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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

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| FIRST FISHERY DEVELOPMENT SERVICES, INC., d/b/a SEAGATE a California corporation,<br><br>Plaintiff,<br>v.<br><br>UNITED STATES FOOD AND DRUG ADMINISTRATION; DR. MARGARET A. HAMBURG, in her official capacity as Commissioner of the U.S. Food and Drug Administration; ROBERT J. DEININGER, in his Official Capacity as Director of the Southwest Import District of the U.S. Food and Drug Administration; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and KATHLEEN SEBELIUS, in her Official Capacity as the Secretary of the U.S. Department of Health and Human Services,<br>Defendants. | Civil Case No.: 09CV2346 W (AJB)<br><br>MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS COMPLAINT<br><br>DATE: March 15, 2010<br><br>NO ORAL ARGUMENT PURSUANT TO LOCAL RULE 7.1 d(1)<br><br>Hon. Thomas J. Whelan |

## I. INTRODUCTION

Plaintiff First Fishery Development, Inc. ("First Fishery") filed a complaint alleging that the Food and Drug Administration ("FDA") had improperly detained a shipment of its olive leaf powder extract that Plaintiff imported from Jose Peralta Pena ("Pena") in Mexico and improperly placed Pena's olive leaf extract powder on an Import Alert under which future imports of the product were subject to Detention Without Physical Examination ("DWPE"). An import alert for DWPE informs FDA field

personnel that FDA has sufficient evidence or other information to consider refusing admission of future shipments of an imported article. FDA field staff use the information contained in import alerts, along with other information, to help determine whether they will detain articles. This initiates the process for determining whether articles are ultimately refused entry.

Since the filing of Plaintiff's Complaint, FDA voluntarily released the detained shipment, and removed Pena's product from the Import Alert. Accordingly, because there is no remaining case or controversy, this case is moot, and must be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction.

## II. BACKGROUND

On January 28, 2009, First Fishery attempted to import a shipment of olive leaf powder extract, a dietary supplement, originating from Pena's farms in Mexico, into the United States. See Complaint, ¶ 17. Upon examination, FDA determined that the product contained a pesticide chemical, O-Phenyl Phenol, at 2.72 parts per million. See Notice of FDA Action, attached as Exhibit 1 to Complaint. Based on this finding, and the fact that no tolerance had been established for this pesticide in this product, the agency detained the shipment. See id. In addition, FDA placed all olive leaf powder imported by Pena on Import Alert 99-08, subjecting the products to DWPE. See Notice of FDA Action for Entry D01-0823502-5, attached as Exhibit 5 to Complaint, and Import Alert 99-08, attached in pertinent part as Exhibit 5 to Complaint.

In response to the detention, Plaintiff provided information in support of its claim that the product was not adulterated. See, e.g., Exhibits 2 and 6 to Complaint. In its consideration of whether or not the detained product was subject to refusal of admission, FDA had discussions with the Environmental Protection Agency ("EPA") and with Plaintiff. The discussions continued through October 2009, when Plaintiff filed the Complaint. Based on these discussions with EPA and the Plaintiff, FDA voluntarily released the detained product on November 16, 2009 and removed Pena from Import Alert 99-08 on December 3, 2009. [Exhibit 1, attached hereto.][1/]

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[1/]"Unlike a Rule 12 (b)(6) motion, a Rule 12 (b)(1) motion can attack the substance of a complaint's jurisdictional allegations despite their formal sufficiency, and in so doing rely on affidavits

(continued...)

## III. ARGUMENT

Jurisdiction of federal courts is limited "to the decision of 'Cases' or 'Controversies.'" Arizonans For Official English v. Arizona, 520 U.S. 43, 64 (1997). For a federal court to entertain jurisdiction over an action, "an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed." Id. at 67 (quoting Steffel v. Thompson, 415 U.S. 452, 459 n. 10 (1974)); see also North Carolina v. Rice, 404 U.S. 244, 246 (1971) (noting that the court may exercise its power only where there is "a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from ... an opinion advising what the law would be upon a hypothetical state of facts") (quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240-241 (1937)).

The doctrine of mootness requires that a case be dismissed when "the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." L.A. County v. Davis, 440 U.S. 625, 631 (1979) (quoting Powell v. McCormack, 395 U.S. 486, 496 (1969)). A case is moot when "interim relief or events have completely and irrevocably eradicated the effects of [an] alleged violation" of the law. Id. at 631. Simply put, a court "cannot take jurisdiction over a claim to which no effective relief can be granted." See Headwaters, Inc. v. Bureau of Land Mgmt., 893 F.2d 1012, 1015 (9th Cir. 1989).

Indeed, even in matters where a party has requested declaratory relief, a "case or controversy exists . . . only when the challenged government activity is not contingent, has not evaporated or disappeared, and, by its continuing and brooding presence, casts what may well be a substantial adverse effect on the interests of the petitioning parties." See Feldman v. Bomar, 518 F.3d 637, 642 (9th Cir. 2009). "The adverse effect . . . must not be so remote and speculative that there is no tangible prejudice to the *existing interests* of the parties." See id. (emphasis in original).

Here, Plaintiff asked the Court to enter an injunction requiring FDA to release the detained product and remove Pena's product from Import Alert 99-08. As FDA has released the detained product and removed Pena's product from the Import Alert, the Court cannot grant Plaintiff's requested relief

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[1/](...continued)
or any other evidence properly before the court." St. Clair v. City of Chico, 880 F.2d 199, 201 (9th Cir. 1989).

of an injunction forcing FDA to take those very actions. See Friends of the Earth, Inc. v. Bergland, 576 F.2d 1377, 1379 (9th Cir. 1978) (finding that "[W]here the activities sought to be enjoined have already occurred," the action is moot). Plaintiff also seeks to enjoin FDA from, in its words, "superseding" the regulatory authority of the EPA, which Plaintiff argues would allow the import of their product containing the pesticide in question. See Complaint, ¶¶ 62-4. Again, such relief would be superfluous at this juncture, as FDA has now allowed Plaintiff's product to be imported into the United States. The controversy has therefore been mooted, and Plaintiff's request for injunctive relief should be dismissed due to lack of subject matter jurisdiction.

In addition, Plaintiff requested that the Court issue several declaratory judgments regarding the legality of FDA's actions in detaining the olive leaf powder extract and placing Pena's product on Import Alert 99-08, and FDA's authority regarding tolerances for pesticides in Plaintiff's food products. See Complaint, Prayer for Relief, pp. 28-31. For example, Plaintiff asks that the Court issue a declaratory judgment stating that FDA's detention of the olive leaf powder extract and its placement of Pena's product on Import Alert 99-08 were arbitrary and capricious actions and violative of the Fifth Amendment. See id. Plaintiff also asks that the Court declare that FDA usurped the role of the EPA by detaining Plaintiff's products and adding Pena's products to Import Alert 99-08 based on the finding of pesticide in the products. See id. at p. 29. Because the Plaintiff's requests for declaratory judgments are directly related to FDA's decisions to detain Plaintiff's product and place Pena's product on Import Alert 99-08, there is "no tangible prejudice to the *existing interests*" of the Plaintiff. See Feldman, 518 F.3d at 642. Plaintiff is not suffering any continuing harm from FDA's actions, and it is purely speculative whether Plaintiff might ever again be added to an Import Alert or have one of its products detained for containing a pesticide. See Doe v. Madison Sch. Dist., 177 F.3d 789, 799 (9th Cir. 1999) (finding that voluntary cessation of challenged conduct would not moot a case only if there was a "reasonable expectation that the wrong will be repeated"). As Plaintiff admits in its Complaint, "[t]he detention which forms the basis of this lawsuit is the first import entry of First Fishery that has been detained by FDA in the company's 28 years of operation." See Complaint, ¶ 16. Accordingly, this matter is now moot, and First Fishery's Complaint should be dismissed for lack of subject matter jurisdiction.

## CONCLUSION

For the foregoing reasons, FDA respectfully requests that this Court grant the defendants' motion and dismiss Plaintiff's Complaint.

DATED: DECEMBER 23, 2009

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s/ Steven J. Poliakoff

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# EXHIBIT

# "1"

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20857

Richard Lentz, President
First Fisheries Development Services, Inc.
9484 Chesapeake Drive Suite# 802
San Diego, California 92123

For: Jose Jorge Peralta Pena
California Norte, Mexico

Dear Mr. Lentz

This letter is to inform you that Jose Jorge Peralta Pena, California Norte, Mexico has been removed from Import Alert # 99-08, "Detention Without Physical Examination of Processed Products For Pesticides."

Routine surveillance coverage of entries will resume once the DWPE has been lifted.

Further correspondence in this matter may be addressed to Martin Muckenfuss, U.S. Food & Drug Administration, Division of Import Operations and Policy, 5600 Fishers Lane, Room 12-36, Rockville, MD 20857, phone 301-594-3874.

Sincerely,

Domenic J. Veneziano, CDR, USPHS
Director, Division of Import Operations and Policy

cc: Fuerst, Humphrey, & Ittleman PL
1001 Brickell Bay Drive Suite# 2002
Miami, FL 33131

DJV:mfm

Enclosure

o: Richard Lentz, First Fisheries Development Services, Inc.

cc: Subject File IA 99-08