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

) NO. 07-CV-00996-SS
) THE UNITED STATES' PETITION FOR AN ORDER TO SHOW CAUSE
) WHY DEFENDANTS SHOULD NOT
BE HELD IN CIVIL CONTEMPT
)
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Petitioner, the United States of America, by its attorneys, hereby petitions the Court for an Order that Thomas L. Crofut and Judith H. Crofut (hereinafter collectively referred to as "Defendants") show cause why they should not be held in civil contempt for failing to comply with the Consent Decree of Permanent Injunction ("Consent Decree") entered by this Court on May 6, 2008. The United States hereby submits the attached Memorandum of Law and Declaration of Reynaldo R. Rodriquez, Jr., Director of the Dallas District Office of the United States Food and Drug Administration ("FDA"), in support of this Petition and states as follows:

- 1. Defendants operate the Good Flow Honey and Juice Company in Austin, Texas and produce juice for human consumption;
- 2. On May 6, 2008, the Court entered the Consent Decree which required the Defendants, among other things, to cease manufacturing and distributing juice until they satisfied certain criteria set forth in Paragraphs 4 and 11 of the Consent Decree;
  - 3. Defendants failed to meet those criteria;

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- 4. Paragraph 4 of the Consent Decree provides that a cessation of operations shall continue until certain requirements are met;
- 5. Notwithstanding the express requirements of the Consent Decree, Defendants have continued manufacturing juice;

Moreover, when the FDA notified Defendants pursuant to the Consent Decree that their continued production violated the unequivocal requirements of the Consent Decree and must be immediately halted, Defendants failed to comply with FDA's direction.

### **WHEREFORE**, the United States of America respectfully requests that this Court:

- 1. Issue an order directing Defendants to appear before the Court to show cause, if any they have, at such time and place as the Court shall direct, why they should not be held in civil contempt for failure to comply with the Consent Decree of Permanent Injunction entered on May 6, 2008;
- 2. Following the issuance of the Order to Show Cause and an appropriate hearing, enter a judgment of civil contempt against Defendants for violations of the Consent Decree;
- 3. Make factual findings as are necessary to require Defendants to cease production in accordance with Paragraphs 4 and 11 of the Decree, and such cessation shall continue until the requirements of Paragraphs 4 and 6(A) and 6(B) are met to FDA's satisfaction;
- 4. Following entry of this Order, should Defendants violate any provision of the Consent Decree, including, but not limited to, the production or distribution of juice prior to satisfying the requirements of Paragraph 4 of the Consent Decree; Defendants will, upon written

notice from FDA, and without further order of the Court, pay conditional fines to the United States Treasury in the amount of \$1,000 per each day of violation;

- 5. Award plaintiff its attorneys' fees, all investigational expenses, and court costs relating to Defendants' violation of the Consent Decree and this contempt proceeding; and
  - 6. Grant any such other relief as the Court deems just and proper.

Dated this 10<sup>th</sup> day of July, 2008.

Respectfully submitted,

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# UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA,	)	NO. 07-CV-00996-SS
	)	
Plaintiff,	)	MEMORANDUM IN SUPPORT OF
	)	PLAINTIFF'S PETITION FOR AN
v.	)	ORDER TO SHOW CAUSE WHY
	)	DEFENDANTS SHOULD NOT BE
THOMAS L. CROFUT AND	)	HELD IN CIVIL CONTEMPT
JUDITH H. CROFUT,	)	
individuals d/b/a	)	
GOOD FLOW HONEY AND JUICE CO.,	)	
	)	
Defendants.	)	
	)	

# I. <u>INTRODUCTION</u>

Plaintiff, United States of America, submits this Memorandum of Law, with the Declaration of Reynaldo R. Rodriquez, Jr., Director of the Dallas District Office of the United States Food and Drug Administration ("FDA") (attached as Exhibit A), in support of its application for an Order to show cause why Thomas L. Crofut and Judith H. Crofut (hereinafter collectively referred to as "Defendants") should not be held in civil contempt for violations of the Consent Decree of Permanent Injunction. See Civil Docket No. 15.

Should the Court find Defendants in contempt, the United States requests that the Court issue an order requiring Defendants cease production in accordance with Paragraphs 4 and 11 of the Decree, and such cessation shall continue until the requirements of Paragraphs 4 and 6(A) and 6(B) are met to FDA's satisfaction, conditional award plaintiff its attorneys' fees, all investigational expenses, and court costs relating to Defendants' violation of the Consent Decree and this contempt proceeding; and grant any such other relief as the Court deems just and proper.

## II. FACTUAL BACKGROUND

### A. Prior Violations

Defendants Thomas L. Crofut and Judith H. 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). FDA inspected Defendants' plant on three separate occasions prior to litigating this matter. See Rodriguez Decl. ¶¶ 5,6.

## 1. September 2003 Inspection

An 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 Hazard Analysis Critical Control Point ("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. See Rodriguez Decl. ¶ 13.

## 2. August/September 2006 Inspection

FDA conducted a 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 current good manufacturing processess ("CGMP"); and Defendants failed to maintain records that, at a minimum, document their monitoring and correction of Sanitation Standard Operating Procedure conditions and practices. As a result of this inspection, FDA issued a Warning Letter to Defendants on January 24, 2007. See Rodriguez Decl. ¶ 12.

## 3. March, 2007 Inspection

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 the Defendants failure 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. See Rodriguez Decl. ¶ 11.

In addition, 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, a 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). See also Civil Docket No. 1.

Finally, 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.

### B. The Complaint

On December 10, 2007, the United States filed a Complaint against the Defendants, the owners and operators of Good Flow Honey and Juice Company, under the injunction provision of the Federal Food, Drug and Cosmetic Act (hereinafter the "Act"), 21 U.S.C. § 332(a). See Civil Docket No. 1. The Complaint sought to enjoin the Defendants from violating 21 U.S.C.

§ 331(k) by causing food – in this case fruit and vegetable juices – to become adulterated within the meaning of 21 U.S.C. § 342(a)(4). <u>Id.</u>

The Complaint alleged, among other things, that the Defendants produced unpasteurized fresh-squeezed juice – a high-risk food that has been shown to be a source of *Salmonella* and other bacterial pathogens – at their facility in Austin, Texas, but failed to comply with applicable regulations. <u>Id.</u> The Complaint also detailed the Defendants' history of promising corrective actions after FDA inspections revealed significant deficiencies, but then failing to actually implement effective corrections. Id. ¶¶ 24-26. See also Rodriguez Decl. ¶¶ 9-14.

# C. The Consent Decree of Permanent Injunction

After extensive negotiations, the parties and their counsel signed the Consent Decree, and it was entered by this Court on May 6, 2008. See Civil Docket No. 15. In signing the Consent Decree, Defendants agreed to take specific steps in order to bring their manufacturing processes into compliance with the law. Most significantly, the Consent Decree requires the Defendants to cease production and distribution of juice until four criteria are satisfied. First, under Paragraph 4(A), Defendants are required to retain an independent HACCP expert. Id. ¶ 4. Second, under Paragraph 4(B), Defendants' expert must develop and submit for FDA review HACCP plans for each type of juice processed. Id. Third, under Paragraph 4(C), Defendants' expert must certify that the HACCP plans are adequate to consistently produce "a 5-log reduction in the 'pertinent microorganism,' as defined in 21 C.F.R. § 120.24(a)." Id. Finally, pursuant to Paragraph 4(D), Defendants must receive written notification from FDA that their HACCP plans appear to satisfy the requirements of Paragraphs 4(A) - (C) of the Consent Decree, the Act, and 21 C.F.R. § 120.

<u>Id.</u> Importantly, all of these steps must be complete and evaluated by FDA, and the agency must authorize the resumption of operations.

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Pursuant to Paragraph 6 of the Consent Decree, after Defendants receive the required written notification from FDA under Paragraph 4(D), they are given 120 days to fully implement the HACCP plans developed by their expert and approved by FDA. <u>Id.</u> ¶ 6. Within this 120-day window, Defendants must also have their expert certify to FDA that the HACCP plans approved by FDA have been fully implemented and that the control measures in the plans have achieved the requisite 5-log reduction in the "pertinent microorganism," as defined in 21 C.F.R. § 120.24(a). <u>Id.</u> ¶ 6(B). Upon receipt of this certification, FDA must inspect Defendants' facility to determine the Defendants' compliance with the Consent Decree and the law. <u>Id.</u> If FDA determines that the firm is not in compliance, it may order Defendants to cease operations. <u>Id.</u>

In addition to these requirements, Paragraph 13 of the Consent Decree requires

Defendants to provide FDA with an affidavit, within 30 calendar days after entry of the Consent

Decree, certifying that Defendants have provided a copy of the Consent Decree by personal
service or by certified mail to each of Defendants' "agents, employees, attorneys, successors,

assigns, and any persons in active concert or participation with any of them . . . . " Id. ¶ 13.

Paragraph 11 of the Consent Decree also states that if, after entry of the Consent Decree, FDA determines that the Defendants have failed to comply with any provision of the Consent Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance, FDA can order Defendants to immediately cease their production and distribution of juice. Id. ¶ 11. Morever, pursuant to Paragraph 11, if such

an order is issued by FDA, the Defendants are obligated to "immediately comply with any such orders." Id.

#### Conduct in Contempt of the Consent Decree of Permanent Injunction D.

On June 19, 2008, an FDA investigator from FDA's Dallas District Office observed activity at or around Defendants' manufacturing facility that indicated that Defendants were manufacturing juice. Rodriguez Decl. ¶ 18. Later that day, the investigator observed that Defendants' unpasteurized fresh-squeezed juices were being sold at a local grocery store. Id.<sup>1</sup>

On June 24, 2008, FDA sent Defendants a letter via overnight mail that identified the Defendants' violations of Paragraphs 4 and 13 of the Consent Decree. Id. ¶ 19. Pursuant to Paragraph 11 of the Consent Decree, the letter instructed Defendants to cease receiving, processing, preparing, packing, holding or distributing any juice. Id. ¶ 19. The letter also noted that, pursuant to Paragraph 12 of the Consent Decree, this cessation of operations shall contine until Defendants receive written notification from FDA that they are in compliance with the Consent Decree and the Act. Id. Finally, the letter directed Defendants to immediately contact FDA to discuss their intentions. Id. FDA has not received any written response from Defendants to its June 24, 2008 letter. Id. ¶ 21. However, on June 26, 2008, FDA was contacted by Defendants' HACCP expert. Id. ¶ 20. During a teleconference on June 27, 2008, Defendants' expert confirmed that his clients' operations needed significant modifications to obtain compliance with the FDA's juice HACCP requirements. Id. He also stated that he was in the

<sup>&</sup>lt;sup>1</sup> On June 20, 2008, Defendants' counsel confirmed that Defendants were still manufacturing and distributing their fresh-squeezed unpasteurized juices. Counsel suggested, despite the clear requirements of the Consent Decree, that he thought their activities were permissible.

process of developing a HACCP plan that will be submitted to FDA at a future date. <u>Id.</u> Finally, with respect to his clients' operations, he indicated his belief that the firm was continuing to produce juice. <u>Id.</u>

## III. <u>LEGAL ARGUMENT</u>

## A. The Court Should Find Defendants in Civil Contempt

## 1. Standard for Civil Contempt

It is unquestioned that the federal courts have inherent power to force entities to comply with their lawful orders through actions for civil contempt. Spallone v. United States, 493 U.S. 265, 276 (1990); Shillitani v. United States, 384 U.S. 364, 370 (1966). "[T]he power of courts to punish for contempts is a necessary and integral part of the independence of the judiciary, and is absolutely essential to the performance of the duties imposed on them by law." Gompers v. Buck's Stove & Range, Co., 221 U.S. 418, 450 (1911). Federal courts have the authority to issue contempt sanctions for violations of judicial orders, including consent decrees. Whitfield v. Pennington, 832 F.2d 909, 913 (5th Cir. 1987).

The primary purposes of civil contempt are to coerce compliance with the court's order and to compensate the complainant for losses sustained by the other party's disobedience.

American Airlines, Inc v. Allied Pilots Ass'n, 228 F.3d 574, 585 (5th Cir. 2000) (citing United States v. United Mine Workers of America, 330 U.S. 258, 303-04 (1947)). Civil contempt is justified where there is a violation of a court order, regardless of the intent of the contemnor. Jim Walter Res., Inc. v. Int'l Union, United Mine Workers of America, 609 F.2d 165, 168 (5th Cir. 1980).

To justify a finding of civil contempt, the moving party must show the following elements by clear and convincing evidence: (1) a court order was in effect; (2) the order required certain conduct by the respondent; and (3) the respondent failed to comply with the court's order.

United States v. City of Jackson, 359 F.3d 727, 731 (5th Cir 2004); American Airlines, Inc. v.

Allied Pilots Ass'n, 228 F.3d at 581; Martin v. Trinity Indus. Inc., 959 F.2d 45, 47 (5th Cir. 1992). A demonstration that the party violated the order is sufficient; willfulness is not an issue.

See McComb v. Jacksonville Paper Co., 336 U.S. 187, 191 (1949) (noting that "[a]n act does not cease to be a violation of a law and of a decree merely because it may have been done innocently."). The facts in this case clearly support a finding that the Defendants are in civil contempt of a court order by violating the Consent Decree.

## 2. Defendants Should Be Held in Civil Contempt

## a. A Court Order Was In Effect

The Supreme Court has consistently recognized that a consent decree entered by the court reflects "an agreement that the parties desire and expect will be reflected in, and be enforceable as, a judicial decree that is subject to the rules generally applicable to other judgments and decrees." Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 378 (1992). Accordingly, a party who fails to comply with the terms of a court-ordered consent decree is subject to the court's contempt power. Whitfield v. Pennington, 832 F.2d 909, 913 (1987). In the present case, the Consent Decree unquestionably took effect and became binding on the parties when it was entered by this Court on May 6, 2008. See Civil Docket No. 15.

## b. The Consent Decree Requires Defendants to Take Certain Actions

The Consent Decree expressly requires Defendants to take certain well-defined actions. Three requirements are at issue in this petition. First, pursuant to Paragraph 4 of the Consent Decree, the Defendants are explicitly "restrained and enjoined" from "receiving, processing, preparing, packing, holding, or distributing juice at or from Defendants' juice processing plant located at 2601 East Cesar Chavez Street, Austin, Texas . . . . " Id. ¶ 4. As detailed in Paragraph 4, the cessation of operations must continue "unless and until" all four requirements set forth in Paragraphs 4(A) - (D) are satisfied. Id. Specifically, Paragraph 4(A) requires Defendants to retain an independent HACCP expert. Paragraph 4(B) requires Defendants to have their expert develop and submit for FDA review HACCP plans for each type of juice processed. Id. Paragraph 4(C) requires Defendants to have the expert certify that the HACCP plans are adequate to consistently produce "a 5-log reduction in the 'pertinent microorganism,' as defined in 21 C.F.R. § 120.24(a)." Id. Finally, under Paragraph 4(D), Defendants must receive written notification from FDA that their HACCP plans appear to satisfy the requirements of Paragraphs 4(A) - (C) of the Consent Decree, the Act, and 21 C.F.R. § 120. Id. This shutdown ensures that the public will not continue to be exposed to hazardous products that violate the law.

In recognition of the fact that the Defendants juice processing plant will remain shutdown until all of the requirements of Paragraph 4 are satisfied, the Consent Decree requires FDA to complete its review of Defendants' HACCP plans and expert certification submitted pursuant to Paragraphs 4(B) and (C) "within a reasonable time after such documents are received, or as soon thereafter as is reasonably practicable in the event that FDA representatives are attending to other FDA matters." Id.

Second, under Paragraph 13 of the Consent Decree, the Defendants are required to provide an affidavit to FDA confirming that the Consent Decree had been provided to all of Defendants' "agents, employees, attorneys, successors, assigns . . . " within thirty (30) calendar days after entry of the Consent Decree. Id. ¶ 13. This is to make certain that all involved in the business are aware of the requirements and obligations imposed by the Consent Decree.

Third, under Paragraph 11 of the Consent Decree, FDA is authorized to order Defendants to immediately cease their production and distribution of juice if, after entry of the Consent Decree, FDA determines that the Defendants have failed to comply with any provision of the Consent Decree, or have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance. Id. ¶ 11. Pursuant to Paragraph 11, if such an order is issued by FDA, the Defendants are obligated to "immediately comply with any such orders." Id. Similarly, under Paragraph 16 of the Consent Decree, Defendants are required to "abide by the decisions of FDA, which decisions shall be final." Id. ¶ 16. This provision is a critical part of the effort to keep violative food out of the channels of commerce where it could endanger public health.

> Defendants Have Failed to Comply With Several Requirements of c. the Consent Decree

Defendants have unabashedly failed to comply with several paragraphs of the Consent Decree. First, although Paragraph 4 of the Consent Decree clearly requires Defendants to cease operations until four specifically identified requirements are met, it is undisputed that Defendants have continued to manufacture and distribute juice before all of those requirements have been satisfied. Rodriguez Decl. ¶ 20. Specifically, of the four requirements set forth in Paragraph 4,

only Paragraph 4(A) appears to have been met.<sup>2</sup> Defendants' continued operation after entry of the Consent Decree was not only observed by an FDA investigator but confirmed by Defendants' attorney and more recently by their expert. Id. ¶¶ 18, 20.

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Second, although Paragraph 13 of the Consent Decree requires Defendants to provide an affidavit to FDA confirming that the Consent Decree had been provided to all of Defendants' "agents, employees, attorneys, successors, assigns . . ." within thirty (30) calendar days after entry of the Consent Decree, Defendants have failed to provide FDA with the required affidavit. Id. ¶ 19.

Third, while Paragraph 11 of the Consent Decree requires Defendants to "immediately" cease their production and distribution of juice upon receiving a written order from FDA to do so, Defendants have continued to produce juice after receiving such an order from FDA on June 24, 2008. Id. ¶¶ 18, 20. This violation is perhaps the most troubling of Defendants' violations since it represents a complete repudiation of Paragraph 11's requirement that Defendants "immediately comply" with an FDA letter directing them to cease operations and Paragraph 16's requirement that Defendants "abide by the decisions of FDA . . . . ." See Consent Decree ¶¶ 11, 16. Moreover, it demonstrates profound defiance – not only of the agency, but of this Court as well, and exhibits a clear disregard for the public health.

<sup>&</sup>lt;sup>2</sup> Plaintiff was informed during negotiations that Defendants had retained a HACCP expert. However, Defendants' expert has not yet submitted to FDA the HACCP plans and certifications required by Paragraphs 4(B) and 4(C) of the Consent Decree. Rodriguez Decl. ¶¶ 17, 20. Indeed, the first time that FDA received any communication from Defendants' HACCP expert was on June 26, 2008 − after FDA ordered the Defendants to cease operations pursuant to Paragraph 11 of the Consent Decree. Id. ¶ 20.

Not only has Defendants' unlawful conduct challenged the integrity of this Court's Order, but the United States and the public have also suffered as a result of Defendants' malfeasance.

First, as in all of its civil enforcement actions, the FDA's primary goal in enjoining the Defendants' manufacturing operation is to protect the public health. By failing to comply with the Consent Decree's requirements – which merely require Defendants to comply with applicable regulations or those things they should be doing as responsible members of the industry – Defendants continue to expose the public to illegal and adulterated food, and profit from this unlawful activity. The Act's protections are designed to prevent just such an circumstance. See United States v. Dotterweich, 320 U.S. 277, 285 (1943) ("Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.").

Second, the United States has spent considerable time and resources negotiating the terms of the Consent Decree, reviewing Defendants' proposals, communicating with Defendants' counsel, and documenting Defendants' non-compliance with the Consent Decree and the law, all at the public's expense. Yet the public continues to be exposed to Defendants' illegal products.

Finally, it is hard to overstate the importance of deterring similar actions in the future. Compliance with decrees such as this one will be dramatically undercut if Defendants, and others similarly situated, learn that they can violate and disregard court orders with impunity. Such an occurrence not only lessens respect for the rule of law, as embodied in this Court's Order, but in cases under the Act, exposes the public to illegal, and hazardous products. For all of the abovementioned reasons, Defendant should be held in civil contempt of the Consent Decree.

# d. <u>Defendants' Claims of Good Faith and/or Ambiguity are Unavailing</u>

Although Defendants have not yet articulated any detailed explanation for their failure to comply with the express terms of the Consent Decree, they have suggested through counsel that their continued production of juice has been in good faith. This is no defense in a contempt proceeding. Indeed, the Fifth Circuit has "consistently held that good faith is not a defense to a finding of civil contempt." <u>City of Jackson</u>, 359 F.3d at 735 n.25. Similarly, the willfulness of a party's action need not be established in a civil contempt action. <u>Petroleos Mexicanos v.</u>

<u>Crawford Enters., Inc.</u>, 826 F.2d 392, 401 (5th Cir. 1987). Accordingly, to the extent Defendants assert that their non-compliance with the express requirements of the Consent Decree should be excused because they are acting in good faith or unwillingly, their defense is unavailing.

Defendants have also suggested that their actions should be excused because the Consent Decree is ambiguous. This defense, however, is also deficient for several reasons. First, the provisions of the Consent Decree at issue are patently unambiguous. Paragraph 4 explicitly enjoins Defendants from "receiving, processing, preparing, packing, holding, or distributing juice at or from Defendants' juice processing plant located at 2601 East Cesar Chavez Street, Austin, Texas . . . unless and until . . . . " four requirements set forth in Paragraphs 4(A) - (D) are met. Consent Decree ¶ 4. Similarly, Paragraph 11 requires Defendants to "immediately comply" with a written order from FDA to cease operations. Consent Decree ¶ 11. Defendants' decision to remain in operation after entry of the Consent Decree and after being ordered to cease production under Paragraph 11 appears to be less about confusion about the Consent Decree and more about profits. See Martin v. Trinity Indus., Inc., 959 F.2d at 47 (finding a warrant that permitted OSHA

personnel to affix sampling or testing equipment to steel plant employees "certain enough" for a finding of contempt).

Even if the requirements set forth in Paragraphs 4 and 11 were ambiguous – which they are not – the proper course of action for Defendants to follow is to seek clarification or modification from the Court. See NASCO, Inc. v. Calcasieu Television & Radio, Inc., 583 F. Supp. 115, 120 (W.D. La. 1984) (noting that "respondents had an affirmative duty to petition for a clarification, modification, or construction of the Order before performing acts in the ambiguous area."). Any effort to modify the Consent Decree, however, would have to satisfy the standards set forth in Rule 60(b) of the Federal Rules of Civil Procedure. See Rufo, 502 U.S. at 379-81.

# 3. <u>Sanctions Should Be Imposed for Defendants' Violations of the Consent Decree</u>

District courts have broad discretion in determining appropriate sanctions in civil contempt proceedings. American Airlines, 228 F.3d at 585. This includes the authority to determine proper remedies when parties violate the terms of consent decrees. Test Masters Educ. Servs., Inc. v. Singh, 428 F.3d 559, 582 (5th Cir. 2005). In explaining this broad authority, the Supreme Court has noted that "[t]he measure of the court's power in civil contempt proceedings is determined by the requirement of full remedial relief." McComb v. Jacksonville Paper Co., 336 U.S. at 193.

In exercising its discretion, the Court may properly consider the following factors, among others: (1) the extent of the contemnor's disobedience; (2) the seriousness of the consequences of the conduct; (3) the need to terminate the conduct to protect the public interest; and (4) the

importance of deterring similar actions in the future. <u>United Mine Workers of America</u>, 330 U.S. at 303.

Here, despite the plain language of the Consent Decree, Defendants have blatantly continued producing and distributing its juices after failing to meet its requirements.

Furthermore, even though FDA exercised its authority under Paragraph 11 of the Consent Decree to order Defendants to cease operations, Defendants have refused to comply with FDA's order.

Civil sanctions are necessary to force Defendants to comply with the Consent Decree, to compensate the United States for losses occurred due to breach of this Court's Order, and to deter similar actions in the future to protect the public interest.

a. <u>Defendants Should Be Ordered to Cease Manufacturing and Distributing Juice Until They Bring Their Operations Into Compliance With The Law To FDA's Satisfaction</u>

Despite their knowledge of the Consent Decree's requirements, Defendants have unabashedly ignored these requirements by continuing to manufacture and distribute juices after entry of the Consent Decree. Moreover, when the FDA notified Defendants of their non-compliance with the Consent Decree and instructed them to cease production under Paragraph 11, Defendants refused to comply with FDA's letter. This Court should not tolerate such brazen defiance of a its Order. Nor should the Court tolerate Defendants' continued production of juice in a manner that violates the law. Accordingly, this Court should order Defendants to immediately cease receiving, processing, preparing, packing, holding, or distributing any juice at their facility unless and until the requirements of Paragraphs 4, 6(A) and 6(B) are satisfied. That is, Defendants should be required to halt their operations until they are brought into full compliance with the law, including implementation of an acceptable expert's plan in a manner

acceptable to FDA and the proper installation of new equipment.<sup>3</sup> Because the Defendants have demonstrated that they cannot be trusted to adhere to the law, they should not be permitted to operate until they have fully implemented necessary changes to FDA satisfaction.

b. <u>Defendants Should Be Ordered to Pay Conditional Fines to Deter</u> Future Violation of the Consent Decree

As detailed above, it has become clear that simply ordering Defendants to obey that which this Court has already ordered will provide no additional inducement for Defendants to comply. Therefore, Plaintiff requests that this Court impose conditional fines on Defendants to ensure their compliance with the Consent Decree and to deter any future violations of the Consent Decree. See Int'l Union, United Mine Workers of America v. Bagwell, 512 U.S. 821, 827 (1994) ("[C]ivil contempt sanctions, or those penalties designed to compel future compliance with a court order, are considered to be coercive and avoidable through obedience, and thus may be imposed in an ordinary civil proceeding upon notice and an opportunity to be heard.").

Specifically, Plaintiff requests that this Court order, in the event that Defendants violate any other provision of the Consent Decree, including, but not limited to, the production or distribution of juice prior to satisfying the requirements of Paragraph 4 of the Consent Decree, that Defendants shall pay to the United States Treasury \$1,000 per each day of continued violation. See Workers

<sup>&</sup>lt;sup>3</sup> Under the Consent Decree, as entered, the requirements of Paragraphs 6(A) and 6(B) must be completed within 120-days after Defendants resume operations after receiving written notice from FDA pursuant to Paragraph 4(D) that they appear to be in compliance with Paragraph 4(A) - (C) of the Consent Decree, the Act, and 21 C.F.R. § 120. However, given Defendants' failure to comply with Paragraphs 4 and 11, the 120-day implementation window in Paragraph 6 should be forfeited. The requirements of Paragraphs 6(A) and 6(B) – like the requirements of Paragraph 4 – should be fully met to FDA's satisfaction before Defendants are permitted to resume operations.

of America v. Bagwell, 512 U.S. at 829 (stating that a common civil contempt sanction "is a per diem fine imposed for each day a contemnor fails to comply with an affirmative court order.").

c. <u>Defendants Should Be Ordered to Pay Attorneys' Fees,</u>
<u>Investigational Expenses and Costs</u>

As set forth above, Defendants have failed to abide by the terms of the Consent Decree and acted in blatant contempt of this Court's Order. Consequently, Plaintiff requests that this Court order Defendants to reimburse the United States for its attorneys' fees, all investigational expenses, and court costs related to Defendants' violation of the Consent Decree and these contempt proceedings pursuant to Paragraph 10 of the Consent Decree.<sup>4</sup> See City of Jackson, 359 F.3d at 732 (noting that the government was entitled to attorneys fees in a civil contempt proceeding when the plain language of the consent decree at issue specifically contemplated the award of such fees).

WHEREFORE, the United States of America respectfully requests that this Court:

- 1. Issue an order directing Defendants to appear before the Court to show cause, if any they have, at such time and place as the Court shall direct, why they should not be held in civil contempt for failure to comply with the Consent Decree entered on May 6, 2008;
- 2. Following the issuance of the Order to Show Cause and an appropriate hearing, enter a judgment of civil contempt against Defendants for violations of the Consent Decree;
  - 3. Make factual findings as are necessary to requireDefendants to cease production

<sup>&</sup>lt;sup>4</sup> Paragraph 10 of the Consent Decree states: "If any Defendant violates this Consent Decree and is found in civil or criminal contempt, that Defendant shall, in addition to other remedies, reimburse Plaintiff for its attorney fees (including overhead), investigational expenses, expert witness fees, and court costs relating to such contempt proceedings." Consent Decree ¶ 10.

in accordance with Paragraphs 4 and 11 of the Decree, and such cessation shall continue until the requirements of Paragraphs 4 and 6(A) and 6(B) are met to FDA's satisfaction;

- 4. Following entry of this Order, should Defendants violate any provision of the Consent Decree, including, but not limited to, the production or distribution of juice prior to satisfying the requirements of Paragraph 4 of the Consent Decree; Defendants will, upon written notice from FDA, and without further order of the Court, pay conditional fines to the United States Treasury in the amount of \$1,000 per each day of violation;
- 5. Award plaintiff its attorneys' fees, all investigational expenses, and court costs relating to Defendants' violation of the Consent Decree and this contempt proceeding; and
  - 6. Grant any such other relief as the Court deems just and proper.

Dated this 10<sup>th</sup> day of July, 2008.

Respectfully submitted,

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## **CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing United States' Petition for Order to Show Cause and Memorandum in Support was filed electronically via the ECF system which serves upon counsel of record for Defendants as recorded below, on this 10th day of July, 2008. Notice has been electronically mailed to:

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/s/ K. Beaumont

Katherine E. Beaumont