDA issuing a letter to the Defendants on May 24, 2004 outlining deficiencies observed and encouraging necessary improvements.

PRIOR NOTICE

24. Defendants have received ample notice that their juice processing operations violate the law and that continued violations could lead to regulatory action. At the close of the September 2003, August/September 2006, and March 2007 inspections, FDA investigators issued Forms FDA-483 List of Inspectional Observations ("Forms 483") to Defendant Judith Crofut, that notified Defendants of the investigators' observations. FDA investigators also discussed their observations with Defendant Judith Crofut and encouraged her to make necessary corrections.

25. In addition, FDA sent Defendants a letter following the September 2003 inspection noting observed deficiencies and a Warning Letter following the September 2006 inspection.

26. In response to the inspections and Warning Letter, Defendants have repeatedly promised to bring their facility into full compliance with regulatory requirements. Following the

September 2003 inspection, Defendant Thomas Crofut promised to correct all deficiencies, and noted that the firm was "working diligently" to achieve compliance with the juice HACCP requirements. In response to the August/September 2006 inspection, Defendant Judith Crofut promised to correct the noted deficiencies, but expressed concern about the "financial risk[s]" associated with equipment upgrades. After receiving the Warning Letter in January 2007, Defendants stated that the firm intended to "fully comply with HACCP" but was in the process of "redefining" to bring the firm "in line with 21st century realities." Following the March 2007 inspection, Defendant Judith Crofut promised corrections and acknowledged the firm's need to comply with the 5-log reduction requirement. However, she noted that the process was "complicated" and "could easily take two years."

27. Despite multiple inspections by FDA, and Defendants' promises that violations would be corrected, Defendants have failed to institute effective measures to bring their juice processing operations into compliance with the law.

28. The United States is informed and believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

WHEREFORE, the United States respectfully requests that this Court:

I. Permanently and restrain and enjoin Defendants Thomas L. Crofut and Judith H. Crofut, individuals, and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's order, from violating 21 U.S.C. § 331(k) by directly or indirectly causing any article of food, within the meaning of 21 U.S.C. § 321(f), to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce.

II. Order Defendants Thomas L. Crofut and Judith H. Crofut, individuals, and each and all of their agents, employees, attorneys, successors, assigns, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's order, to cease receiving, processing, preparing, packing, holding, and distributing all juice at or from their plant, or at any other location(s) from which Defendants receive, process, prepare, pack, hold, or distribute food, unless and until:

A. Defendants bring their receiving, processing, preparing, packing, holding, and distribution operations into

compliance with the Act and its implementing regulations to the satisfaction of FDA;

B. Defendants destroy all adulterated food currently held in their plant according to procedures approved by and under the supervision of FDA;

C. Defendants establish and implement adequate written HACCP plans, developed by an independent juice HACCP expert and approved in writing by FDA, that are sufficient to control food safety hazards likely to occur in the processing of each type of juice processed by Defendants, as required by 21 C.F.R. §§ 120.7 and 120.8;

D. Defendants have an independent juice HACCP expert validate the adequacy of control measures in Defendants' HACCP plans to consistently produce, at a minimum, a 5-log reduction in the most resistant organism of public health significance that is likely to occur in each juice, as required by 21 C.F.R. § 120.24, and the results of the validation study have been admitted to and approved in writing by FDA;

E. To the extent Defendants utilize in their production of citrus juice a surface treatment process to achieve a 5-log reduction of the most resistant organism of public significance, Defendants analyze their unpasteurized, finished citrus juice products for *E. coli* in accordance with the frequency and methods of analysis prescribed in 21 C.F.R. § 120.25;

F. Defendants have accomplished all of the above to FDA's satisfaction and have been so notified by FDA in writing.

III. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated this _____ day of December, 2007.

Respectfully submitted,

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