

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

ALLIED PACIFIC FOOD (DALIAN) CO.,  
LIMITED, a foreign Limited Company,  
888 Yong Zheng Industrial Area  
San Li  
Jinzhou District  
Dalian 116100  
China

Plaintiff,

vs.

Civil Action No.:

UNITED STATES FOOD AND DRUG  
ADMINISTRATION,  
5600 Fishers Lane  
Rockville, MD 20857

ANDREW C. VON ESCHENBACH, M.D.,  
Commissioner of the United States Food  
and Drug Administration,  
5600 Fishers Lane  
Rockville, MD 20857

UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES,  
200 Independence Ave., S.W.,  
Washington, D.C. 20201

and

MICHAEL O. LEAVITT, Secretary of the  
United States Department of Health and  
Human Services  
200 Independence Ave., S.W.  
Washington, D.C. 20201,

Defendants.

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**COMPLAINT FOR DECLARATORY JUDGMENT  
AND INJUNCTIVE RELIEF**

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AND INJUNCTIVE RELIEF**

Plaintiff, Allied Pacific Food (Dalian) Co., Ltd. (“Allied”), sues Defendants, U.S. Food and Drug Administration, Andrew C. Von Eschenbach, M.D., Food and Drug Administration Commissioner (“Dr. Von Eschenbach”), United States Department of Health and Human Services (“HHS”), and Michael O. Leavitt, Secretary of Health and Human Services (“Secretary Leavitt”) (collectively “FDA”) for a declaratory judgment and injunctive relief and alleges the following:

**Introduction**

Allied, a Chinese limited company, is an exporter of aquaculture products into the United States and has received international recognition for its aquaculture safety and compliance practices. In Import Alert 16-131, the FDA has implemented an unconstitutional rule that was passed in contravention of the Administrative Procedures Act (“A.P.A.”) and the World Trade Organization (“W.T.O.”) rule-making procedure, unfairly damages Allied as a Chinese exporter, and deprives it of fundamental Due Process rights. Specifically, FDA requires verifiably non-compliant food testing procedures by third-party laboratories to serve as the basis for prohibiting the importation of safe food products.

Import Alert 16-131 includes a strict methodology for testing, among other things, shrimp imports from China. Pursuant to this alert, Allied's customers – International Pacific, LLC, d/b/a Pacific Supreme (“Pacific Supreme”), Seacoast Seafood Supply, Inc. (“Seacoast”), and Thunder Bay Seafood Co., Inc. (“Thunder Bay”) (the “Customers”) – are to contract with third-party laboratories for the examinations, to be conducted according to the FDA methodology. Certain laboratories contracted by the Customers to conduct their tests fail to take many of the steps

required in the Import Alert; fail to submit to FDA any form of scientific validation of their un-validated testing; fail to notify the importer of record that the laboratory utilized an un-validated methodology; and fail to present the full laboratory analysis to the importer of record. Without this information, the Customers and affected third parties such as Allied cannot verify the accuracy or validity of the testimonial evidence presented to FDA for FDA's subsequent administrative adjudicative process. And because FDA has adopted a policy whereby the third-party laboratories are not allowed to test the shrimp a second time or to modify their initial reports in any way, Allied stands to suffer irreparable damage.

Allied's most catastrophic damage would be the result of an FDA refusal of any of Allied's shipments, followed by FDA's posting that refusal on FDA's OASIS website ([http://www.fda.gov/ora/oasis/ora\\_oasis\\_ref.html](http://www.fda.gov/ora/oasis/ora_oasis_ref.html)). FDA's OASIS website is the official FDA website for import refusals, and the website the Chinese Inspection and Quarantine ("CIQ") department relies upon in regulating Chinese companies which export into the United States. Should FDA refuse even one of Allied's shipments, Allied will suffer a one year suspension from exporting out of China. Such a suspension would effectively destroy the company.

Import Alert 16-131 also includes a procedure by which an exporter can exempt itself from compliance with the rule. Allied has conducted itself in accordance with each of the requirements for exempt status. Nevertheless, despite's Allied's strict adherence to the requirements, FDA – as the direct result of its own inconsistent procedures and policies and arbitrary and capricious enforcement of the Import Alert – has refused to exempt allied from the Import Alert.

Additionally, FDA has failed to educate its compliance officers in a consistent manner, rendering the compliance officers incapable of rationally applying the un-validated test results of

the third party laboratories. FDA's administrative adjudication process thereby deprives Allied of due process. FDA's inconsistent application of un-validated testing methodologies under Import Alert 16-131 results in retroactive determination of admissibility standards without any rational basis, factual support, or scientific justification, all of which threatens to cause Allied hundreds of millions of dollars in damages.

**PARTIES, JURISDICTION AND VENUE**

1. Allied is a foreign limited company with its principal place of business in Dalian, China.

2. HHS is a department of the United States Federal Government and oversees the Food and Drug Administration. Its principal place of business is located at 200 Independence Ave., S.W., Washington, D.C., 20201.

3. Secretary Leavitt is the Secretary of the Department of Health and Human Services. He is sued in his official capacity. He maintains offices at 200 Independence Ave., S.W., Washington, D.C., 20201.

4. The Food and Drug Administration is a United States regulatory agency within the HHS, with its principal place of business at 5600 Fishers Lane, Rockville, Maryland 20857.

5. Dr. Von Eschenbach is the Food and Drug Administration Commissioner and senior official. He is sued in his official capacity. He maintains offices at 5600 Fishers Lane, Rockville, Maryland 20857.

6. This action arises under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et. seq.*; the Administrative Procedures Act, 5 U.S.C. § 551 *et. seq.*; the Declaratory Judgment Act, 28 U.S.C. § 2201 *et. seq.*; and the All Writs Act, 28 U.S.C. § 1651.

7. 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.

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

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391 (e).

10. There exists an actual, substantial and continuing controversy between the parties regarding FDA's Import Alert 16-131. This Court may declare the rights and legal relations of the parties under 28 U.S.C. § 2201, *et. seq.*

### **FACTS**

#### **Allied**

11. Allied is a manufacturer of aquacultured or "farm grown" shrimp products in China. The specific product at issue in this action is Allied's breaded shrimp. Allied enjoys an impeccable record of food safety compliance, is a certified member of the BRC Global Standard, is a certified member of the Aquaculture Certification Council, maintains third-party audits, and incorporates various antibiotic testing procedures in compliance with both FDA and Chinese Inspection and Quarantine ("CIQ") requirements.

12. As an exporter of aquaculture products, including shrimp, to the United States, Allied is cognizant of all FDA policies and Import Alerts and acts in compliance with each of them.

13. As a Chinese exporter, Allied is required to have a Hazard Analysis and Critical Control Point ("HACCP") plan. Allied's HACCP plan is a comprehensive program required by FDA which meticulously details the processing, production, packaging, and preparation of the

breaded shrimp, including any and all potential hazards and the preventive measures and corrective actions being taken to address them. *See* 21 CFR §123.

14. As part of its HACCP plans, Allied inspects and examines its own raw and finished products for all prohibited substances, and is compliant with all Chinese export laws and United States import laws. Allied's HACCP plans for its Breaded shrimp are attached hereto as Exhibit 1.

15. Compliance with the CIQ and FDA is a priority for Allied, particularly because CIQ has adopted a policy whereby a single FDA refusal and subsequent posting on OASIS results in a one-year suspension of a company's license to export from China. Such a suspension would be a death sentence for Allied.

#### **The Customers**

16. After passing Allied's internal HACCP tests and the CIQ's inspections, Allied exported several shipments of breaded shrimp ("Shrimp Entries") to the United States.

17. In compliance with HACCP and CIQ exporting requirements, all of Allied's Shrimp Entries tested negative for each of the banned substances prior to leaving Allied and China. Without a negative test, neither Allied nor the Chinese Government would have allowed the Shrimp Entries to leave China; *see* Allied Raw/Finished Product tests, attached hereto as Exhibit 2.

18. Allied's exported products were then imported into the United States by domestic Customers. For purposes of this action, the interested Customers of record are Pacific Supreme, Seacoast, and Thunder Bay.

19. Pacific Supreme is a California limited liability company with its principal place of business in Gardena, California.

20. Seacoast is a Florida corporation with its principal place of business in Jacksonville, Florida.

21. Thunder Bay is a Florida corporation with its principal place of business in Wesley Chapel, Florida.

22. Samples from the Shrimp Entries were then delivered by the respective U.S. Customers to third-party laboratories for testing in accordance with Import Alert 16-131.

23. The Customers each have their own HACCP plans and comply with all applicable FDA requirements.

24. Each of the previously identified Customers has an Allied shipment that has been unlawfully detained and is pending refusal due to Import Alert 16-131.

#### **FDA**

25. In response to political pressure and without a legitimate basis for food safety, FDA, among other actions, has embraced the United States Government's 'Trade War' with China. Consequently, FDA has enacted several heavy-handed rules which unduly and unfairly burden Chinese imports into the United States, simply based on the imports' country of origin.

26. Import Alert 16-131 is one such rule. Officially titled, "Detention Without Physical Examination of Aquacultured Catfish, Basa (*Pangasius* sp.), Shrimp, Dace and Eel Products From the People's Republic of China Due To the Presence of New Animal Drugs and/or Unsafe Food Activities," Import Alert 16-131 unfairly and unnecessarily targets only Chinese aquaculture exports; *see* Import Alert 16-131, attached hereto as Exhibit 3. [Emphasis added]. Aquaculture exports from no other nation are named in the Import Alert.

27. Import Alert 16-131 requires that third-party laboratories perform a specific examination of Chinese aquaculture products using acceptable FDA methods available at <http://www.cfsan.fda.gov/seafood1.html>, the results of which, under FDA policy, are to be provided directly to FDA. The procedure for shrimp testing reads in part:

The sample should consist of a minimum of 12 sub-samples. When an entry consists of multiple lines of similar products (e.g., multiple sizes of headless shrimp), the sample should be representative of the entire entry and should be collected across all lines, with a minimum of two sub-samples per line. The sampling should be proportional based on the quantity of product (e.g. more sub-samples should be obtained from larger lines, fewer sub-samples from smaller lines). Obtaining 12 sub-samples from a single line or a limited number of lines when multiple lines of similar products are offered for the entry will not provide a representative sample for that entry.

If an entry contains only one line of aquacultured product, then a minimum of 12 sub-samples should be obtained from that single line. If the entry includes multiple date codes, the sample should reflect a range of date codes (e.g., all sub-samples should not be collected from a single date code).

Each sample should consist of 12 sub-samples, minimum 225g (0.5 lb.) per sub-sample, total 2.7 kg (6.0 lb.) of product. If the product unit size is larger than 225g (0.5 lb.) and less than or equal to 3 lb., collect one product unit per sub-sample. If the unit size is less than 225g. (0.5 lb.), collect an adequate number of units so that the amount collected per sub-sample equals a minimum of 225 grams (0.5 lb.).

*Id.*

28. More specifically as it relates to this action, the Import Alert provides as follows:

Analysis for Nitrofurans should be conducted on *individual subsamples*. Analysis for all other residues should be conducted on a composite sample.

*Id.*; [Emphasis added].

29. Import Alert 16-131 provides the sole testing protocol for shrimp, and does not provide for any alternative or modified testing procedure:

Prepare one composite from an equal amount of each subsample for the testing of malachite green, fluoroquinolones, and gentian violet.

Shrimp are to be analyzed on an individual sub basis for nitrofurans. When sampling guidance directs the collection of six subsamples, two portions from each of the six subsamples should be individually analyzed. \*\*\*

30. Pursuant to Import Alert 16-131, laboratories must test for Malachite Green, Fluoroquinolones, Nitrofurans, and Gentian Violet.

31. Import Alert 16-131 does not state what levels of each prohibited antibiotic render an import acceptable for admission, but the stated policy of FDA is that any amount less than one part per billion is allowable.

32. Purportedly in order to prevent 'laboratory shopping', FDA has allegedly adopted a rule whereby FDA does not allow re-testing, regardless of the circumstances.<sup>1</sup>

33. Furthermore, FDA has also adopted a rule providing that only one report may be submitted for a given shipment, even if that report contains errors as admitted by the reporting laboratory, and even though the report constitutes testimony on behalf of the interested party, i.e. the importer.

### **The Exemption**

34. Import Alert 16-131 includes language that exempts exporters such as Allied from complying with the requirements imposed by the Import Alert.

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1. *But see* 71 F.R. 75865, permitting retesting for medical gloves.

35. Specifically, Import Alert 16-131 reads:

In order to remove a firm from detention without physical examination, information should be provided to FDA to adequately assess whether a manufacturer has the appropriate controls and processes in place to ensure the quality of the product, the firm or shipper should provide the following information (In English):

1) Documentation showing that a minimum of five (5) consecutive entries have been released by FDA based on third-party laboratory analysis of a representative sample of the lot verifying that products do not contain malachite green and its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet and fluoroquinolones. The chart provided above identifies which residues should be screened for each species. Third-party laboratory must use methods acceptable to FDA (e.g., see <http://www.cfsan.fda.gov/seafood1.html>); and

2) Documentation, from an appropriate third-party (e.g. a government inspection authority such as AQSIQ) demonstrating that an inspection of the processor was conducted and that the seafood was processed in accordance with FDA's Seafood HACCP regulations, 21 CFR part 123, including controls for aquaculture drugs. See 21 CFR 123.12(a).

Documentation should include test results of any products sampled during the course of the inspection, demonstrating that the products do not contain malachite green or its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet or Fluoroquinolones; and

3) Documentation that the processor is in compliance with all Chinese government requirements for exporting aquacultured seafood to the U.S.

Documentation should include copies of any registration that may be required by the Chinese government.

Documentation should include copies of any registration that may be required by the Chinese government.

36. On September 10, 2007, Allied applied to FDA to secure a position as an exempt foreign manufacturer.

37. In accordance with Import Alert 16-131's requirements, Allied submitted a large binder containing: **a)** Documentation showing that a minimum of five (5) consecutive entries have been released by FDA based on third-party laboratory analysis...; **b)** Documentation from an appropriate third-party demonstrating that an inspection of the processor was conducted and that the seafood was processed in accordance with FDA's Seafood HACCP regulations, 21 CFR part 123; and, **c)** Documentation that the processor is in compliance with all Chinese government requirements for exporting aquacultured seafood to the U.S. A copy of the cover letter from counsel is attached hereto as Exhibit 4.

38. Allied is awaiting an FDA ruling on its (Allied's) exempt status. FDA has advised Allied that two barriers stand in the way of Allied's receipt of exempt status. These barriers include **a)** pending administrative adjudications discussed *infra*, and **b)** Allied's requirement to validate the qualifications of third party auditors supplied to FDA in support of Allied's application for exempt status. Neither barrier has previously been required by Import Alert 16-131.

### **Certified Labs**

39. The Customers initially contracted Certified Laboratories, Inc. (“Certified”) and Adpen Laboratories, Inc. (“Adpen”) to conduct the examinations of the Allied Entries in accordance with the Import Alert.

40. Certified was contracted separately by both Pacific Supreme and Thunder Bay to conduct the requisite tests on the Entries.

41. Certified tested Pacific Supreme Entry AQZ-0250069-5 and Thunder Bay Shrimp Entries AQZ-0250569-4 and AQZ-0250573-6.

42. On July 31, 2007, Certified issued its test results, among which were impermissible and impossible levels of Gentian Violet.

43. Based on these findings, and in strict accordance with FDA rule 71 F.R. 75865 (which states that testimony cannot be reviewed by the importer), Certified published its results to FDA.

44. Certified’s publication of its results to FDA would have resulted in FDA’s refusal of the Shrimp Entries, FDA’s publication of the refusal on its OASIS webpage, and the one year suspension of Allied in China, however, prior to FDA refusing the Shrimp Entries, undersigned counsel was retained and on August 31, 2007 petitioned FDA for an Administrative Stay of Action under 21 CFR § 10.35, a copy of which is attached hereto as Exhibit 5.

45. Unbeknownst to Allied, Pacific Supreme and Thunder Bay, Certified notified FDA that it had initially submitted erroneous reports, and submitted corrected reports to replace the erroneous submissions. The corrected reports comply with Import Alert 16-131.

46. To date, FDA has not acknowledged Certified's corrected reports.

47. Because of the erroneous reports, Allied retained a third party testing facility – SGS Group (“SGS”), a world renowned, independent compliance testing company – to perform tests on retained samples, pursuant to Allied's HACCP plan, on the questioned lots shipped to the Customers in the United States.

48. SGS tested the samples in accordance with FDA's approved Laboratory Information Bulletin 4363 (“LIB”) and determined that the questioned lots did not, in fact, contain any traces of Gentian Violet or any other prohibited substance, and were, in fact in compliance with Import Alert 16-131.

49. Additionally, notwithstanding FDA's “One Test – One Report” rule, Pacific Supreme and Thunder Bay subsequently retained Michelson Laboratories, Inc. (“Michelson”) to conduct additional tests on the Shrimp.

50. Michelson concluded that **a)** Certified was not conducting a confirmation analysis in accordance with acceptable FDA methodology, and that **b)** the test results presented false positives. Like the SGS findings, Michelson's conclusions revealed that the Shrimp Entries were compliant with Import Alert 16-131.

51. FDA has received the Michelson test results, Certified's subsequent recantation of the erroneous results, and Certified's revised report. FDA has nevertheless refused to admit the Shrimp Entries into the United States or to provide Allied or undersigned counsel with the results of the revised Certified reports.

52. Additionally, FDA has tested its own samples from the Certified Shrimp Entries. In anticipation of an administrative hearing, Allied, Pacific Supreme, Thunder Bay, and undersigned counsel have requested those results, which will serve as the evidence in those administrative hearings. Upon request, FDA has refused to provide counsel with that evidence.

53. Accordingly, notwithstanding **a)** Allied's internal examinations demonstrating a compliant product; **b)** CIQ's examinations demonstrating a compliant product; **c)** Additional third party laboratory testing confirming a compliant product; **d)** Certified's recanted report demonstrating a compliant product; **e)** Michelson's examination and subsequent report demonstrating a compliant product; and **f)** FDA's own examinations, the Shrimp Entries remain detained by FDA without evidence supporting a violation that merits detention.

#### **Adpen Labs**

54. Adpen was contracted by both Seacoast and Thunder Bay to conduct the requisite tests on both importers' Shrimp Entries.

55. Adpen uses a modified methodology that varies from acceptable FDA methods.

56. Adpen claims that its machinery is ultra-sensitive to the prohibited antibiotics. However, Adpen employs a noncompliant, rogue, and un-validated methodology whereby it samples only three sub-samples, despite Import Alert 16-131's specific requirement that a "minimum of 12 individual sub-samples" of each shrimp entry, in accordance with FDA Laboratory Information Bulletin ("LIB") "Detection of Nitrofurans in Shrimp."

57. Adpen's procedures clearly violate the required methodologies approved under Import Alert 16-131.

58. Adpen's abbreviated report reveals that Adpen's methodology is contradictory. Both a composite analysis and a full 12 individual subsample analysis are reported. Adpen's test results yielded Nitrofurantoin amounts that were compliant with FDA admissibility standards.

59. On several occasions, Adpen reported positive amounts of prohibited antibiotics, only to subsequently recant and say that those tests were negative. On other occasions, Adpen refused to retest the positive results in conformity with the FDA mandated tests, citing FDA's "One Test – One Report" rule.

60. Adpen's report does not indicate whether the breaded shrimp were de-breaded before the tests were conducted. Removal of the bread is a required procedure, a failure of which can yield false positives.

61. Adpen has refused to produce the complete reports to Seacoast and Thunder Bay, (the importers of record), claiming a proprietary work product privilege.

62. FDA has also refused to produce the complete reports to Seacoast and Thunder Bay.

63. Allied and the Customers have consequently been left unable to challenge the testimony which will form the basis of the FDA administrative adjudication.

64. FDA compliance officers cannot properly interpret the reports of the modified methodologies utilized by third party laboratories such as Adpen. Adpen, for instance, only tests one-quarter of the required samples. Accordingly, in an effort to interpret Adpen's noncompliant test results against the Import Alert's requirement that each laboratory must test a "minimum of 12 individual sub-samples" of each shrimp entry, some but not all FDA compliance officers have

actually, in some cases, been multiplying the laboratory results *by a factor of four*. Such quadruple-counting finds no support in either the Import Alert or in any related guidance materials.

65. The maelstrom of misinformation created by Adpen's rogue methodology, FDA's lack of control over the enforcement of its unlawful rules, and FDA's failure to educate their compliance officers yields the erroneous conclusion that the prohibited antibiotics are present at *four times their actual levels*. Consequently, the compliant Shrimp Entries are deemed impermissible and Allied faces irreparable damage.

66. Adpen has refused to disclose its methodology to Allied, the Customers, or FDA.

67. Adpen's official and complete test results and the reason for the Shrimp Entries' failure have not been disclosed to Seacoast, Thunder Bay, Allied or its counsel.

68. FDA has not provided either Allied or the importers of record with a complete explanation of the basis for refusal. Without that information, neither Allied nor the Importers can participate in the FDA administrative adjudications.

69. Upon information and belief, like the false-positives that Certified recanted, the Adpen test results were false-positives as well.

70. Refusal of the Shrimp Entries is still pending, preventing Allied from being listed as an exempt entity under the Import Alert. Allied thus faces irreparable harm.

71. An ultimate refusal by FDA of any Allied shrimp entry, accompanied by a posting on the OASIS refusal website, will result in the Chinese government's suspension of Allied's

exporting privileges for a term of one year. FDA knows of this threat, and knows that such a suspension would be tantamount to a death sentence for Allied.

72. Failure to address the immediacy of Allied's plight will result in a loss to Allied for this coming shrimp season of hundreds of millions of dollars in damages and tens of thousands of jobs.

## **CLAIMS FOR RELIEF**

### **COUNT ONE**

#### **Import Alert 16-131 is Unlawful as a Matter of Law**

73. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

74. Import Alert 16-131 is unlawful and contains binding requirements that have not been properly promulgated in accordance with the Administrative Procedures Act; *see* 5 U.S.C. § 553.

75. Allied has suffered and continues to suffer irreparable harm as a result of FDA's improper detention pursuant to Import Alert 16-131.

WHEREFORE, Allied respectfully prays that this Honorable Court **a)** enter a judicial decision, pursuant to 28 U.S.C § 2201 *et. seq.*, declaring Import Alert 16-131 unlawful as a matter of law; **b)** enjoin the enforcement of Import Alert 16-131 pursuant to the All Writs Act, 28 U.S.C. §1651; **c)** assess costs and attorneys' fees; and **d)** grant such other relief that the Court may deem just and proper.

**COUNT TWO**

**FDA's Failure to Enforce Standards Leads to the Arbitrary and Capricious Enforcement of Import Alert 16-131 in Violation of the Administrative Procedures Act**

76. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

77. Allied and its Customers are required by Import Alert 16-131 to retain third party laboratories. Following the conclusion of the testing of Allied's product, the third party laboratories are required to provide their test results to the FDA.

78. FDA exercises no oversight or control over the third party laboratories, and therefore cannot ensure that each laboratory is complying with the requirements set forth in the Import Alert and/or the LIB.

79. Consequently, rogue laboratories use intrepid methods, circumvent Import Alert requirements, and yield inconsistent and unreliable results.

80. Such inconsistent and unreliable results are then misinterpreted by FDA's compliance officers and ultimately lead to unwarranted refusals.

81. 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 compliance officers. FDA's failure to promulgate standards or guidelines for the 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 lead to substantially different determinations.

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

WHEREFORE, Allied respectfully prays that this Honorable Court **a)** enter a judicial decision, 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 16-131 in violation of the Administrative Procedures Act; **b)** enjoin the enforcement of Import Alert 16-131 pursuant to the All Writs Act, 28 U.S.C. §1651; **c)** assess costs and attorneys' fees; and **d)** grant such other relief that the Court may deem just and proper.

**COUNT THREE**

**The Defendants have Arbitrarily and Capriciously Enforced the Exemption Provision of Import Alert 16-131**

83. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

84. Import Alert 16-131 provides that firms may apply to be exempt from Import Alert 16-131. To do so, the Import Alert provides the exporter or importer must provide FDA with “[d]ocumentation showing that a minimum of five (5) consecutive entries have been released by FDA based on third-party laboratory analysis of a representative sample of the lot verifying that products do not contain malachite green and its metabolite leucomalachite green, nitrofurans, gentian violet, leucogentian violet and fluoroquinolones.”

85. In this case, however, upon Allied's application for exemption, FDA arbitrarily and capriciously required Allied to provide FDA with far more evidence than is required by the Import Alert.

86. First of all, even though Allied provided FDA with evidence of five consecutive released entries when it applied for exempt status, FDA has refused to grant Allied exempt status under the Import Alert. Instead, without any stated reason or justification, FDA has required Allied to submit more than the requisite “five consecutive entries” as provided in the Import

Alert, and even though Allied has provided FDA with all available evidence of its prior released entries, FDA has nevertheless refused to grant Allied exempt status.

87. Secondly, FDA has required Allied to submit evidence to the FDA proving that the SGS Group – the independent testing facility first retained by Allied following Allied’s receipt of the results of the erroneous tests performed by Certified Laboratories – tested Allied’s product in compliance with FDA compliance standards. Although the SGS Group is the largest inspection, verification, testing and certification company in the world, and although FDA knows who SGS is and the methods that SGS employs, FDA has nevertheless refused to grant Allied exempt status.

88. Finally, FDA has also advised Allied that Allied may not achieve exempt status under the Import Alert unless and until Allied proves to the FDA that the three Allied samples which tested positive for Gentian Violet did not, in fact, contain Gentian Violet. In spite of the fact that the laboratories which found that Allied’s product contained Gentian Violet either a) employed bogus testing methodologies, b) retracted their test results, or c) both, and in spite of the fact that Allied, Allied’s Customers, the Chinese Government, and two renowned independent testing facilities have conclusively found that Allied’s product did not contain any Gentian Violet, FDA – even though it is on knowledge of all of the above-listed information – has nevertheless refused to grant Allied exempt status.

89. Allied has suffered and continues to suffer irreparable damages as a result of FDA’s improper detention pursuant and arbitrary and capricious enforcement of Import Alert 16-131.

WHEREFORE, Allied respectfully prays that this Honorable Court a) enter a judicial decision, pursuant to 28 U.S.C § 2201 *et. seq.*, declaring that the defendants have arbitrarily and

capriciously enforced the exemption provision of Import Alert 16-131; b) enjoin the enforcement of Import Alert 16-131 pursuant to the All Writs Act, 28 U.S.C. §1651; c) assess costs and attorneys' fees; and d) grant such other relief that the Court may deem just and proper.

**COUNT FOUR**

**FDA's "One Test – One Report" Policy is Violative of the Fifth Amendment Due Process Clause**

90. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

91. Import Alert 16-131 requires Allied and its Customers to provide third party laboratory results to the FDA.

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

93. FDA bases its decisions, or "informal adjudications," as to whether to refuse or permit an entry entirely upon these third party test results.

94. The detention and subsequent refusal of foodstuffs constitutes a deprivation of property.

95. Under this policy, FDA only allows the third party laboratory to perform one test per entry. Additionally, under this policy, FDA accepts only one report for each test performed.

96. FDA applies this "One Test – One Report" rule even if the third party test result was incorrect. In other words, even if FDA learns that the test result with which it was presented was erroneous or based upon erroneous methodologies, FDA will not accept additional test results.

97. Also pursuant to this policy, the manufacturer of the tested products is not permitted to either review or challenge the tests of the independent third party laboratories when such tests are submitted to the FDA.

98. FDA's informal adjudications are performed without affording any interested parties due process of law. Allied faces irreparable harm as a result.

WHEREFORE, Allied respectfully prays that this Honorable Court **a)** enter a judicial decision, pursuant to 28 U.S.C § 2201 *et. seq.*, declaring that Import Alert 16-131 violates the Fifth Amendment to the United States Constitution; **b)** enjoin the enforcement of Import Alert 16-131 pursuant to the All Writs Act, 28 U.S.C. §1651; **c)** assess costs and attorneys' fees; and **d)** grant such other relief that the Court may deem just and proper.

#### **COUNT FIVE**

##### **Import Alert 16-131 Was Enacted in Contravention to the WTO**

99. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

100. Import Alert 16-131 is unlawful and contains binding requirements that have not been properly promulgated in accordance with the Administrative Procedures Act.

101. Review of Import Alert 16-131 is proper pursuant to 5 U.S.C. § 702.

102. Import Alert 16-131 violates WTO procedure for the proper enactment of a non-tariff trade barrier.

103. WTO promulgates that non-tariff trade barriers must be made by rule.

104. Rule-making requires compliance with the APA.

105. FDA made no attempt to comply with either WTO policy or APA policy.

106. FDA made no attempt to distinguish Chinese shrimp from shrimp with other national origins.

107. Alternatively, Import Alert 16-131 is an order that continues to affect Allied's rights without Allied being able to adjudicate the order. Allied is not a named party, nor can it seek review of any final order under Import Alert 16-131 because it does not include a process of adjudication.

108. Allied has suffered and continues to suffer irreparable damages as a result of FDA's improper detention pursuant to Import Alert 16-131.

WHEREFORE, Allied respectfully prays that this Honorable Court **a)** enter a judicial decision, pursuant to 28 U.S.C § 2201 *et. seq.*, declaring that Import Alert 16-131 was enacted in contravention of the WTO, **b)** enjoin the enforcement of Import Alert 16-131 pursuant to the All Writs Act, 28 U.S.C. §1651, **c)** assess costs and attorneys' fees, and **d)** grant such other relief that the Court may deem just and proper.

### **COUNT SIX**

#### **Injunction Against FDA Showing A Refusal On FDA's OASIS Website**

109. Allied repeats and realleges paragraphs 1-73 as though fully alleged herein.

110. Import Alert 16-131 requires Allied and its Customers to provide third party laboratory results to the FDA.

111. FDA bases its decisions, or "informal adjudications," as to whether to refuse or permit an entry entirely upon these third party test results.

112. All FDA refusals are posted on FDA's OASIS website.

113. FDA's adjudication process and the results of that adjudication process are completely unreliable.

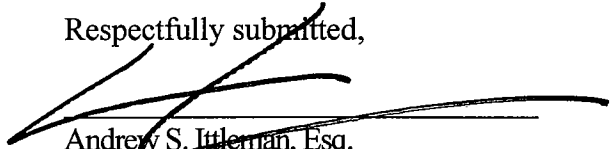
114. Should an Allied shipment be posted to the OASIS webpage, Allied will face a one-year exportation suspension at the hands of the Chinese government. Such a suspension will be tantamount to a death sentence for Allied.

115. FDA should be enjoined from refusing any of the Shrimp Entries in controversy. Additionally, FDA should be enjoined from posting any Allied refusal on OASIS.

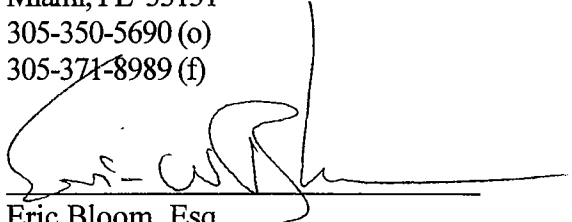
WHEREFORE, Allied respectfully prays that this Honorable Court, pursuant to the All Writs Act, 28 U.S.C. §1651, enjoin FDA from posting any refusal of the plaintiff's product on FDA's OASIS webpage.

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Respectfully submitted,



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