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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

'09 CV 2346 W AJB

FIRST FISHERY DEVELOPMENT SERVICES, INC., d/b/a SEAGATE, a California corporation, Plaintiff, v. 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, Defendants.	CASE NO. **COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF**

FIRST FISHERY'S COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

First Fishery Development Services, Inc., d/b/a Seagate ("First Fishery") hereby sues Defendants, United States Food and Drug Administration (FDA), Dr. Margaret Hamburg, Commissioner, FDA ("Dr. Hamburg"), Robert J. Deininger, Director of the Southwest Import District, FDA ("Director Deininger"), United States Department of Health and Human Services ("HHS"), and Kathleen Sebelius, Secretary, HHS ("Secretary Sebelius") (collectively "FDA") for a declaratory judgment and injunctive relief and alleges the following:

NATURE OF ACTION

This is an action for declaratory judgment and injunctive relief based on FDA's improper detention of First Fishery's Olive Leaf Powder Extract, Bulk, a dietary supplement ("Product"), as well as FDA's illegal and unwarranted placement of First Fishery and Product on Import Alert 99-08. FDA detained the Product alleging that it contained 2.72 parts per million (ppm) of o-phenylphenol (OPP, a pesticide) improperly claiming that no tolerance exists for this commodity/pesticide combination despite the fact tolerance levels are recognized in the Code of Federal Regulations for other food products and start at a level nearly twice that allegedly found in the imported Product, see further details below. Further, the cause for the presence of whatever level of OPP may have been found in the Product is the result of compliance with FDA's Good Manufacturing Practices requirements and is the result of contact transfer, a statutorily recognized exception, and so no violation exists, again see further details below.

FDA unconstitutionally and unlawfully, without complying with its statutory authority, own administrative procedures, proper notice and without just cause, placed First Fishery and Product on a local Detention Without Physical Examination (DWPE) list in contravention of the Administrative Procedures Act (APA); additionally, FDA placed First Fishery and the Product on national Import Alert 99-

08 without first providing First Fishery with a final administrative adjudication, thereby denying First Fishery its basic fundamental right to due process under the Federal Constitution.

FDA's actions in this case are arbitrary and capricious. Its placement of First Fishery and Product on a public, national Import Alert is meritless and flawed based on both fact and law. FDA has acted in complete disregard of First Fishery's unblemished regulatory reputation and in contravention of its own statutes, regulations, guidances and policies. FDA failed to provide any form of evidence to support its position the Product is in violation of law or regulation thereby acting as advocator rather than in its more proper adjudicatory role. FDA has failed to make findings of fact from any evidence in any adjudicatory proceeding and thereby denied First Fishery its due process rights by failing to meaningfully hear First Fishery on its petition and by placing its Product on an Import Alert unsupported by evidence and/or applicable law. First Fishery has and will continue to suffer irreparable and unnecessary harm because of FDA's decision to contravene the APA, deny First Fishery due process and place First Fishery on a public, national Import Alert. The very fact of First Fishery and Product being listed on Import Alert 99-08 bars First Fishery from being able to import its compliant goods due to the unwillingness or inability of FDA to comply with its own processes and procedures.

PARTIES, JURISDICTION AND VENUE

1. First Fishery is a seafood, vegetable and herbs processor, fishing company, and supplement manufacturer established in 1981. It is a California corporation which is based in San Diego, California.

2. HHS is a department of the United States federal government and is the parent agency to the Food and Drug Administration ("FDA"). HHS is an "agency" within the definitions of the Administrative Procedures Act (APA), Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified at 5 U.S.C. §§ 551, et seq.). Its principal place of business is located at 200 Independence Avenue, S.W., Washington, D.C. 20201.

3. Secretary Sebelius is the Secretary of HHS and its senior official. She is sued in her official capacity. She maintains offices located at 200 Independence Avenue, S.W., Washington, D.C. 20201.

4. FDA is a United States regulatory agency within HHS, with its principal place of business located at 5600 Fishers Lane, Rockville, Maryland 20857. FDA is an "agency" within the definitions of the APA.

5. Dr. Hamburg is the Commissioner of the FDA and its senior official. She is sued in her official capacity. She maintains offices located at 5600 Fishers Lane, Rockville, Maryland 20857.

6. Director Deininger is the Director and senior official of FDA's Southwest Import District (SWID). He is sued in his official capacity. He maintains offices located at 3310 Live Oak Street, Dallas, Texas 75204.

7. This action arises under the Federal Food, Drug, and Cosmetic Act (FDCA), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at 21 U.S.C. §§ 301, et seq.); the APA; the Declaratory Judgment Act of 1934, Pub. L. No. 73-512, 48 Stat. 955 (codified at 28 U.S.C. §§ 2201, et seq.); and the All Writs Act, 28 U.S.C. § 1651.

8. This Court has personal jurisdiction over the Defendants because they are either located in, conduct substantial business in, or have regular, systematic contact with this District.

9. This Court has subject matter jurisdiction under 5 U.S.C. § 702 and 28 U.S.C. § 1331 and 1346.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391 (e) since these are defendants that reside in this district, a substantial part of the events or omissions giving rise to the claim occurred in this District and/or there is property the subject of this action which is in this district.

11. There exists an actual, substantial and continuing controversy between the parties regarding FDA's Import Alert 99-08, for which the rights of the parties

are in doubt. This Court may declare the rights and legal relations of the parties under 28 U.S.C. §§ 2201, et seq.

12. Plaintiff has exhausted its administrative remedies, or such administrative remedies are futile in that FDA fails and refuses and continues to fail and refuse to take action and rule on the submissions made to it in accord with existing law and policy.

FACTS

13. First Fishery manufactures and processes all of its own dietary supplements, including the Product at issue.

14. With respect to the Product, First Fishery employees hand-select all of the olive tree leaves from trees and branches grown by tree farmers, usually in Mexico. First Fishery uses only the leaves of the olive tree. At all times pertinent, First Fishery did not own the groves where the leaves were harvested.

15. As a member of the health food industry, First Fishery manufactures the Product using a cold press, freshwater extraction process, without the use of any added chemicals, solvents, or alcohol. It then uses a mechanical process to crush the leaves, before they are placed in a freshwater bath, where the phytochemicals naturally present in the leaves are dissolved. This whole herb extraction process concentrates the phytochemicals and antioxidants, without altering the delicate structure and balance of the phytochemicals and nutritional components of the olive trees leaves. The olive leaf powder extract is then imported, in bulk form, into the United States from Mexico.

16. The 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.

ADMINISTRATIVE PROCEDURAL HISTORY

17. On or about January 28, 2009, First Fishery offered for import into the United States a shipment of Olive Leaf Powder Extract, Bulk, from its facility in

Mexico through the border port of entry at Otay Mesa, California, under Entry D01-08211001-0.

18. On or about March 10, 2009, FDA detained the Product because it allegedly contained 2.72 ppm of o-phenylphenol (OPP) and claimed, "No tolerance exists for this commodity/pesticide combination." See Notice of FDA Action attached hereto as Exhibit 1 at 2.

19. On or about March 30, 2009, First Fishery submitted its response to FDA's detention of Entry D01-08211001-0. See Response to Notice of FDA Action for Entry D01 08211001-0 attached hereto as Exhibit 2 (hereinafter, the "Petition").

20. Again on or about March 30, 2009, First Fishery received an email communication from Southwest Import District (SWID) Compliance Officer Brian Ravitch ("CO Ravitch") confirming "the product has yet to be recommended for addition to an Import Alert. Pending [FDA's Center for Food Safety and Applied Nutrition (CFSAN)] review and comments a recommendation may or may not be submitted by the District."

21. Prior to importing another shipment of the Product, First Fishery had the Product tested by Eurofins Scientific Inc. ("Eurofins") to ensure the Product was not adulterated with OPP. Eurofins tested the Product and found a tolerance of less than 0.05 mg OPP in it. See, Eurofins Report of Analysis attached hereto as Exhibit 3. On or about April 2, 2009, First Fishery imported this shipment and presented the Eurofins Report of Analysis to an FDA inspector at the port of entry who then permitted the Product to enter the United States.

22. Despite the fact the April 2, 2009 shipment was not adulterated with OPP, SWID informed First Fishery that CFSAN had responded to SWID and was supporting SWID's decision to detain the Product. First Fishery then requested a meeting with CFSAN to discuss its support of SWID's decision to detain the Product and place it on Import Alert 99-08. SWID did not respond to this request.

23. In a telephone conference on or about May 15, 2009, an FDA official advised that SWID needed more information showing that OPP was used pursuant to a tolerance exemption promulgated by the U.S. Environmental Protection Agency (EPA). Further, that FDA Compliance Officer – CO Ravitch - assured First Fishery that no action would be taken by SWID regarding a recommendation the Product be placed in Detention Without Physical Examination (DWPE) status or placed on an Import Alert until such additional evidence was received, reviewed by SWID and sent to CFSAN for review and a decision rendered. As part of this same conversation, another request was made to speak with the CFSAN personnel who supported SWID's position vis-à-vis the Product. CO Ravitch advised he would attempt to set up a phone conference but that it was up to CFSAN to decide whether they wanted to speak to anyone.

24. In an email exchange on or about June 23, 2009, FDA was advised that First Fishery had obtained evidence in the form of affidavits from First Fishery's Plant Manager and a Supervisor of Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación (SAGARPA), the federal body in Mexico charged with regulating the fertilizers, chemicals, and pesticides used in all Mexican farms, and First Fishery was shortly providing the affidavits to SWID.

25. On or about June 24, 2009, First Fishery attempted to import 40 barrels of bulk olive leaf powder extract into the United States from Mexico again through the border port of entry at Otay Mesa, California (Entry D01-0823502-5). Just as with the April 2nd shipment, First Fishery had Eurofins test the product prior to export, which again found the product was not adulterated with OPP residue. Upon arrival at the port of entry, the importer presented the FDA inspector with a copy of Eurofins' Report of Analysis for the product. The FDA inspector returned the analysis to the importer stating that it was "meaningless because it was from a Mexican lab." The importer immediately pointed out the laboratory results were from a well-known, highly respected U.S. laboratory. At that point, the FDA

inspector stated that he was made aware of the product and importer and was told that it was contaminated with pesticides and being placed on DWPE status.

26. Shortly thereafter, on or about June 29, 2009, Entry D01-0823502-5 was detained by SWID under DWPE. See Notice of FDA Action for Entry D01-0823502-5 attached hereto as Exhibit 4. DWPE for this shipment was ordered despite:

- prior assurances by CO Ravitch that no action would be taken by SWID until a final adjudication was made by SWID and CFSAN with regard to the original January 28, 2009 entry;
- the entry of the product through SWID on April 2, 2009 without any detention or examination;
- the Eurofins Report of Analysis presented to SWID's inspection officer at the border showing that Entry D01-0823502-5 was not adulterated by OPP; and
- communications between the parties that exculpatory evidence was being prepared to shortly be presented to FDA in a supplemental petition.

27. On or about July 2, 2009, First Fishery was placed on Import Alert 99-08. In fact, it is the supplier who is placed on Import Alert. In this case, see Import Alert 99-08, excerpted in pertinent part and attached hereto as Exhibit 5 at 2, where it references Jose Jorge Peralta Pena who is the Production Manager for First Fishery at its Mexican operation.

28. In a letter dated July 6, 2009, First Fishery submitted to SWID a Response to FDA's Letter Regarding Entry No. D01-0821001-0 (the "Supplemental Petition"). In the Supplemental Petition, First Fishery provided evidence from SAGARPA that First Fishery "did not use any chemical product containing O-phenyl phenol [as a pesticide on the Product]." See Response to FDA Letter

Regarding Entry No. D01-0821001-0, dated July 6, 2009, attached hereto as Exhibit 6 at 5 and Exhibit B thereto.

29. As a result of the events surrounding First Fishery's June 24, 2009 entry and the subsequent DWPE, plus placement of First Fishery and the Product on Import Alert 99-08, on July 7, 2009, First Fishery sent a detailed email to Director Deininger regarding the unwarranted actions by SWID. It was brought to Director Deininger's attention that DWPE was being ordered in contravention of FDA policies and procedures.

30. On or about July 8, 2009, FDA SWID sent an email to First Fishery stating that First Fishery had been placed on DWPE and Import Alert 99-08. See Email from FDA to Adrianne Torres (without attachments), dated July 8, 2009, attached hereto as Exhibit 7. Again, FDA ordered DWPE and recommended that First Fishery be placed on Import Alert 99-08 despite:

- prior assurances by CO Ravitch that no action would be taken by SWID until a final adjudication was made by SWID and CFSAN with regard to the original January 28, 2009 entry;
- the entry of the product through SWID on April 2, 2009 without any detention or examination;
- the Eurofins Report of Analysis presented to SWID's inspection officer at the border showing that Entry D01-0823502-5 was not adulterated by OPP; and
- communications between First Fishery and FDA that exculpatory evidence was being prepared to shortly be presented to FDA in a supplemental petition.

31. In that same July 2008 email, CO Flores attached SWID-specific procedures for third-party laboratory testing that were rogue procedures, in that they had not been approved by FDA in accordance with established procedures, and

contradict and contravene established FDA policies and procedures. See documents attached hereto as Exhibit 8.

32. In a July 14, 2009 email to First Fishery, FDA responded to the Supplemental Petition. In this response, FDA affirmed the DWPE and Import Alert statuses for First Fishery and the Product. See Email from FDA to Christine Humphrey, dated July 14, 2009, attached hereto as Exhibit 9.

33. On or about July 15, 2009, First Fishery informed FDA that it was having Entry D01-0823502-5 retested by an FDA-approved laboratory because the Eurofins Report of Analysis conducted pre-importation was deemed insufficient by SWID.

34. On or about July 21, 2009, FDA sent an email to First Fishery regarding CFSAN's response to the Supplemental Petition. In this email, FDA reported that CFSAN supports SWID's decision to recommend placement of First Fishery and the Product on Import Alert and DWPE. See Email from FDA to Adrianne Torres and Christine Humphrey, dated July 21, 2009, attached hereto as Exhibit 10.

35. On or about July 22, 2009, First Fishery sent an email to FDA and SWID regarding their intent to refuse Entry D01-0821001-0 based on the statement of an unidentified CFSAN employee. It was explained the importer has been continuously denied the opportunity to speak to anyone at CFSAN and that SWID's lack of correspondence regarding this entry was a deprivation of First Fishery's due process rights. The SWID's actions deprived First Fishery of the opportunity to contest the agency's actions through the administrative adjudicatory process. First Fishery informed SWID that it was acting in a manner that was abhorrent, arbitrary and capricious, and would result in court action by First Fishery. See Email from Christine Humphrey to FDA dated July 22, 2009, attached hereto as Exhibit 11.

36. On or about July 28, 2009, almost three months following First Fishery's initial request to meet with CFSAN, FDA stated that CFSAN had agreed

to meet telephonically with First Fishery to discuss the legal arguments presented in the Petition and Supplemental Petition.

37. On or about August 13, 2009, First Fishery held a telephone conference with representatives from SWID and CFSAN to discuss the Product, the DWPE, and the placement of First Fishery and the Product on Import Alert 99-08. The telephone conference did not produce any results.

38. On or about August 13, 2009, First Fishery received confirmation from Michelson Labs, the second laboratory to test and confirm that Product imported via Entry D01-0823502-5 (the June 24 2009 shipment of 40 barrels) was tested and found to not be adulterated by OPP. This information was provided orally to FDA, including representatives from SWID and CFSAN, during the telephone conference of August 13, 2009 mentioned in paragraph 37 above. Despite receiving this information, SWID and CFSAN refused to remove the DWPE or remove First Fishery and the Product from Import Alert 99-08.

FDA FAILED TO FIND THROUGH AN ADVERSE FORMAL ADJUDICATION THE PRODUCT VIOLATED FIFRA

39. The regulation of food and feed containing pesticide residues is governed by the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Pub. L. 95 396, 92 Stat. 819 (codified at 7 U.S.C. §§ 136, et seq.), as well as by sections 402, 408, and 409 of the FDCA.

40. FIFRA mandates that EPA is responsible for the registration of pesticides and setting tolerances, if the use of a particular pesticide may result in residues in or on food.

41. The tolerances established by the EPA apply equally to domestic and imported food.

42. Section 408 of the FDCA also authorizes the EPA to establish a tolerance for the maximum amount of a pesticide residue that may be legally present in or on a raw agricultural commodity.

43. The tolerances and exemptions from tolerances established by EPA for pesticide residues in commodities are listed in 40 C.F.R. Part 180. In particular, 40 C.F.R. § 180.940(c) provides an exemption from a pesticide tolerance for OPP when used as an ingredient in an antimicrobial pesticide formulation applied to food-processing equipment and utensils.

44. The FDA is responsible for the enforcement of pesticide tolerance and food additive regulations established by the EPA. This enforcement authority is derived from section 402(a)(2)(B) of the FDCA.

45. Under section 402(a)(2)(B) of the FDCA, a raw agricultural commodity or a processed food or feed is deemed to be adulterated and subject to FDA enforcement action if it contains either:

a. pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or

b. a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

46. However, there are exceptions to FDA's enforcement of EPA tolerances under section 402 and 408 of the FDCA for a pesticide residue in food. These exceptions include, inter alia:

a. when pesticide chemical residues occur in processed foods due to the use of agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the FDCA (21 C.F.R. § 170.19); and

b. a substance used in a food-contact article (e.g. food-packing or food processing equipment) that migrates, or that may be expected to migrate, into food will be exempt from regulation (21 C.F.R. § 170.39).

47. Based upon the statement from SAGARPA, any OPP allegedly detected in the Product was not the result of direct spraying on the olive leaves as a pesticide. The FDA, through SWID, has disregarded the statement of the Mexican relevant government agency - SAGARPA - on this issue and its rejection and disregard of SAGARPA's position and affidavit constitutes a non-tariff trade barrier in contravention of the North American Free Trade Agreement (NAFTA).

48. Therefore, migration from a food contact article sanitized with an antimicrobial cleaning solution, required by FDA's own Good Manufacturing Practices, containing OPP as an ingredient is the only possible source for any OPP allegedly detected in the Product.

49. As such and due to its level, any use of OPP as an antimicrobial sanitizing solution for food contact surfaces would make the Product exempt from an EPA tolerance under 21 C.F.R. § 170.39.

50. The Product is not in violation of EPA tolerances or of the requirements of FIFRA or FDCA. The FDA has not found any differently in the exercise of its adjudicatory functions.

FDA UNLAWFULLY ASSERTS FIRST FISHERY'S PRODUCT IS ADULTERATED PURSUANT TO FDCA SECTION 402(A)(2)(B)

51. Under FDCA section 402(a)(2)(B), a raw agricultural commodity or a processed food or feed is deemed to be adulterated and subject to FDA enforcement if it contains either a pesticide residue at a level greater than that specified by a tolerance or food additive regulation, or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

52. EPA has established a tolerance exemption for use of OPP as an ingredient in an antimicrobial sanitizing solution for food contact surfaces.

53. As the fields where the olive trees grew were not sprayed with OPP, the OPP allegedly detected in the Product could only result from the antimicrobial sanitizers used by First Fishery to sanitize its food contact surfaces, manufacturing

and processing equipment, actions which again are in accord with FDA's Good Manufacturing Practices.

54. Any OPP allegedly found in the Product was not the result of use as a pesticide on the raw product.

55. Because a tolerance exemption exists for the OPP found in the Product, section 402(a)(2)(B) of the FDCA does not apply.

56. Because section 402(a)(2)(B) of the FDCA does not apply, the Product cannot be deemed "adulterated" under that statute, so no violation has occurred and the shipment should be allowed to be imported in its current state and without further documentation being required. The FDA has not found in any formal adjudication that the Product is adulterated, and its placing of the Product on the Import Alert is arbitrary, capricious, an abuse of discretion, and contrary to law.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

(Declaratory Judgment and Injunctive Relief)

FDA's Decision that First Fishery is in Violation of Section 402(a)(2)(B) of the FDCA is Arbitrary and Capricious

57. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

58. In order for FDA to allege a violation of section 402(a)(2)(B), it first must find a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

59. There are only two possible ways the OPP allegedly detected in the Product by FDA could have migrated into the Product:

a. OPP was sprayed directly on the olive tree leaves that constitute the Product by the Mexican growers; or

b. OPP migrated from a food contact article sanitized using an antimicrobial formulation containing OPP into the Product during processing, which sanitizer was used by First Fishery pursuant to the FDA's Good Manufacturing Practices (requiring that antimicrobial and sanitizing agents be used to sanitize all food contact surfaces, food processing equipment and utensils used in food processing).

60. First Fishery has provided direct evidence in the form of a sworn statement from the Supervisor of the Secretaria de Agricultura, Ganaderia, Desarrollo Rural, Pesca y Alimentacion (SAGARPA), the federal body in Mexico charged with regulating the fertilizers, chemicals, and pesticides used on all Mexican farms, which states the Mexican olive grove(s) from which the olive leaves that constitute the Product were obtained did not use any chemical product containing OPP. See Statement of Jorge Saladana Ledesma, attached hereto as Exhibit 12. Therefore, any OPP allegedly detected in the Product was not the result of direct spraying on the olive leaves as a pesticide.

61. Migration from a food contact article sanitized with an antimicrobial cleaning solution containing OPP as an ingredient is the only possible source for any OPP allegedly detected in First Fishery's Product.

62. First Fishery's Product qualifies under the tolerance exemption for OPP as established by the EPA in 40 C.F.R. § 180.940(c) as an indirect food additive that migrated into the food product as an ingredient used in an antimicrobial sanitizing solution for food-contact surfaces.

63. Because any OPP found in the Product was not used as a pesticide, section 402(a)(2)(B) of the FDCA does not apply.

64. Further, because section 402(a)(2)(B) of the FDCA does not apply, the Product cannot be deemed "adulterated" under that statute, no violation has occurred

and so the Product should be forthwith released without the need for the submission of any additional documentation.

65. The FDA's actions are arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.

66. The FDA's actions are in excess of statutory authority or limitations.

67. The FDA's actions are unwarranted by the facts.

68. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

69. Plaintiff does not have an adequate remedy at law.

70. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

71. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

72. The public interest weighs in favor of the granting of injunctive relief in this case.

73. First Fishery respectfully requests this Honorable Court: a) enter a declaratory judgment pursuant to 28 U.S.C. §§ 2201, et seq., declaring that First Fishery's Product is not in violation of section 402(a)(2)(B) of the FDCA, including removal of First Fishery and the Product from DWPE; b) enjoin FDA from superseding the regulatory authority provided to it under section 402(a)(2)(B) of the FDCA; c) require that FDA release the Product currently in detention status without the submission of any further documentation; d) assess costs and attorney's fees pursuant to the Equal Access to Justice Act, 28 U.S.C. Sec. 2412(d)(1)(A); and e) grant such other relief that the Court may deem just and proper.

SECOND CAUSE OF ACTION

(Declaratory Judgment and Injunctive Relief)

The Act of Establishing Pesticide Tolerances and Exemptions is Statutorily Conferred on the U.S. Environmental Protection Agency and is Beyond the Scope of the FDA's Regulatory Authority and Jurisdiction

74. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

75. The regulation of food and feed containing pesticide residues is governed by the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

76. FIFRA gives the U.S. Environmental Protection Agency (EPA) the authority to approve the use of pesticides and establish tolerances or exemptions from tolerance if use of a particular pesticide may result in residues in or on food.

77. The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for enforcing EPA tolerances for meat, poultry, and certain egg products, while the FDA is charged with enforcing tolerances in all other food products, both imported and domestic shipped in interstate commerce.

78. FDA's authority to enforce tolerances established by the EPA is derived from sections 402, 408, and 409 of the FDCA.

79. FDA's attempt to unilaterally establish or assert a non-existent tolerance level on olive leaf extract is beyond the scope of the FDA's regulatory authority and jurisdiction.

80. First Fishery's Product is exempt from FDA regulatory action under section 402(a)(2)(B) of the FDCA because any OPP allegedly detected in the Product was the result of migration from the use of an antimicrobial sanitizer used on a food contact surface, and is properly subject to a tolerance exemption issued by the EPA in 40 C.F.R. § 180.940(c).

81. The FDA's actions are arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.

82. The FDA's actions are in excess of statutory authority or limitations.

83. The FDA's actions are unwarranted by the facts

84. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

85. Plaintiff does not have an adequate remedy at law.

86. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

87. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

88. The public interest weighs in favor of the granting of injunctive relief in this case.

89. First Fishery respectfully requests this Honorable Court: a) enter a declaratory judgment pursuant to 28 U.S.C. §§ 2201, et seq., declaring the act of establishing pesticide tolerances and exemptions is statutorily conferred on the U.S. Environmental Protection Agency and is beyond the scope of the FDA's regulatory authority and jurisdiction; b) enjoin FDA from superseding the regulatory authority provided to it under section 402(a)(2)(B) of the FDCA; c) require that FDA release the Product currently in detention status without the submission of any further documentation; d) require that FDA remove First Fishery and the Product from DWPE; e) assess costs and attorney's fees under the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and f) grant such other relief that the Court may deem just and proper.

THIRD CAUSE OF ACTION

(Declaratory Judgment and Injunctive Relief)

The U.S. Environmental Protection Agency has Established Pesticide Residue Tolerance Exemptions Applicable to First Fishery's Product which Preempt FDA's Regulatory Enforcement Action, including Placement of First Fishery and the Product on Import Alert 99-08 and Detention Without Physical Examination

90. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

91. Under section 402(a)(2)(B) of the FDCA, a raw agricultural commodity or a processed food or feed is deemed to be adulterated and subject to FDA enforcement action if it contains either:

a. a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or

b. a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

92. These tolerance exemptions under section 402(a)(2)(B) of the FDCA include, in pertinent part:

a. when pesticide chemical residues occur in processed foods due to the use of agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the FDCA (21 C.F.R. § 170.19); and

b. a substance used in a food-contact article (e.g. food-packing or food processing equipment) that migrates, or that may be expected to migrate, into food will be exempt from regulation (21 C.F.R. § 170.39).

93. In this case, EPA has established a tolerance exemption for OPP when used as an active or inert ingredient for use in an antimicrobial formulation for food contact surface sanitizing. 40 C.F.R. § 180.940(c).

94. Any OPP allegedly detected in the Product resulted from the use by First Fishery of antimicrobial sanitizing solutions containing OPP for food contact surfaces, as explained above.

95. Any OPP allegedly detected in the Product was not the result of direct spraying on the olive leaves as a pesticide as also explained above.

96. Migration from a food contact article sanitized with an antimicrobial cleaning solution containing OPP as an ingredient is the only possible source for any OPP allegedly detected in First Fishery's Product.

97. Furthermore, OPP is exempt from EPA tolerances because it constitutes an indirect food additive.

98. Under 21 C.F.R. § 170.39, a substance used in a food contact article that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive when it becomes a component of food at levels that are below the threshold of regulation if it is not a carcinogen, does not present other health or safety concerns, has no technical effect on the food and has no adverse significant impact on the environment, all of which apply to OPP.

99. EPA has determined that OPP is neither a carcinogen, nor does it present health or safety issues, has no technical effect on food nor has any significant environmental impact at a threshold below 200 mg per day.

100. EPA has established tolerances between 5 ppm and 25 ppm for citrus fruit, tomatoes and cherries. While olive leaves are not included in the list of commodities with an EPA tolerance, the tolerance levels that have been established by EPA for these other foods are all well above the 2.72 ppm allegedly detected in First Fishery's Product. Moreover, these tolerance levels of OPP in food – between 5 ppm to 25 ppm – have been deemed safe for human consumption by EPA.

101. As such, FDA's assertion that the level of OPP allegedly detected in the Product constitutes a potentially significant health hazard is unsupported by the facts, regulations or the law.

102. FDA's placement of First Fishery and Product on DWPE is unlawful and in contravention of the APA as no violation of law has occurred and no formal adjudication of a violation has been made.

103. FDA's placement of First Fishery and Product on Import Alert 99-08 is unlawful and in contravention of the APA as no violation of law has occurred and no formal adjudication of a violation has been made.

104. The FDA's actions are arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with the law.

105. The FDA's actions are in excess of statutory authority or limitations.

106. The FDA's actions are unwarranted by the facts.

107. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

108. Plaintiff does not have an adequate remedy at law.

109. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

110. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

111. The public interest weighs in favor of the granting of injunctive relief in favor of Plaintiff in this case.

112. First Fishery respectfully prays that this Honorable Court: a) enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring First Fishery's and the Product's placement on Import Alert 99-08 as unlawful as a matter of law; b) enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651; c) direct FDA to remove First Fishery and the Product from DWPE; d) direct FDA to forthwith

release the Product from detention status without the submission of any further documentation; e) assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and f) grant such other relief that the Court may deem just and proper.

FOURTH CAUSE OF ACTION

(Declaratory Judgment and Injunctive Relief)

Defendants have Arbitrarily and Capriciously Placed First Fishery and the Product on Import Alert 99-08

113. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

114. In order for FDA to allege a violation of section 402(a)(2)(B), it must first find a pesticide residue at a level greater than that specified by a tolerance or food additive regulation, or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

115. First Fishery's Product is covered by a tolerance exemption for OPP established by the EPA in 40 C.F.R. § 180.940(c) as an indirect food additive that migrated into the food product as an ingredient used in an antimicrobial sanitizing solution for food-contact surfaces.

116. Because any OPP allegedly found in the Product was not used as a pesticide, but rather an indirect food additive which migrated from a food contact surface sanitized by a product containing OPP under an authorized EPA tolerance exemption, section 402(a)(2)(B) of the FDCA does not apply.

117. Further, because section 402(a)(2)(B) of the FDCA does not apply, as a matter of law, the Product cannot be deemed "adulterated" under that statute and so no violation has occurred.

118. No violation of section 402(a)(2)(B) of the FDCA has occurred; therefore, FDA has no authority to charge First Fishery or the Product with

"adulteration," and so placement of First Fishery and the Product on Import Alert 99-08 is unlawful.

119. FDA's placement of First Fishery and the Product on DWPE is unlawful and in contravention of the APA as no violation of law has occurred.

120. FDA's placement of First Fishery and Product on Import Alert 99-08 is unlawful and in contravention of the APA as no violation of law has occurred.

121. The FDA's actions are arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.

122. The FDA's actions are in excess of statutory authority or limitations.

123. The FDA's actions are unwarranted by the facts.

124. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

125. Plaintiff does not have an adequate remedy at law.

126. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

127. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

128. The public interest weighs in favor of the granting of injunctive relief in favor of Plaintiff in this case.

129. First Fishery respectfully prays that this Honorable Court: a) enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that the Defendants have arbitrarily and capriciously ignored the exemption provision of Import Alert 99-08 (see Exhibit 5 at 2); b) enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651; c) require FDA to remove First Fishery and the Product from DWPE; d) direct FDA to forthwith release the Product from detention status without the submission of any further documentation; e) assess costs and attorneys' fees

pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and f) grant such other relief that the Court may deem just and proper.

FIFTH CAUSE OF ACTION

(Declaratory Judgment and Injunctive Relief)

FDA's Failure to Enforce Standards Leads to the Arbitrary and Capricious Enforcement of Import Alert 99-08 in Violation of the Administrative Procedures Act

130. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

131. In order to secure the release of detained products, First Fishery is required by Import Alert 99-08 to retain third-party laboratories to test products. Following the conclusion of the testing of First Fishery's product, the third-party laboratories are required to provide their test results directly to FDA.

132. In the same way that FDA fails to oversee or control the testing procedures of the third-party laboratories, FDA fails to oversee or control FDA's compliance officers. FDA's failure to promulgate standards or guidelines for FDA compliance officers responsible for enforcing the Import Alert has yielded – and will continue to yield – unwarranted refusals. Substantially identical test results provided to different compliance officers very often leads to substantially different determinations, as described above in the Administrative Procedural History at Paragraphs 21 and 22.

133. FDA's failure to enforce the standards contained in the Import Alert has caused, and will continue to cause, irreparable harm to First Fishery.

134. The FDA's actions are arbitrary, capricious, an abuse of discretion, or not otherwise in accordance with law.

135. The FDA's actions are in excess of statutory authority or limitations.

136. The FDA's actions are unwarranted by the facts.

137. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

138. Plaintiff does not have an adequate remedy at law.

139. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

140. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

141. The public interest weighs in favor of the granting of injunctive relief in favor of Plaintiff in this case.

142. First Fishery respectfully prays this Honorable Court: a) enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that FDA's failure to promulgate standards has led to the arbitrary and capricious enforcement of Import Alert 99-08 against First Fishery and the Product in violation of the Administrative Procedures Act; b) enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651; c) direct FDA to remove First Fishery and the Product from DWPE; d) direct FDA to forthwith release the Product from detention status without the submission of any further documentation; e) assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and f) grant such other relief that the Court may deem just and proper.

SIXTH CAUSE OF ACTION

(Declaratory and Injunctive Relief)

FDA's Procedural Actions in this Case are Violative of the Fifth Amendment Due Process Clause

143. First Fishery repeats and realleges paragraphs 1-56 as though fully alleged herein.

144. Section 801(a) of the FDCA states:

> If it appears from the examination of such samples or otherwise that (1) such article has been manufactured,

> processed, or packed under insanitary conditions [...] or (3) such article is adulterated, misbranded, or in violation of Section 505 [...] then such article shall be refused admission[.]

145. Any FDA unit may recommend DWPE whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a).

146. If FDA recommends DWPE based on one violative sample, FDA must have evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard.

147. EPA has established a tolerance level for OPP residues in other foods for human consumption at much higher levels than those allegedly found in First Fishery's Product.

148. Given that OPP in levels allegedly detected in the Product is regarded by EPA, the agency charged by law and regulation to make the determination, as safe for human consumption in other foods, it cannot be alleged that the violation allegedly detected by FDA "represents a potentially significant health hazard."

148. Further, the OPP residue allegedly found in this Product is exempt from the requirement of a tolerance by the EPA due to how it arose, by contact transfer.

150. FDA does not have evidence to demonstrate the presence of OPP in the levels allegedly found in the Product represents a potentially significant health hazard.

151. As such, placement of First Fishery and the Product on DWPE and Import Alert 99-08 is unlawful and in violation of the APA.

152. SWID placed First Fishery on a "local" DWPE prior to providing First Fishery its right to an administrative adjudication of the alleged violations. This action deprives Plaintiff of its Fifth Amendment Due Process right to challenge FDA's alleged violations.

153. First Fishery and the Product were then placed on Import Alert 99-08 without having any opportunity to challenge the product's placement on an Import Alert and prior to any informal adjudication of any petitions made by First Fishery to the FDA.

154. Moreover, Import Alert 99-08 requires First Fishery and its customers to provide third-party laboratory results to the FDA which adds significantly to the cost of the Product and is totally unwarranted and illegal given the Product is compliant and does not violate the relevant laws or regulations.

155. The lab results constitute the testimony of the third-party witness and is the sole evidence that the FDA is willing to accept.

156. FDA bases its informal adjudications on the result of third-party testing and can accept or reject such results at will and without guidance, policy or regulation.

157. FDA's informal adjudications are made without affording Plaintiff the opportunity to be heard in violation of the Due Process Clause of the Fifth Amendment.

158. he detentions and any refusals of the Product due to Import Alert 99-08 constitute a deprivation of property without due process of law.

159. There is a substantial likelihood that Plaintiff will succeed on the merits of its claim.

160. Plaintiff does not have an adequate remedy at law.

161. Plaintiff will suffer irreparable harm if injunctive relief is not granted in its favor.

162. Defendants will not suffer irreparable harm or substantial hardship if injunctive relief is granted in Plaintiff's favor.

163. The public interest weighs in favor of the granting of injunctive relief in this case, in that it is in the public interest that Plaintiff's claims be heard and adjudicated in conformity with the Federal Constitution, existing law and

regulations, and that Plaintiff's Product not be detained and prohibited from entry without Plaintiff having the opportunity to litigate the propriety of the FDA's actions.

164. First Fishery respectfully prays that this Honorable Court: a) enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that placement of First Fishery and the Product on Import Alert 99-08 violates the Due Process Clause of the Fifth Amendment to the United States Constitution; b) enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651; c) direct FDA to remove First Fishery and the Product from DWPE; d) direct FDA to forthwith release the Product from detention status without the submission of any further documentation; e) assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and f) grant such other relief that the Court may deem just and proper.

WHEREFORE, PLAINTIFF PRAYS FOR RELIEF AS FOLLOWS:

As to the First Cause of Action:

a) Enter a declaratory judgment pursuant to 28 U.S.C. §§ 2201, et seq., declaring that First Fishery's Product is not in violation of section 402(a)(2)(B) of the FDCA, including removal of First Fishery and the Product from DWPE;

b) Enjoin FDA from superseding the regulatory authority provided to it under section 402(a)(2)(B) of the FDCA;

c) Require that FDA release the Product currently in detention status without the submission of any further documentation;

d) Assess costs and attorney's fees pursuant to the Equal Access to Justice Act, 28 U.S.C. Sec. 2412(d)(1)(A); and

e) Grant such other relief that the Court may deem just and proper.

As to the Second Cause of Action:

a) Enter a declaratory judgment pursuant to 28 U.S.C. §§ 2201, et seq., declaring the act of establishing pesticide tolerances and exemptions is statutorily conferred on the U.S. Environmental Protection Agency and is beyond the scope of the FDA's regulatory authority and jurisdiction;

b) Enjoin FDA from superseding the regulatory authority provided to it under section 402(a)(2)(B) of the FDCA;

c) Require that FDA release the Product currently in detention status without the submission of any further documentation;

d) Require that FDA remove First Fishery and the Product from DWPE;

e) Assess costs and attorney's fees under the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and

f) Grant such other relief that the Court may deem just and proper.

As to the Third Cause of Action:

a) Enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring First Fishery's and the Product's placement on Import Alert 99-08 as unlawful as a matter of law;

b) Enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651;

c) Direct FDA to remove First Fishery and the Product from DWPE;

d) Direct FDA to forthwith release the Product from detention status without the submission of any further documentation;

e) Assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and

f) Grant such other relief that the Court may deem just and proper.

As to the Fourth Cause of Action:

a) Enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that the Defendants have arbitrarily and capriciously ignored the exemption provision of Import Alert 99-08;

b) Enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651;

c) Require FDA to remove First Fishery and the Product from DWPE;

d) Direct FDA to forthwith release the Product from detention status without the submission of any further documentation;

e) Assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and

f) Grant such other relief that the Court may deem just and proper.

As to the Fifth Cause of Action:

a) Enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that FDA's failure to promulgate standards has led to the arbitrary and capricious enforcement of Import Alert 99-08 against First Fishery and the Product in violation of the Administrative Procedures Act;

b) Enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651;

c) Direct FDA to remove First Fishery and the Product from DWPE;

d) Direct FDA to forthwith release the Product from detention status without the submission of any further documentation;

e) Assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and

f) Grant such other relief that the Court may deem just and proper.

As to the Sixth Cause of Action:

a) Enter a declaratory judgment, pursuant to 28 U.S.C §§ 2201, et seq., declaring that placement of First Fishery and the Product on Import Alert 99-08

violates the Due Process Clause of the Fifth Amendment to the United States Constitution;

b) Enjoin the enforcement of Import Alert 99-08 with respect to First Fishery and the Product pursuant to the All Writs Act, 28 U.S.C. § 1651;

c) Direct FDA to remove First Fishery and the Product from DWPE;

d) Direct FDA to forthwith release the Product from detention status without the submission of any further documentation;

e) Assess costs and attorneys' fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412 (d)(1)(A) and

f) Grant such other relief that the Court may deem just and proper.

DATED: October 21, 2009

MITCHELL SILBERBERG & KNUPP LLP

By: _____

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July 6, 2009

Aleta T. Flores, Compliance Officer
U.S. Food and Drug Administration
Southwest Import District, Otay Mesa Resident Post
2320 Paseo De Las Americas, Suite 200
HFR-SW6540
San Diego, CA 92154

Re: Response to FDA Letter Regarding Entry No. D01-0821001-0

Dear Ms. Flores:

The undersigned counsel, on behalf of our client, First Fishery Development Services, Inc. (hereinafter, "First Fishery"), submits this response to a letter from the U.S. Food and Drug Administration (FDA), dated May 13, 2009, regarding Entry No. D01-0821001-0. This response serves as a supplement to our original Response to Notice of FDA Action for Entry #D01-0821001-0, dated March 30, 2009 (the "Original Response"), and should be read in conjunction with all facts, law and legal analysis set forth in our original analysis. A copy of the Original Response is attached for your convenience as Exhibit A.

The OLIVE LEAF POWDER EXTRACT, BULK (hereinafter, the "Product"), currently detained by the FDA should be released because there has been no violation of section 402(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FDCA) and the U.S. Environmental Protection Agency (EPA) has issued a Registration Eligibility Decision (RED) for o-phenyl phenol (OPP) (CAS 90-43-7)[1] that states that OPP is not harmful for human consumption in the levels found in this Product. Further, placing First Fishery on Detention without Physical Examination (DWPE) under Import Alert 99-08 (IA 99-08) would be unlawful and in violation of the Administrative Procedures Act.

[1] O-phenyl phenol (CAS 90-43-7) is also called 2-Phenylphenol, biphenylol, [1,1'-Biphenyl] – 2-ol, 2-hydroxybiphenyl, ortho phenyl phenol, o-xenol and orthoxenol.

First Fishery respectfully requests that the FDA re-evaluate the position set forth in its letter dated May 13, 2009, release the Product, and not place it on IA 99-08 based the information provided in the Original Petition to FDA as well as the supplemental information provided below.

I. FACTS

The facts of this case were set forth in the Original Response and remain unchanged.

II. LAW GOVERNING PESTICIDES

The statutes, regulations, and policies relevant to this response were set forth in the Original Response and remain unchanged.

However, the following regulatory provisions provided in the Original Response were not addressed by the Agency in its May 13, 2009 letter. Because these regulations are highly relevant to the legal arguments set forth herein, the information is being provided again for further edification.

Tolerances and exemptions from tolerances established by EPA for pesticide residues in commodities are listed in 40 C.F.R. Part 180. That agency also has set forth tolerance exemptions for OPP when used as an active or inert ingredient in antimicrobial formulations (food-contact surface sanitizing solutions).[2]

A. Tolerance Exception for OPP Pesticide Used as an Antimicrobial Ingredient under 40 C.F.R. § 180.940(c).

The EPA has created a tolerance exemption for active and inert ingredients for use in antimicrobial formulations used for food-contact surfaces sanitizing solutions.[3] Section 180.940 of title 40, Code of Federal Regulation states, in pertinent part:

> Residues of the following chemical substances are exempt from the requirement of tolerance when used in accordance with good manufacturing practices as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi- permanent

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[2] *See* 40 C.F.R. § 180.940(c).

[3] *Id.*

> or permanent food contact surface (other than being applied on food packaging) [...]
>
> (c) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.

[1,1'-Biphenyl]-2-ol	90-43-7	When ready for use, the end-use concentration is not to exceed 400 ppm

40 C.F.R. § 180.940(c).

As evidenced above, the EPA allows up to 400 parts per million (ppm) of OPP as an end-use antimicrobial pesticide on all food-processing equipment and utensils. As such, OPP may be used in amounts up to 400 ppm as an ingredient in antimicrobial pesticides to be applied to food contact surfaces, food processing equipment, and utensils without being subject to FDA prosecution for adulteration under sections 402(a)(2)(B) or 408 of the FDCA.

B. Tolerance Exception for OPP Pesticides used as Inert Ingredients in Food Packing Material under 40 C.F.R. § 180.4

The EPA also has excepted certain substances from the definition of "pesticide chemical" and "pesticide chemical residue" from regulation under the FDCA sections 402(a)(2)(B) and 408. Specifically, 40 C.F.R. § 180.4 provides, in pertinent part:

> The substances listed in this section are exempted from the definition of "pesticide chemical" and "pesticide chemical residue" under FDCA section 201(q)(3) and are therefore exempt from regulation under FDCA section 402(a)(2)(B) and 408. These substances are subject to regulation by the FDA as food additives under FDCA section 409.
>
> (a) Inert ingredients in food packaging treated with a pesticide, when such inert ingredients are the components of food packaging material.

III. LEGAL ANALYSIS

A. No Violation of Section 402(a)(2)(B) of the FDCA has Occurred

As mentioned in the Original Response, in order for the FDA to allege a violation of section 402(a)(2)(B), it must find a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.[4] In the case at hand, the product at issue is covered under several exemptions which invalidate the FDA's allegation that this product is in violation of 402(a)(2)(B). Further, FDA's determination that the OPP residue allegedly found in this product came from direct spraying of OPP onto the crop is unsubstantiated.

1. Any O-Phenyl Phenol Allegedly Detected in the Product was not the Result of Direct Spraying on the Olive Leaves as a Pesticide

In the letter from the FDA dated May 13, 2009 and in numerous communications with the Agency, FDA has requested evidence to support First Fishery's contention that the OPP detected in the Product was not the result of direct spraying on the olive crop as a pesticide. As FDA Compliance Officer Brian Ravitch stated in the above referenced letter:

> [A]lthough, the firm has raised a legitimate question regarding whether OPP is present from legal indirect food additive uses, they did not provide any specific information that authorized indirect food additive use was the source of OPP in the product.

The evidence in support of that contention is provided herein and is both direct and indirect.

In a statement from the *Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* (SAGARPA), the federal body in Mexico in charge of regulating fertilizers, chemicals, and pesticides used in all Mexican farms, Jorge Saldana Ledesma, an Agricultural Engineer and Seeding Supervisor with first hand knowledge of the farm from which the olive leaves used in the Product came, specifically states:

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[4] *See* Compliance Policy Guide 575.100, Section 7141.01, Food and Drug Administration, available at http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html.

> [A]s supervisor in charge of this area of farmland [...] we are acquainted with the operations of every individual farm within our area, including the use of chemicals and fertilizers which farmers **must** register with this office[.] I can attest that Olivares company's olive tree farm located in the Guadalupe Valle in Ensenada, Baja California, **did not use any chemical product containing O-phenyl phenol** (OPP)(CAS 90-43-7) between June 1999 and December 2006.

Statement of Jorge Saldana Ledesma, attached hereto as Exhibit B (emphasis added).

This statement provides direct, material evidence that no OPP was used as a pesticide on the olive leaves used in the Product.[5]

While First Fishery has now provided direct evidence that no OPP was used as a pesticide on the subject olive leaves, in contrast, the FDA's allegation that OPP was used as a pesticide chemical on the subject olive trees is not supported by any facts, and is refuted by scientific reason. In the Original Response to the agency, it was explained that the amount of OPP residue allegedly found in First Fishery's Product – 2.72ppm – was so miniscule that it made FDA's assumption that the OPP was sprayed directly on the commodity highly improbable. If OPP had been used as a spray pesticide in the case at hand, the amount of OPP found in the Product would have been astronomically larger than the tiny amount allegedly detected in the Product.

To support this argument, examples of OPP used as a fungicide on crops such as citrus fruit and pears were given. In these application examples, OPP is sprayed directly on the commodities as a fungicide pursuant to EPA tolerances established for these fruits. Specifically, the EPA established that OPP residues on citrus fruits and pears are safe for human consumption in levels between 5ppm and 25ppm.[6] This EPA approved tolerance level is two-times to eight-times greater than the amount of OPP found on the Product. Therefore, if OPP had been used as a fungicide sprayed directly

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[5] First Fishery has made a better than good faith attempt to produce additional evidence to support its arguments in this case. Officers from the company traveled to Mexico on several occasions in an attempt to develop additional evidence. However, as previously explained, the olive tree farm from which the raw commodity used in the Product was obtained is no longer in existence. First Fishery was unable to locate the owner of the Olivares farm, the farm from which the olive leaves came, or anyone else with relevant, first-hand knowledge of the case.

[6] 40 C.F.R. § 180.129.

onto the raw commodity prior to manufacturing, the levels of OPP detected in the product would have been much larger than 2.72 ppm.

Further, First Fishery, in good faith, has been consistently testing their product for OPP since the detention of the Product at issue. First Fishery has imported several shipments into the U.S. and all shipments have tested negative for any traces of OPP. See Eurofins Report of Analysis attached as Exhibit C.

Based upon the statements from the SAGARPA official, it is evident that OPP was not used as a pesticide on the farm from which the olive leaves in the Product came. In the face of this evidence, the FDA cannot produce any evidence to the contrary. Moreover, the alleged amounts of OPP found on the Product were so small that it supports the argument that any OPP reportedly discovered did not come from pesticide application.

Section 402(a)(2)(B) of the FDCA states that a raw agricultural commodity or a processed food or feed is deemed to be adulterated and subject to FDA enforcement action if it contains either a pesticide residue at a level greater than that specified by a tolerance or food additive regulation, or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation. Because any OPP found on the Product was not used as a pesticide, section 402(a)(2)(B) of the FDCA does not apply. Furthermore, if section 402(a)(2)(B) of the FDCA does not apply, by definition, the Product could not have been deemed "adulterated" under that statute and no violation has occurred.

Having established that the Product being imported into the United States by First Fishery is not adulterated pursuant to section 402(a)(2)(B) of the FDCA, First Fishery requests that the FDA release the Product, and not place the company or its products on IA 99-08.

2. Migration from a Food Contact Article is the only Possible Source for any O-Phenyl Phenol Allegedly Detected on the Product

In the Original Response, it was stated that First Fishery regularly uses antimicrobial sanitizers to clean and disinfect all food contact surfaces as well as to sanitize the manufacturing equipment and packaging equipment. This sanitization is done pursuant to the FDA's Good Manufacturing Practices, which require that antimicrobial and sanitizing agents be used to sanitize all food contact surfaces, food processing equipment and utensils used in food processing. The Original Response further asserted that most commercial sanitizers contain OPP as an active ingredient and this was the inferred source of the OPP allegedly detected on the Product.

In its letter dated May 13, 2009, the FDA stated, "FDA has one sanitizer formulation on the books containing OPP so the assertion that most commercial sanitizers contain OPP is unsubstantiated." Based upon less than one hour of online research, First Fishery was able to identify **four hundred and eighty-five (485)** commercial sanitizers which contain OPP as an active ingredient.[7] *See* list attached as Exhibit D.

Assuming *arguendo* that OPP was detected on the Product, it could only come from one of two sources: from being sprayed on the olive leaves themselves as a pesticide, or from the manufacturing process as a food contact article. Having proven that OPP was not used as a pesticide on the olive leaves in question, and given the number of commercial sanitizers containing OPP as an active ingredient, it is not only reasonable that any OPP detected would have come from a food contact article, it is the only other possibility.

Most importantly, the FDA itself assumes that chemical substances such as OPP found on foods in these trace amounts comes from food processing, not from direct spraying. In its publication, *Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations* (2007), the FDA's Center for Food Safety & Applied Nutrition supported a number of general assumptions to be taken into consideration when calculating the amount of chemical substances found in food products. Among these assumptions are the facts that chemical substances such as OPP found in foods can result from a one time use or repeat use of a product, or contact with a product, containing such substances. Furthermore, the FDA assumes that 100% of the antimicrobial present in the packaging will migrate into the food commodities. The EPA's exhaustive analysis of OPP in the RED supports these assumptions.

First Fishery has provided documentation from a supervising official of SAGARPA, the leading Mexican government authority on the use of pesticides, fungicides and chemicals, which provides a sworn statement that OPP was not used as a pesticide on the olive leaf crop that went into the Product. Further, the use of OPP as

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[7] *See, e.g.*, Pharmaceutical Manufacturing Online Databases available, Over 100,000 approved drugs and health products, available at http://drugs-about.com/ing/o-phenylphenol.html; *see also, e.g.*, Scorecard The Pollution Information Site, available at http://www.scorecard.org/chemicalprofiles/pesticides.tcl?edf_substance_id=90%2d43%2d7.

an active ingredient in sanitizing solutions is widespread.[8] Based on the forgoing evidence, coupled with the FDA's own publications which state that the Agency assumes that chemical substances such as OPP will migrate in small amounts into food, there is no other possible source for any OPP allegedly detected in the Product than as a food contact article.

In order for FDA to allege a violation of section 402(a)(2)(B), it must find a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation. Section 170.19 of title 21 Code of Federal Regulations provides an exemption when pesticide chemical residues occur in processed foods due to the use of an agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted under section 408 of the FDCA. In this case, OPP has tolerance exemption as an active or inert ingredient used in antimicrobial formulations for food contact surface sanitizing solutions. Therefore, any OPP allegedly detected in the Product does not constitute a violation of section 402(a)(2)(B).

B. The EPA Has Exempted this Product from Regulation when Used as an Active or Inert Ingredients for Use in Antimicrobial Formulations Under 40 C.F.R. § 180.940

The agency's May 13, 2009 response to First Fishery's Original Response neither mentioned nor addressed the argument that the EPA has exempted OPP from regulation when used as an active or inert ingredient for use in antimicrobial formulations.[9] As previously stated, section 180.940 of title 40, Code of Federal Regulation states, in pertinent part:

> Residues of the following chemical substances are exempt from the requirement of tolerance when used in accordance with good manufacturing practices as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi- permanent or permanent food contact surface (other than being applied on food packaging) [...]

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[8] First Fishery has no definitive evidence that OPP was present in the antimicrobials it used to regularly sanitize its food contact surfaces; the Product at issue here was processed approximately three years ago.

[9] See 40 C.F.R. § 180. 940(c).

(c) The following chemical substances when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.

[1,1'-Biphenyl]-2-ol	90-43-7	When ready for use, the end-use concentration is not to exceed 400 ppm

40 C.F.R. § 180.940(c).

Having proven above that any OPP allegedly detected on the Product did not come from spraying as a pesticide, it can be inferred with almost total certainty that any OPP found must have derived from food contact additives. Furthermore, First Fishery has demonstrated that almost 500 sanitizing products contain OPP as an active ingredient. Given these facts and the above-described EPA exemption from a tolerance when OPP is used in amounts up to 400 ppm as an ingredient in antimicrobial pesticides to be applied to food contact surfaces, food processing equipment, and utensils, the Product cannot be subject to FDA prosecution for adulteration under sections 402(a)(2)(B) or 408 of the FDCA.

C. FDA has Issued an Exemption for OPP from EPA Tolerances as a Safe Food Contact Article

In its May 13, 2009 letter, the FDA did not address First Fishery's argument that the Agency specifically provides an exemption from regulation as a food additive that is recognized as safe by the EPA.

Under 21 C.F.R. § 170.39(a):

A substance used in a food-contact article (e.g. food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if:

(1) The substance has not been shown to be a carcinogen in humans[;]

(2) The substance presents no other health or safety concern[;]

(3) The substance has no technical effect in or on the food to which it migrates; and

(4) The substance use has no significant adverse impact on the environment.

While the FDA states in its letter that this regulatory provision was misinterpreted by First Fishery in the Original Response, that position was predicated on the purported fact that 21 C.F.R. § 170.39 pertains to use of a substance as a sanitizer, and the FDA could only identify one sanitizer product containing OPP. However, First Fishery now has established that over 500 commercially available sanitizers contain OPP as an active ingredient.[10]

Having established that OPP is widely used as a sanitizer, it is illustrative to examine the purpose behind the FDA exemption granted under 21 C.F.R. § 170.39. In its proposed rule for that regulation, the FDA stated that "it is proposing to establish a process for determining when the likelihood or extent of migration to food of a substance used in a food contact article is **so trivial as not to require regulation of the substance as a food additive.**"[11] Certainly, the use of OPP here qualifies under that standard.

According to the EPA's Reregistration Eligibility Determination, OPP is 1) not a carcinogen (under 200 mg per day); 2) does not present health or safety issues; 3) has no technical effect on food and 4) has no significant environmental impact within the levels present in the Product.[12] In fact, the EPA found that OPP in the Product's level has been deemed safe for human consumption:

> As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with OPP and salts. The Agency has determined that the established tolerance exemption for [...] OPP as a food contact sanitizer, as well as the existing tolerance for OPP [...] for their post-harvest use **meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FDCA**, and that there is a reasonable certainty no

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[10] *See* Note 7, supra.

[11] Food Additives; Threshold of Regulation for Substances Used in Food-Contact Articles, 58 Fed. Reg. 52,719 (proposed Oct. 12, 1993) (to be codified at 21 C.F.R.§ 170) (emphasis added).

[12] *See generally*, United States Environmental Protection Agency, *Reregistration Eligibility Decision for 2-phenylphenol and Salts (Orthophenylphenol or OPP)*, at 5-6 (July 2006) [hereinafter, the "RED"], available at: http://www.epa.gov/oppsrrd1/REDs/phenylphenol_red.pdf.

harm will result to the general population or any subgroup from the use of OPP.[13]

Furthermore, the FDA itself has deemed OPP safe as an indirect food additive in adhesive and components of coatings[14], paper and paperboard components,[15] polymers,[16] and in adjuvants, production aids, and sanitizers.[17] As such, OPP is exempt from tolerance requirements in all of the above manufacturing, packaging, transporting and food holding capacities the firm has demonstrated is likely the source of any OPP residue which may be present in the product.

Given the fact that any OPP allegedly detected in the Product would have had to come from food contact with surfaces on which OPP had been used as a sanitizer, and given the safety of OPP in concentrations similar to those allegedly found on the Product (2.72 ppm), OPP would qualify under 21 C.F.R. § 170.39 as exempt from regulation as a food additive. Therefore, any OPP allegedly detected on the Product does not constitute a violation of section 402(a)(2)(B).

D. Issuing a DWPE or Recommending this Manufacturer be added to Import Alert 99-08 would Constitute Unlawful Rulemaking by the FDA as well as Arbitrary and Capricious Use of its Authority

Section 801(a) of the FDCA states:

> If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions [...] or (3) such article is adulterated, misbranded, or in violation of Section 505 [...] then such article shall be refused admission[.]

Any FDA unit may recommend detention without physical examination (DWPE) whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a). If the FDA recommends DWPE based on one violative sample, the FDA **must have**

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[13] *Id.* at 51.

[14] See 21 C.F.R. § 175.105.

[15] See 21 C.F.R. § 176.210.

[16] See 21 C.F.R. § 177.1632.

[17] See 21 C.F.R. § 178.1010.

evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard.[18]

First Fishery has provided evidence that the olive leaves used in the Product were not sprayed directly with OPP-based pesticides. Furthermore, José Jorge Peralta Peña, the Production Manager for First Fishery, testified in a sworn statement that the company has not bought any more olive leaves from the farm that is the source of the alleged OPP contamination. See Statement of José Jorge Peralta Peña attached as Exhibit E. First Fishery has also provided evidence from the EPA that OPP is safe for consumption in the amounts allegedly detected on the Product.

Given that OPP in levels allegedly detected on the Product is regarded by the federal government as safe for human consumption, **it cannot be alleged that the violation detected by the FDA "represents a potentially significant health hazard." As such, if the FDA were to issue a DWPE in this matter is would be unlawful and in violation of the Administrative Procedures Act.** First Fishery strongly argues that it should not be placed on any Import Alert.

IV. CONCLUSION

The Detention Notice issued by the FDA for this entry of the Product is not supported by law or fact because First Fishery has not violated section 402(a)(2)(B) of the FDCA. As described in the Original Response and reiterated here, any OPP alleged to have been detected on the Product would have had to come from contact with surfaces as a food additive; evidence conclusively supports that OPP was not sprayed on the Product's constituent olive leaves as a pesticide. As such, there are numerous exemptions from EPA tolerances and from FDA regulation that apply to the product. Furthermore, the issuance of a DWPE for the Product or the placement of First Fisheries on an Import Alert would be contrary to FDA policy and would run counter to the facts.

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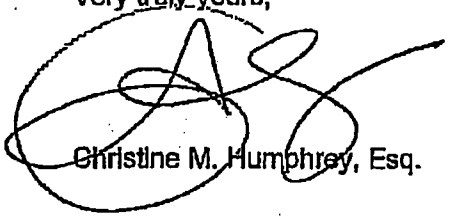
[18] FDA, Regulatory Procedures Manual, Ch. 9 "Import Operations And Actions" (March 2009) at 9-21.

Therefore, First Fishery respectfully requests that the FDA re-evaluate the position set forth in its letter dated May 13, 2009, release the Product, and not place it on IA 99-08 based the information provided in the Original Petition to FDA as well as the supplemental information provided above.

Very truly yours,



Christine M. Humphrey, Esq.

CMH/aft

FUERST
HUMPHREY
ITTLEMAN PL
Attorneys and Counselors at Law

Exhibit A

FUERST
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March 30, 2009

Via Email and Certified Mail (No. 7008 2810 0002 0304 3501)

Mr. Brian Ravitch
Compliance Officer
U.S. Food and Drug Administration
Southwest Import District
2320 Paseo De Las Americas, Suite 200
San Diego, CA 92154

Re: Response to Notice of FDA Action for Entry # D01-0821001-0

Dear Mr. Ravitch:

Undersigned counsel, on behalf of our client, First Fishery Development Services, Inc. (hereinafter, "First Fishery"), submits this Response to Notice of FDA Action for Entry # D01-0821001-0.

The OLIVE LEAF POWDER EXTRACT, BULK (hereinafter, the "Product") currently detained by the U.S. Food and Drug Administration (FDA) should be released because there has been no violation of section 402(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FDCA), and the Environmental Protection Agency (EPA) has issued a Reregistration Eligibility Decision (RED) for o-phenyl phenol (OPP) (CAS 90-43-7)[1] that states that OPP is not harmful for human consumption in the levels found in this Product.

I. Factual Background Information

A. About First Fishery

First Fishery is a seafood, vegetable and herbs processor, fishing company, and supplement manufacturer established in 1981 and based in San Diego, California.

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[1] O-phenyl phenol (CAS 90-43-7) is also called 2-Phenylphenol, biphenylol, [1,1'-Biphenyl] – 2-ol, 2-hydroxybiphenyl, ortho phenyl phenol, o-xenol and orthoxenol.

First Fishery has been producing a diversity of products for over 28 years. It manufactures and processes all of its own dietary supplements because its freeze-dryers, concentrators, pulverizers, and other vacuum equipment provide the capability to process, dry, and grind all of its raw materials.

One of the dietary supplements that First Fishery produces is Olive Leaf Powder Extract. The Product is sold by First Fishery in capsule form.

B. Overview of First Fishery's Processing and Manufacturing Practices

With respect to the Product, First Fishery employees hand-select all of the olive tree leaves from local tree farmers, usually in Mexico, where the olive grove industry is more prominent than in the United States. First Fishery does not own the groves where the leaves are harvested. First Fishery uses only the leaves of the olive tree. Olive trees give fruit during the winter months and the olive fruit is harvested each winter. Immediately after the farmers harvest the olive fruit, in order to capture the leaves during their most nutritious state, First Fishery employees begin the rigorous process of pruning and gathering olive tree branches and transporting them to the processing facility where the leaves are handpicked from the branches in preparation for the manufacturing process of the dietary supplement.

In manufacturing the Olive Leaf Powder Extract, First Fishery employs a cold-press freshwater extraction process, without the use of any added chemicals, solvents, or alcohol. It then uses a mechanical process to crush the leaves, before they are placed in a freshwater bath where the phytochemicals are dissolved. Specially-designed vacuum tanks are then used to recover both dissolved and undissolved solids. This is whole herb extract process concentrates the phytochemicals and antioxidants, without altering the delicate structure and balance of the phytochemicals and nutritional components of the olive leaf.

C. Date and Place of Alleged Violation

On or about January 28, 2009, First Fishery imported the Product from Mexico. The Product was imported through Otay Mesa Station (Port # 2506), Otay Mesa, California, and was entered electronically by First Fishery's customs broker, International Customs Brokers, under Entry Number D01-0821001-0.

On March 10, 2009, the FDA issued a Notice of FDA Action which designated that a hold be placed on First Fishery's Product. *See* Notice of FDA Action enclosed as Attachment A. The Article was detained on March 10, 2009 for allegedly violating the FDCA because the Product contained 2.72 parts per million (ppm) of OPP residue, based on FDA testing. *See* Attachment A. The FDA detention notice states, in pertinent

part, the Product "Contains: o-Phenyl Phenol at 2.72 ppm [...] No tolerance exists for this commodity/pesticide combination." *Id.*

After this shipment was initially detained by the FDA at the end of January, Richard Lentz, President of First Fishery, ordered a third-party inspection of its most recently imported Product. This third-party analysis showed that OPP was present in the Product; however, in quantities less than 0.05 mg. See Eurofins Report of Analysis dated 2/13/09 enclosed as Attachment B.

On March 17, 2009, Mr. Lentz, emailed Brian Ravitch, the FDA Compliance Officer responsible for the Notice of FDA Action in this matter, and stated, "we are checking the olive leaf product prior to importing it. I have been operating the factory in Ensenda for over 28 years and had an almost perfect history with the Food and Drug ... because we are very careful processing our products. (But I do believe that 2.72 ppm is a pretty low number to set off an automatic detention notice.)" See email from Richard Lentz to Brian Ravitch on March 17, 2009 at 5:48 PM, enclosed as Attachment C.

On this same date, Mr. Ravitch responded to Mr. Lentz, as follows: "EPA regulates tolerances. [...] The product will be detained at entry and you can then request to conduct a private analysis." See email response from Brian Ravitch to Richard Lentz on March 17, 2009, enclosed as Attachment C.

II. Legal Framework Governing Pesticides

A. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FDCA)

Three government agencies share responsibility for regulating pesticides used in conjunction with food products. The U.S. Environmental Protection Agency (EPA) registers (i.e., approves) the use of pesticides and establishes tolerances or exemption from tolerances if use of a particular pesticide may result in residues in or on food. The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for enforcing EPA tolerances for meat, poultry, and certain egg products, while the FDA is charged with enforcing tolerances in all other food products, both imported foods and domestic foods shipped in interstate commerce.

The regulation of food and feed containing pesticide residues is governed by the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as well as by sections 402, 408, and 409 of the FDCA. FIFRA mandates that the EPA is responsible for the registration of pesticides and setting tolerances, if use of a particular pesticide may result in residues in or on food. The tolerances established by

the EPA apply equally to domestic food and to imported food. Section 408 of the FDCA also authorizes the EPA to establish a tolerance for the maximum amount of a pesticide residue that may be legally present in or on a raw agricultural commodity.

For example, EPA may establish a tolerance for a pesticide residue resulting from the use of the pesticide in food or feed production in a foreign country. Tolerance and exemptions from tolerances established by EPA for pesticide residues in commodities are listed in 40 C.F.R. Part 180.

The FDA is responsible for the enforcement of pesticide tolerance and food additive regulations established by the EPA. This enforcement authority is derived from section 402(a)(2)(B) of the FDCA. Under this section, a raw agricultural commodity or a processed food or feed is deemed to be adulterated and subject to FDA enforcement action if it contains either:

- a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or
- a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.

However, there are exemptions to FDA enforcing an adulteration charge under section 402 and 408 of the FDCA for a pesticide residue in food. These exceptions include, in pertinent part, *inter alia*:

- When pesticide chemical residues occur in processed foods due to the use of an agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted or a tolerance prescribed under section 408 of the FDCA.[2]
- A substance used in a food-contact article (e.g. food-packing or food processing equipment) that migrates, or that may be expected to migrate, into food will be exempt from regulation.[3]

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[2] 21 C.F.R. § 170.19.

[3] 21 C.F.R. § 170.39.

B. Tolerance and Exemptions from Tolerances Established by EPA for Pesticide Residues in Commodities pursuant to 40 C.F.R. Part 180

The EPA has established tolerances for residues of OPP and its sodium salts applied *post-harvest* in or on a variety of agricultural commodities.[4] These tolerances, which range from 5.0 to 25.0 ppm, result in a theoretical maximum residue contribution of 2.8272 mg/day. Olive leaves are not included in the list of commodities for which a tolerance has been established when OPP is sprayed *directly* on the commodity as a fungicide.

However, notwithstanding the established tolerances for OPP residues applied *post-harvest* directly on food, the EPA has exempted from the requirement of a tolerance OPP used as an ingredient in pesticide formulations applied to growing crops (pre-harvest).[5] The agency has also set forth tolerance exemptions for OPP when used as an active or inert ingredient in antimicrobial formulations (Food-Contact Surface Sanitizing Solutions).[6]

1. Tolerance Exception for OPP Used as an Ingredient in Pesticides used Pre-Harvest under 40 C.F.R. § 180.920

The EPA exempted OPP from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in a pesticide formulation applied to growing crops.[7] Furthermore, OPP when used as a preservative for formulations, is exempt from the requirement of a tolerance.[8] As such, under this regulation, OPP can be applied to growing crops without being subject to FDA prosecution for adulteration under sections 402(a)(2)(B) or 408 of the FDCA.

2. Tolerance Exception for OPP Pesticide Used as an Antimicrobial Ingredient under 40 C.F.R. § 180.940(c).

The EPA has also created a tolerance exemption for active and inert ingredients for use in antimicrobial formulations used for food-contact surfaces sanitizing solutions.[9] Section 180.940 of Title 21, Code of Federal Regulation states, in pertinent part:

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4 40 C.F.R. § 180.129.

5 40 C.F.R. § 180.920.

6 40 C.F.R. § 180.940 (c).

7 *Id.*

8 *Id.*

9 See 40 C.F.R. § 180.940.

> Residues of the following chemical substances are exempt from the requirement of tolerance when used in accordance with good manufacturing practices as ingredients in an antimicrobial pesticide formulation, provided that the substance is applied on a semi- permanent or permanent food contact surface (other than being applied on food packaging) [...]
>
> (c) The following chemical substances [OPP] when used as ingredients in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.

Specifically, the EPA allows up to 400 ppm of OPP as an end-use antimicrobial pesticide on all food-processing equipment and utensils.[10] As such, OPP may be used in amounts up to 400 ppm as an ingredient in antimicrobial pesticides to be applied to food contact surfaces, food processing equipment, and utensils without being subject to FDA prosecution for adulteration under sections 402(a)(2)(B) or 408 of the FDCA.

3. Tolerance Exception for OPP Pesticides used as Inert Ingredients in Food Packing Material under 40 C.F.R. § 180.4

The EPA excepted certain substances from the definition of "pesticide chemical" and "pesticide chemical residue" from regulation under the FDCA sections 402(a)(2)(B) and 408. Specifically, 40 C.F.R. § 180.4 provides, in pertinent part:

> The substances listed in this section are exempted from the definition of "pesticide chemical" and "pesticide chemical residue" under FDCA section 201(q)(3) and are therefore exempt from regulation under FDCA section 402(a)(2)(B) and 408. These substances are subject to regulation by the FDA as food additives under FDCA section 409.
>
> (a) Inert ingredients in food packaging treated with a pesticide, when such inert ingredients are the components of food packaging material.

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[10] See 40 C.F.R. § 180.940 (C).

C. Exemptions from Tolerance Established by FDA for Pesticide Residues in Food Additives pursuant to 21 C.F.R. Part 170.

The FDA itself promulgated 21 C.F.R. § 170.39(a), which states in pertinent part,

> (a) **A substance used in a food-contact article (e.g. food-packaging or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive** because it becomes a component of food at levels that are below the threshold of regulation if:
>
> (1) The substance has not been shown to be a carcinogen in humans[;]
>
> (2) The substance presents no other health or safety concern[;]
>
> (3) The substance has no technical effect in or on the food to which it migrates; and
>
> (4) The substance use has no significant adverse impact on the environment.

(Emphasis added.)

The following indirect food additive provisions established by FDA dictate that OPP may be present in food because it is a food additive exempt from EPA tolerances and it is in compliance with 21 C.F.R. § 170.39, *supra*:

- **OPP has been deemed safe to use as an indirect food additive in Adhesive and Components of Coatings.**[11]
- **OPP has been deemed safe to use as ingredient in Paper and Paperboard Components.**[12]
- **OPP has been deemed safe to use as an ingredient in Polymer.**[13]

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[11] See 21 C.F.R. § 175.105.

[12] See 21 C.F.R. § 176.210.

[13] See 21 C.F.R. § 177.1632.

- **OPP has been deemed safe to use as ingredient in Adjuvants, Production Aids, and Sanitizers.**[14]

(Emphasis added.)

D. The EPA Reregistration Eligibility Decision for OPP Establishes that OPP at Certain Levels is Safe for Human Consumption

1. Toxicity of OPP

The Food Quality Protection Act of 1996 (FQPA) requires that the EPA consider all available information concerning the cumulative effects of particular pesticide's residues and other substances that have a common mechanism of toxicity. EPA has concluded that there is not a concern for neurotoxicity, developmental toxicity, reproduction toxicity with respect to OPP and concluded that OPP is "not likely to be carcinogenic to humans" based on convincing evidence that carcinogenic effects are not likely below a defined dose range – below 200 mg/day.[15]

2. FQPA Safety Factor

Further, the FQPA Safety Factor (as required by the FQPA) is intended to provide an additional ten-fold safety factor (10x), to protect for special sensitivity. The FQPA Safety Factor has been removed for OPP and its salts based on the available developmental toxicity and reproductive toxicity studies for OPP that the EPA considers acceptable.[16]

3. Population Adjusted Dose (PAD)

Dietary risk is characterized under the FQPA in terms of Population Adjusted Dose (PAD). A risk estimate that is less than 100% of the acute or chronic PAD is deemed by the EPA to be not of concern. After the EPA conducted Dietary Risk Assessment, the PAD levels in OPP did not exceed the EPA's level of concern. Specifically, for adults, the chronic dietary risk estimate is 19.68% of the chronic PAD. For children, the most highly exposed population subgroup, the chronic dietary risk

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[14] See 21 C.F.R. § 178.1010.

[15] United States Environmental Protection Agency, *Reregistration Eligibility Decision for 2-phenylphenol and Salts (Orthophenylphenol or OPP)*, July 2006.

[16] *Id.*

estimate is 45.17% of the chronic PAD. Therefore, the chronic dietary risk estimates are below the EPA's level of concern for all population subgroups.[17]

E. Detention without Physical Examination (DWPE)

Section 801(a) of the FDCA states:

> If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions [...] or (3) such article is adulterated, misbranded, or in violation of Section 505 [...] then such article shall be refused admission[.]

Any FDA unit may recommend DWPE whenever there is information that would cause future shipments of a product or products offered for entry to appear violative within the meaning of Section 801(a). If the FDA recommends DWPE based on one violative sample, the FDA must have evidence that at least one sample has been found violative and the violation represents a potentially significant health hazard.

III. Legal Analysis

A. No violation of Section 402(a)(2)(B) of the FDCA has occurred.

In order for FDA to allege a violation of section 402(a)(2)(B), it must find a pesticide residue at a level greater than that specified by a tolerance or food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption or food additive regulation.[18] However, in the case of this Product, there do exist specific exemptions which invalidates the allegation in the detention notice that the Product has violated section 402(a)(2)(B).

1. OPP is exempt from EPA tolerances because it is used at an antimicrobial in food contact surface sanitizing solutions.

Specifically, 21 C.F.R. § 170.19 provides an exemption when pesticide chemical residues occur in processed foods due to the use of an agricultural commodities that bore or contained a pesticide chemical in conformity with an exemption granted under

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[17] *Id.*

[18] *See* Compliance Policy Guide 575.100, Section 7141.01, Food and Drug Administration *available at* http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg575-100.html.

section 408 of the FDCA. In this case, OPP has tolerance exemption as an active or inert ingredient used in antimicrobial formulations for food contact surface sanitizing solutions.

OPP is a bacteriostat, microbiostat, nematicide, fumigant, and bactericide chemical. Its main use is as an inert ingredient in antimicrobials used as disinfectants and sanitizers in food-contact surfaces such as counter tops, tables, refrigerators, preservative in papermaking, preservative in adhesive, plastics and polymers.[19] It is used in applications to hard surfaces, agricultural premises and equipment, air deodorization, as well as in commercial and institutional premises.[20] The maximum rate of application for OPP in sanitizer end-use solutions is 400 ppm.[21] Under the FDA's Good Manufacturing Practices, antimicrobial and sanitizing agents must be used to sanitize all food contact surfaces, food processing equipment and utensils used in food processing.

While First Fishery has no definitive evidence that OPP was present in the antimicrobials it used to regularly sanitize its food contact surfaces,[22] it can state categorically that it regularly uses antimicrobials in sanitization in compliance with the FDA's Good Manufacturing Practices. First Fishery notes that the majority of sanitizing solutions available on the market today contain OPP as an antimicrobial agent.

Given these facts, it is more likely than not that the trace amounts of OPP – less than 3 parts per million – found on the Product came from the cleaning agents First Fishery uses to regularly sanitize its food processing equipment. As such, the OPP detected would be exempt from an EPA tolerance, and therefore, its presence would not constitute a violation of section 402(a(2)(B).

2. OPP is exempt from EPA tolerances because it constitutes an indirect food additive.

Under 21 C.F.R. § 170.39, a substance used in a food-contact article (e.g., food-packing or food-processing equipment) that migrates, or that may be expected to migrate, into food will be exempted from regulation as a food additive because it becomes a component of food at levels that are below the threshold of regulation if it is

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[19] United States Environmental Protection Agency, *Reregistration Eligibility Decision for 2-phenylphenol and Salts (Orthophenylphenol or OPP)*, at 5-6 (July 2006) [hereinafter, the "RED"], available at: http://www.epa.gov/oppsrrd1/REDs/phenylphenol_red.pdf.

[20] *Id.*

[21] *Id.* at 12; *see also*, 40 C.F.R. § 180.940.

[22] The Product at issue here was processed approximately three years ago.

not a carcinogen, does not present other health or safety concerns, has not technical effect on the food and has no significant adverse impact on the environment.

In the case at hand, the Product currently detained by FDA has been found by the EPA to meet this definition. According to the EPA's Reregistration Eligibility Determination, OPP is neither a carcinogen (under 200 mg per day), does not present health or safety issues, has no technical effect on food and has no significant environmental impact within the levels present in the Product.[23] In fact, the EPA found that OPP in the Product's level has been deemed safe for human consumption:

> As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with OPP and salts. The Agency has determined that the established tolerance exemption for [...] OPP as a food contact sanitizer, as well as the existing tolerance for OPP [...] for their post-harvest use **meets the safety standards under the FQPA amendments to section 408(b)(2)(D) of the FDCA**, and that there is a reasonable certainty **no harm will result to the general population or any subgroup from the use of OPP.**[24]

Moreover, the FDA itself has deemed OPP safe as an indirect food additive in adhesive and components of coatings[25], paper and paperboard components,[26] polymers,[27] and in adjuvants, production aids, and sanitizers.[28] As such, OPP is exempt from tolerance requirements in all of the above manufacturing, packaging, transporting and food holding capacities.

Because OPP meets the FDA's regulatory definition, it is an indirect food additive. As such, OPP is exempt from EPA tolerances. Therefore, the OPP found in the Product does not constitute a violation of section 402(a)(2)(B).

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[23] *See generally*, RED.

[24] *Id.* at 51.

[25] See 21 C.F.R. § 175.105.

[26] See 21 C.F.R. § 176.210.

[27] See 21 C.F.R. § 177.1632.

[28] See 21 C.F.R. § 178.1010.

eurofins

Eurofins Scientific Inc., Des Moines
3507 Delaware
Des Moines, IA 50313

Tel.+1 515 265 1461
Fax:+1 515 266 5453

Eurofins Sample Code: 464-2009-02200228
Sample Description: Olive Leaf Extract Powder
Client Sample Code: 2/13/09
PO Number:
Client Code: QD0003479

Reporting Date:03/09/2009
Entry Date:02/20/2009

First Fishery
attn: Richard Lentz
9484 Chesapeake Dr. #802
San Diego, CA 92123

First Fishery
attn: Richard Lentz
9484 Chesapeake Dr. #802
San Diego, CA 92123

AR-09-QD-020340-01

REPORT OF ANALYSIS

Test	Result
Aldicarb sulfone	< 0.05 mg/kg
Aldicarb sulfoxide	< 0.05 mg/kg
Aldicarb	< 0.05 mg/kg
Carbaryl	< 0.05 mg/kg
Carbofuran	< 0.05 mg/kg
3-OH Carbofuran	< 0.05 mg/kg
Methiocarb	< 0.05 mg/kg
Methomyl	< 0.05 mg/kg
O-Phenyl Phenol	< 0.05 mg/kg
Oxamyl	< 0.1 mg/kg
Propoxur	< 0.1 mg/kg
Thiodicarb	< 0.05 mg/kg
Acephate	< 0.02 mg/kg
Azinphos-methyl	< 0.02 mg/kg
Bensulide	< 0.02 mg/kg
Bolstar (Sulprofos)	< 0.02 mg/kg
Carbofenothion	< 0.02 mg/kg
Chlorfenvinphos	< 0.02 mg/kg
Chlorpyrifos	< 0.02 mg/kg
Chlorpyrifos-methyl	< 0.02 mg/kg
Clodrin (Crotophos)	< 0.02 mg/kg
Coumaphos	< 0.02 mg/kg
DEF	< 0.02 mg/kg
Demeton (Systox) S/O Analogues	< 0.02 mg/kg
Diazinon	< 0.02 mg/kg
Dibrom	< 0.02 mg/kg
Dicrotophos	< 0.02 mg/kg
Dimethoate	< 0.02 mg/kg
Disulfoton	< 0.02 mg/kg
EPN	< 0.02 mg/kg
Ethion	< 0.02 mg/kg
Ethoprop	< 0.02 mg/kg

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Fax:+1 515 266 5463

Eurofins Sample Code: 464-2009-02200228

Client Sample Code: 2/13/09

AR-09-QD-020340-01

REPORT OF ANALYSIS

Test	Result
Fenamiphos	< 0.02 mg/kg
Fenitrothion	< 0.02 mg/kg
Fenthion	< 0.02 mg/kg
Fonofos	< 0.02 mg/kg
Isofenphos	< 0.02 mg/kg
Malathion	< 0.02 mg/kg
Metasyatox-R	< 0.02 mg/kg
Methamidophos	< 0.02 mg/kg
Methidathion	< 0.02 mg/kg
Methyl Parathion	< 0.02 mg/kg
Mevinphos	< 0.02 mg/kg
O-methoate	< 0.02 mg/kg
Parathion	< 0.02 mg/kg
Phorate	< 0.02 mg/kg
Phosalone	< 0.02 mg/kg
Phosmet	< 0.02 mg/kg
Phosphamidon	< 0.02 mg/kg
Primiphos-methyl	< 0.02 mg/kg
Profenofos	< 0.02 mg/kg
Propetamphos	< 0.02 mg/kg
Ronnel (Fenchlorfos)	< 0.02 mg/kg
Tetrachlorvinphos	< 0.02 mg/kg
Thionazin	< 0.02 mg/kg
Acetamaprid	< 0.02 mg/kg
Atrazine	< 0.02 mg/kg
Azoxystrobine	< 0.02 mg/kg
Benthiocarb	< 0.02 mg/kg
Cyanazine (Organonitrogen Pesticide)	< 0.02 mg/kg
Cyprodinil	< 0.02 mg/kg
Cyromazine	< 0.02 mg/kg
Dimethomorph	< 0.02 mg/kg
Diphenyl Amine	< 0.02 mg/kg
Fenamidone	< 0.02 mg/kg
Fipronil	< 0.02 mg/kg
Fludioxinil	< 0.02 mg/kg
Hexazinone	< 0.02 mg/kg
Imazalil	< 0.02 mg/kg
Kresoxim-methyl	< 0.02 mg/kg
Metalaxyl	< 0.02 mg/kg
Metolachlor	< 0.02 mg/kg
Metribuzin (Organonitrogen Pesticide)	< 0.02 mg/kg
Molinate	< 0.02 mg/kg
Myclobutanil (Organonitrogen Pesticide)	< 0.02 mg/kg
Prometon	< 0.02 mg/kg