UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

DEL MONTE FRESH PRODUCE N.A., Inc.,
241 Sevilla Avenue, Coral Gables, FL 33134,

Plaintiff,

vs.

UNITED STATES OF AMERICA,
c/o Office of the United States Attorney for the District of Maryland,
U.S. Courthouse, Suite 400,
6500 Cherrywood Lane, Greenbelt,
Prince George's County, MD 20770-1249

and

UNITED STATES FOOD AND DRUG ADMINISTRATION,
c/o Office of the Chief Counsel,
United States Food and Drug Administration, WO Building 31,
Room 4536, 10903 New Hampshire Avenue, Silver Spring, Montgomery County, MD 20933,

Defendants.

C.A. No. _____

COMPLAINT FOR
DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Del Monte Fresh Produce N.A., Inc. ("Del Monte") brings this action for judicial review of actions by the United States Food and Drug Administration ("FDA") restricting Del Monte's importation of wholesome fresh cantaloupes into the United States. Del Monte is the largest importer of cantaloupes into the United States and is well known for selling cantaloupes of the highest quality, which are farmed, processed, transported and stored under state-of-the-art food safety controls that far exceed FDA regulatory requirements. FDA has nonetheless imposed harmful restrictions on Del Monte's importation of cantaloupes from a major source in Guatemala, based upon an erroneous speculative assumption, unsupported by evidence, that cantaloupes previously imported from that source were contaminated with the pathogen Salmonella. The Court should issue a declaratory judgment holding that FDA's actions restricting importation are unlawful, set aside the actions, and issue a permanent injunction prohibiting FDA from enforcing or effectuating them in the future.

Jurisdiction and Venue

1. This Court has jurisdiction over this case under 28 U.S.C. § 1331, to provide remedies set forth in 5 U.S.C. § 706 and 28 U.S.C. § 2201 and remedies provided under the doctrine of nonstatutory review.

2. Venue is proper in this District under 28 U.S.C. § 1391(e).

Parties

3. Plaintiff Del Monte Fresh Produce N.A., Inc. imports large quantities of seasonal fresh produce, including cantaloupes, into the United States. Plaintiff's only supplier of

cantaloupes in Guatemala is Productos Agricolas de Oriente, S.A. ("PAO"). PAO supplies Plaintiff with cantaloupes harvested from farms in San Jorge, Asuncion Mita and Estenzuella, Guatemala.

4. Defendant United States Food and Drug Administration is a federal agency with headquarters at 10903 New Hampshire Avenue, Silver Spring, MD, within the jurisdiction of this Court. The Food and Drug Administration is the agency responsible for administering the statutes and regulations at issue in this case.

5. Defendant United States of America is named as a defendant pursuant to 5 U.S.C. §§ 702-703, because this is an action for judicial review of actions and inactions of an agency of the United States — FDA — that have affected Plaintiff adversely.

Statutory and Regulatory Background

6. The Federal Food, Drug, and Cosmetic Act ("FFDCA") gives FDA authority to collect, and conduct an "examination" of, samples of food offered for import into the United States. 21 U.S.C. § 381(a). FDA has authority under the FFDCA to refuse admission of the food into domestic commerce if it "appears from the examination of . . . samples or otherwise" that the food meets one of four statutory criteria: (1) it "has been manufactured, processed, or packed under insanitary conditions"; (2) it "is forbidden or restricted in sale in the country in which it was produced or from which it was exported"; (3) it "is adulterated, misbranded" or a food to which certain drugs have been added; or (4) it is in violation of certain recordkeeping requirements. 21 U.S.C. § 381(a).

7. FDA has promulgated regulations relating to its authority to refuse admission of food as described above. If it appears that an import entry may be subject to refusal of admission, FDA gives the owner or consignee notice and an opportunity for an informal hearing in which the owner or consignee can dispute the potential refusal. 21 C.F.R. § 1.94(a). Following the hearing, if FDA determines that it still appears that any of the statutory criteria have been met, the agency issues a "notice of refusal" that requires U.S. Customs and Border Protection to demand redelivery of the food, so that Customs can require its export or destruction. Alternatively, if the owner or consignee prevails at the informal hearing, FDA issues a "notice of release" that permits the food to enter domestic commerce.

8. FDA also has adopted rules for Detention Without Physical Examination, under which FDA "detains" food offered for import without sampling it and requires the importer to hold the food until the owner or consignee provides evidence to FDA that the food does not meet the statutory criteria for refusal. These rules, which require the owner or consignee to prove that food is not violative in order for the food to be admitted into domestic commerce, do not appear in the FFDCA or in FDA's regulations published in the Code of Federal Regulations. Instead, the rules are stated in internal agency documents such as the FDA Regulatory Procedures Manual.

9. Under these rules, FDA imposes Detention Without Physical Examination by issuing an Import Alert describing particular foreign shippers, manufacturers, products and/or countries of origin of imports that will be subject to such Detention and potential refusal.

10. An Import Alert uniformly imposes Detention Without Physical Examination rules on all imports of products listed on the Import Alert from companies listed on the Import Alert. Under an Import Alert, FDA refuses admission into domestic commerce for every import entry of listed products from listed companies unless the owner or consignee submits the evidence described above and FDA decides to release the entries into domestic commerce. Detention Without Physical Examination will continue for all import entries of listed products from listed companies until such time as FDA decides to remove the companies from an Import Alert.

11. An Import Alert is a "rule" within the meaning of 5 U.S.C. § 551(4) because it is an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy. Promulgation of an Import Alert causes a direct and immediate adverse effect on companies listed therein, and upon those that import from such companies, because the listed companies' products will be detained at the border by FDA without physical examination and will not be admitted into domestic commerce unless and until information is submitted to FDA and FDA authorizes their admission.

FDA's Unsupported Conclusion That
Cantaloupes Imported by Del Monte Were the Likely Source of Illness

12. In February and March 2011, officials at FDA and other federal and state government agencies identified a number of illnesses that they associated with infections by the pathogen Salmonella. These officials indicated that the illnesses occurred in a number of different states.

13. The FDA and other officials described above investigated the illnesses and concluded that they were associated with the consumption of cantaloupes by the patients who became ill. On information and belief, these officials reached this conclusion without a sufficient factual basis to support the conclusion. Among other things, on information and belief, these officials reached this conclusion without ever testing any cantaloupes to determine whether they were contaminated with Salmonella.

14. FDA later concluded that cantaloupes imported by Del Monte from PAO's farm in Asuncion Mita, Guatemala (and allegedly contaminated with Salmonella) were the likely source of the illnesses described above. This conclusion was not rationally supported by the evidence available to FDA. FDA also did not adequately take into account evidence that did not support that conclusion. In addition, FDA's conclusion was a clear error of judgment. Among other things:

a. All of the microbiological evidence available to FDA supports the conclusion that cantaloupes from PAO's farm in Asuncion Mita were not contaminated with Salmonella. FDA has conducted its own microbiological tests on cantaloupes from that farm that FDA has sampled at the border, when the cantaloupes were offered for import. On information and belief, each time that FDA has tested cantaloupes imported from PAO's farm in Asuncion Mita, the cantaloupes have tested "negative" for Salmonella or other pathogens. FDA performed one those "negative" tests in January 2011, immediately before the reports of the illnesses described

above, and two others in April 2011, immediately after the reports of the illnesses described above.

b. All of the information collected by FDA in a recent inspection of PAO supports the conclusion that cantaloupes from PAO's farm in Asuncion Mita were not contaminated with Salmonella. In November 2010, shortly before the illnesses described above occurred, FDA inspected PAO's farm located in San Jorge, Guatemala. FDA did not issue a form FDA-483 at the conclusion of the inspection. A form FDA-483 is a list of inspectional "observations." By deciding not to issue a form FDA-483, FDA acknowledged that it did not identify any objectionable conditions significant enough to provide to the company in writing. By deciding not to issue a form FDA-483, FDA confirmed that PAO's food safety procedures at the San Jorge farm are in substantial compliance with FDA regulatory requirements pertaining to food safety. The same conclusion applies to PAO's Asuncion Mita farm, because the Asuncion Mita farm is subject to the same PAO food safety procedures as the San Jorge farm, and the same PAO quality assurance team monitors compliance with food safety requirements and procedures at both the San Jorge and Asuncion Mita farms.

c. FDA has not adequately accounted for evidence indicating that the illnesses described above were not caused by cantaloupes at all. For example, one of the patients described above denied consuming cantaloupes before becoming ill.

d. FDA has not adequately accounted for the possibility that any allegedly contaminated cantaloupes came from sources other than Del Monte. For example, on

information and belief, the retailer that FDA alleged had sold contaminated cantaloupes to most of the patients described above had three other suppliers of cantaloupes in addition to Del Monte during the relevant time period. On information and belief, FDA never investigated the three other suppliers to determine whether they were a potential source of Salmonella contamination. In addition, one of the patients described above consumed cut cantaloupe reportedly purchased from a retailer that is not supplied by either PAO or Del Monte. Another patient reportedly consumed cantaloupe imported from Honduras, not Guatemala, that could not possibly have come from PAO or Del Monte, because neither company harvests cantaloupes in Honduras.

e. FDA has not adequately accounted for the possibility that any alleged contamination of Del Monte cantaloupes occurred after the cantaloupes left the custody of Del Monte in the domestic commercial supply chain. For example, FDA has not accounted for the possibility that any contamination occurred at the retailer alleged to have sold cantaloupes to most of the patients described above.

FDA's Demand That Del Monte Must Recall Cantaloupes or Suffer the Consequences of an FDA Consumer Advisory Questioning the Wholesomeness of its Products

15. Although FDA did not have an adequate factual basis for concluding that Del Monte cantaloupes imported from Asuncion Mita posed a public health risk, FDA nonetheless demanded that Del Monte must either perform a recall of such cantaloupes or suffer the consequences of an FDA consumer advisory questioning the wholesomeness of Del Monte cantaloupes.

16. The recall demanded by FDA was not justified by the underlying evidence or by the purpose of protecting the public health. FDA lacked evidence that Del Monte cantaloupes were contaminated. Furthermore, the recall demanded by FDA related to cantaloupes that were beyond (or within a day of) their shelf life, and the retailer described above confirmed that no cantaloupes from the relevant time period remained in inventory.

17. Rather than face a general advisory regarding cantaloupes that could potentially affect the entire cantaloupe market, Del Monte acceded to FDA's demands and issued a limited recall on March 22, 2011.

Del Monte's Retention of Outside Experts

18. Del Monte responded to the concerns raised by FDA by conducting its own analysis to determine whether its food safety procedures required enhancements. Contemporaneously with pursuing the limited recall, Del Monte retained third party experts to evaluate PAO's compliance with Good Agricultural Practices in general, and in the exact fields where the allegedly contaminated cantaloupes were harvested, and in its packinghouse handling process. The experts' audit, conducted from April 6-14, 2011, included a review of PAO's compliance with Good Manufacturing Practices, Standard Sanitary Operating Procedures, Food Safety Program and Hazard Analysis and Critical Control Points program. The audit confirmed that PAO's farm and packinghouse operations meet and/or exceed current guidelines required to maintain a high level of food safety and regulatory compliance such that only wholesome food is shipped.

19. In an abundance of caution, Del Monte requested the third party experts to establish a rigorous pre-importation test and hold program for lots of cantaloupes shipped from the Asuncion Mita farm from the time of the limited recall until the end of the growing season. Under the program, samples were taken from packed product before it left the PAO packinghouse and were tested for the presence of Salmonella by an ISO-certified laboratory in Guatemala City. The third party experts concluded that all such samples tested "negative" for any Salmonella species.

FDA's Imposition of Import Alert #22-03

20. On or about July 15, 2011, FDA promulgated Import Alert #22-03, which implements FDA Detention Without Physical Examination Rules for cantaloupes, fresh, frozen and processed (including fresh cantaloupe sliced/chopped) imported from PAO's farm and packinghouse in Asuncion Mita.

21. On information and belief, under Import Alert #22-03, all future import entries of cantaloupes from Asuncion Mita will be prohibited from importation into the United States unless Del Monte provides FDA with information demonstrating that the entries are "negative" for Salmonella and other pathogens. On information and belief, this prohibition will continue indefinitely into the future unless enjoined by this Court.

22. FDA's imposition of Import Alert #22-03 was based entirely on the unsupported alleged association between Asuncion Mita cantaloupes and the illnesses from Salmonella described above. FDA did not have, and never has had, evidence that cantaloupes from

Asuncion Mita caused the Salmonella illnesses described above. In issuing Import Alert #22-03, FDA did not have, and never has had, any evidence of either "spot" contamination or widespread or systemic contamination of Asuncion Mita cantaloupes.

23. Import Alert #22-03 is premised upon FDA's conclusion that cantaloupes from PAO's Asuncion Mita farm were contaminated. Import Alert #22-03 expressly states FDA's conclusion that the source of the contamination is likely one or more of the following: irrigation of fields with water contaminated with sewage; processing produce with Salmonella-contaminated water; poor hygienic practices of workers that harvest and pack the produce; animals in close proximity to product or water sources; and/or lack of adequate cleaning and sanitizing of equipment that comes in contact with the product.

24. On information and belief, FDA has no evidence whatsoever that PAO's Asuncion Mita operation has irrigated fields with water contaminated with sewage; processed produce with Salmonella-contaminated water; used workers for harvesting and packaging that have poor hygienic practices; had animals in close proximity to product or water sources; and/or lacked adequate cleaning and sanitizing equipment that comes in contact with product. To the contrary, the evidence available to FDA from its own microbiological testing of Asuncion Mita cantaloupes, from its recent inspection of PAO's farm in San Jorge, and otherwise, wholly undermines any assertion that such practices have occurred or are occurring.

The Harm Faced by Del Monte From the Import Alert

25. FDA's Import Alert #22-03 is a final agency action that directly and concretely injures Del Monte by imposing the requirements described above and adversely affecting Del Monte's ability to receive perishable fresh produce for sale to its customers in the United States.

26. Import Alert #22-03 has imposed a direct and immediate adverse impact on Del Monte since the time it was issued because the Import Alert threatens the viability of a major import source from Guatemala, and significant resources and commitments must be finalized immediately to ensure that the Guatemalan cantaloupes will be ready for harvest in the near future.

27. Import Alert #22-03 also threatens additional direct and immediate adverse impacts on Del Monte once Detention Without Physical Examination is applied to actual import shipments from Asuncion Mita, which will occur in the near future. In particular, Import Alert #22-03 threatens Del Monte with harm by delaying Del Monte's importation of cantaloupes, which are perishable and deteriorate during the period of delay.

28. On information and belief, Import Alert #22-03 will cause delays for each import entry of cantaloupes from Asuncion Mita. Those delays arise from the time necessary for Del Monte to generate, and for FDA then to review, information proving that the cantaloupes are pathogen-free. The threatened delays will cause Del Monte substantial harm; approximately 27% of all the cantaloupes imported by Del Monte into the United States come from PAO's Asuncion Mita farm restricted by Import Alert #22-03.

29. On information and belief, Import Alert #22-03 also is likely to cause delays for Del Monte's imports of cantaloupes that are not from Asuncion Mita. Although such imports are not within the scope of the Import Alert, the Import Alert taints Del Monte's reputation and is, on information and belief, likely to increase FDA's sampling, at the border, of Del Monte imports from other sources.

30. FDA's regulations expressly require that when an importing owner or consignee is notified that FDA has taken a sample at the border, the owner or consignee must "hold" the food and not distribute it until further notice from the agency. 21 C.F.R. § 1.90. An increase in sampling caused by Import Alert #22-03 will necessarily cause an increase in these "holds," which will delay distribution in domestic commerce until FDA's testing of the samples is complete. These threatened delays will cause Del Monte substantial harm. For example, on information and belief, this increased sampling is threatened to occur for cantaloupes imported from PAO's farms in Guatemala other than the farm in Asuncion Mita; cantaloupes from these other farms account for approximately 51% of all of the cantaloupes imported by Del Monte into the United States.

31. Fresh produce has its highest quality and value in the period shortly after it is harvested. Del Monte has a well-established reputation for providing its customers with the highest quality and freshest cantaloupes in the market. In order to satisfy these customer expectations, Del Monte imports cantaloupes and then holds them in its warehouses in the United States for a maximum of seven days after arrival at the port of entry.

32. If delays caused by Import Alert #22-03 force Del Monte to hold the cantaloupes in its warehouse for more than seven days, the cantaloupes begin to deteriorate and become "carryover" produce that cannot be sold to the company's regular customers and must be sold in a secondary market at a discount. The discounts increase as the cantaloupes get older. At the beginning, the sales price of the cantaloupes on the secondary market (assuming no quality problems) must be reduced by approximately 10% daily (after the initial seven days in the warehouse). If quality problems arise because of the age of the cantaloupes, the discounts are even greater.

33. The secondary market only lasts for the limited period from eight days after arrival at the port of entry until thirteen days after arrival at the port of entry. Cantaloupes that are held in the warehouse for fourteen days after arrival at the port of entry must be dumped because they lose all commercial value at that point.

34. If Import Alert #22-03 is not rescinded, Del Monte will suffer irreparable harm, because it either must discontinue imports from Asuncion Mita (and other farms threatened by delays) without any viable alternative source of cantaloupes to provide to customers or commit to deliver cantaloupes from Asuncion Mita and other farms but suffer the consequences of the losses from the product deterioration described above. In either circumstance, Del Monte is threatened with serious and substantial harm that cannot be remedied by the Court once it has occurred.

Count I
(Arbitrary and Capricious Agency Action)

35. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

36. FDA's imposition of Import Alert #22-03 is an arbitrary and capricious final agency action within the meaning of 5 U.S.C. § 706(2)(A). Among other things, this action (1) is not rationally connected to the evidence before FDA; (2) is based upon a clear error of judgment; (3) has not adequately taken into account evidence that does not support Detention Without Physical Examination.

37. FDA's imposition of Import Alert #22-03 also is an arbitrary and capricious final agency action because it is not justified by the factual conclusions that FDA has relied upon as the justification for the action. Among other things, FDA's conclusions in Import Alert #22-03 as to the likely source of alleged cantaloupe contamination (described in paragraph 23 above) have no evidence supporting them (as explained in paragraph 24 above).

38. Under 5 U.S.C. § 706(1), this Court should hold unlawful and set aside Import Alert #22-03 and enjoin its enforcement or implementation.

39. Under 28 U.S.C. § 2201, this Court should declare that Import Alert #22-03 is an invalid and unlawful arbitrary and capricious final agency action.

Count II
(Agency Action in Excess of Statutory Jurisdiction,
Authority, or Limitations, or Short of Statutory Right)

40. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

41. One of FDA's two statutory bases for Import Alert #22-03 is the allegation that cantaloupes from Asuncion Mita are subject to refusal of admission under section 801(a)(3) of the FFDCA (21 U.S.C. § 381(a)(3)), on grounds of adulteration within the meaning of section 402(a)(1) of the FFDCA (21 U.S.C. § 342(a)(1)). FDA has no statutory authority to refuse admission of a particular import entry under section 801(a)(3) of the FFDCA (21 U.S.C. § 381(a)(3)), on grounds of adulteration within the meaning of section 402(a)(1) of the FFDCA (21 U.S.C. § 342(a)(1)), unless the agency has evidence, from the examination of samples or otherwise, supporting the conclusion that the import entry appears to bear or contain any poisonous or deleterious substance which may render it injurious to health.

42. FDA has justified Import Alert #22-03 under its authority to refuse admission of imports under the provisions of the FFDCA cited above. Just as FDA has no statutory authority (under 21 U.S.C. §§ 381(a)(3)) and 342(a)(1)) to refuse admission of a particular import entry without evidence that the entry appears to bear or contain any poisonous or deleterious substance which may render it injurious to health, FDA has no statutory authority (under 21 U.S.C. §§ 381(a)(3)) and 342(a)(1)) to detain a particular import entry without physical examination if FDA does not have evidence that the entry appears to bear or contain a poisonous or deleterious substance which may render it injurious to health.

43. FDA has no evidence that past imports from Asuncion Mita appeared to bear or contain a poisonous or deleterious substance which may render them injurious to health. FDA also has no evidence that the future imports of cantaloupes from Asuncion Mita, which will be restricted by Import Alert #22-03, appear to bear or contain a poisonous or deleterious substance which may render them injurious to health. On information and belief, FDA will detain future entries of cantaloupes from Asuncion Mita, without evidence that the entries appear to bear or contain any poisonous or deleterious substance which may render them injurious to health, until this Court intervenes.

44. Because FDA has no statutory authority to detain entries of cantaloupes from Asuncion Mita without evidence that the entries appear to bear or contain any poisonous or deleterious substance which may render them injurious to health, Import Alert #22-03 is a final agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" within the meaning of 5 U.S.C. § 706(2)(C).

45. Under 5 U.S.C. § 706(1), this Court should hold unlawful and set aside Import Alert #22-03 and enjoin its enforcement or implementation.

46. Under 28 U.S.C. § 2201, this Court should declare that Import Alert #22-03 is an unlawful and invalid final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

Count III
(Agency Action in Excess of Statutory Jurisdiction,
Authority, or Limitations, or Short of Statutory Right)

47. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

48. The second of FDA's statutory bases for Import Alert #22-03 is the allegation that cantaloupes from Asuncion Mita are subject to refusal of admission because of allegedly insanitary conditions at Asuncion Mita. This basis for the Import Alert rests upon three related statutory provisions – section 801(a)(1) of the FFDCA (21 U.S.C. § 381(a)(1) (which requires refusal of food "manufactured, processed, or packed under insanitary conditions") and sections 801(a)(3) and 402(a)(4) of the FFDCA (21 U.S.C. §§ 381(a)(3) and 342(a)(4)) (which require refusal of food that is "adulterated" because it has been "prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health"). FDA has no statutory authority to refuse admission of a particular import entry under these provisions unless the agency has evidence, from the examination of samples or otherwise, supporting the conclusion that there appear to be insanitary conditions affecting the food at Asuncion Mita.

49. FDA has justified Import Alert #22-03 under its authority to refuse admission of imports under the provisions of the FFDCA cited above. Just as FDA has no statutory authority under these provisions to refuse admission of a particular import entry without evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita, FDA has no statutory authority under the same provisions to detain a particular import entry without physical

examination if FDA does not have evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita.

50. FDA has no evidence that there appear to have been, or appear currently to be, insanitary conditions affecting the food at Asuncion Mita. On information and belief, FDA will detain future entries of cantaloupes from Asuncion Mita, without evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita, until this Court intervenes.

51. Because FDA has no statutory authority to detain entries of cantaloupes from Asuncion Mita without evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita, Import Alert #22-03 is a final agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" within the meaning of 5 U.S.C. § 706(2)(C).

52. Under 5 U.S.C. § 706(1), this Court should hold unlawful and set aside Import Alert #22-03 and enjoin its enforcement or implementation.

53. Under 28 U.S.C. § 2201, this Court should declare that Import Alert #22-03 is an unlawful and invalid final agency action in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.

Count IV
(Nonstatutory Review)

54. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

55. One of FDA's two statutory bases for Import Alert #22-03 is the allegation that cantaloupes from Asuncion Mita are subject to refusal of admission under section 801(a)(3) of the FFDCA (21 U.S.C. § 381(a)(3)), on grounds of adulteration within the meaning of section 402(a)(1) of the FFDCA (21 U.S.C. § 342(a)(1)). FDA has no statutory authority to refuse admission of a particular import entry under section 801(a)(3) of the FFDCA (21 U.S.C. § 381(a)(3)), on grounds of adulteration within the meaning of section 402(a)(1) of the FFDCA (21 U.S.C. § 342(a)(1)), unless the agency has evidence, from the examination of samples or otherwise, supporting the conclusion that the import entry appears to bear or contain any poisonous or deleterious substance which may render it injurious to health.

56. FDA has justified Import Alert #22-03 under its authority to refuse admission of imports under the provisions of the FFDCA cited above. Just as FDA has no statutory authority (under 21 U.S.C. §§ 381(a)(3)) and 342(a)(1)) to refuse admission of a particular import entry without evidence that the entry appears to bear or contain any poisonous or deleterious substance which may render it injurious to health, FDA has no statutory authority (under 21 U.S.C. §§ 381(a)(3)) and 342(a)(1)) to detain a particular import entry without physical examination if FDA does not have evidence that the entry appears to bear or contain a poisonous or deleterious substance which may render it injurious to health.

57. FDA has no evidence that past imports from Asuncion Mita appeared to bear or contain a poisonous or deleterious substance which may render them injurious to health. FDA also has no evidence that the future imports of cantaloupes from Asuncion Mita, which will be

restricted by Import Alert #22-03, appear to bear or contain a poisonous or deleterious substance which may render them injurious to health. On information and belief, FDA will detain future entries of cantaloupes from Asuncion Mita, without evidence that the entries appear to bear or contain any poisonous or deleterious substance which may render them injurious to health, until this Court intervenes.

58. The Court should declare that Import Alert #22-03 is unlawful, set aside Import Alert #22-03, and enjoin the enforcement or implementation of Import Alert #22-03, under the doctrine of nonstatutory review, because FDA has egregiously exceeded its statutory authority described above, disregarded the specific and unambiguous statutory requirements described above and/or patently misconstrued those statutory requirements in imposing the Import Alert in the absence of any evidentiary basis as described above.

59. Under the doctrine of nonstatutory review, this Court has authority to review and set aside agency actions in excess of statutory authority, regardless of whether those actions are final agency actions reviewable under the Administrative Procedure Act. Accordingly, even if Import Alert #22-03 were not a final agency action reviewable under the Administrative Procedure Act, the Court should declare that it is unlawful, set it aside and enjoin its enforcement or implementation.

Count V
(Nonstatutory Review)

60. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

61. The second of FDA's statutory bases for Import Alert #22-03 is the allegation that cantaloupes from Asuncion Mita are subject to refusal of admission because of allegedly insanitary conditions at Asuncion Mita. This basis for the Import Alert rests upon three related statutory provisions – section 801(a)(1) of the FFDCA (21 U.S.C. § 381(a)(1) (which requires refusal of food "manufactured, processed, or packed under insanitary conditions") and sections 801(a)(3) and 402(a)(4) of the FFDCA (21 U.S.C. §§ 381(a)(3) and 342(a)(4)) (which require refusal of food that is "adulterated" because it has been "prepared, packed, or held under insanitary conditions whereby . . . it may have been rendered injurious to health"). FDA has no statutory authority to refuse admission of a particular import entry under these provisions unless the agency has evidence, from the examination of samples or otherwise, supporting the conclusion that there appear to be insanitary conditions affecting the food at Asuncion Mita.

62. FDA has justified Import Alert #22-03 under its authority to refuse admission of imports under the provisions of the FFDCA cited above. Just as FDA has no statutory authority under these provisions to refuse admission of a particular import entry without evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita, FDA has no statutory authority under the same provisions to detain a particular import entry without physical examination if FDA does not have evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita.

63. FDA has no evidence that there appear to have been, or appear currently to be, insanitary conditions affecting the food at Asuncion Mita. On information and belief, FDA will

detain future entries of cantaloupes from Asuncion Mita, without evidence that there appear to be insanitary conditions affecting the food at Asuncion Mita, until this Court intervenes.

64. The Court should declare that Import Alert #22-03 is unlawful, set aside Import Alert #22-03, and enjoin the enforcement or implementation of Import Alert #22-03, under the doctrine of nonstatutory review, because FDA has egregiously exceeded its statutory authority described above, disregarded the specific and unambiguous statutory requirements described above and/or patently misconstrued those statutory requirements in imposing the Import Alert in the absence of any evidentiary basis as described above.

65. Under the doctrine of nonstatutory review, this Court has authority to review and set aside agency actions in excess of statutory authority, regardless of whether those actions are final agency actions reviewable under the Administrative Procedure Act. Accordingly, even if Import Alert #22-03 were not a final agency action reviewable under the Administrative Procedure Act, the Court should declare that it is unlawful, set it aside and enjoin its enforcement or implementation.

Count VI
(Agency Action Without
Observance of Procedure Required by Law)

66. Plaintiff hereby incorporates by reference each and every allegation set forth in paragraphs 1 through 34 above.

67. Import Alert #22-03 is a legislative rule. This agency action is a legislative rule, among other things, because as applied by FDA, it imposes uniform prospective substantive

legal limitations on the importation of cantaloupes from Asuncion Mita that did not exist before the agency action was taken.

68. Under 5 U.S.C. § 553, FDA was required either to follow notice and comment procedures, or to publish written findings establishing good cause that notice and comment procedures were impracticable, unnecessary, or contrary to the public interest, before imposing Import Alert #22-03. FDA violated 5 U.S.C. § 553 because it neither followed notice and comment procedures nor published such findings. Because of this violation of 5 U.S.C. § 553, FDA's imposition of Import Alert #22-03 constitutes final agency action "without observance of procedure required by law" within the meaning of 5 U.S.C. § 706(2)(D).

69. Under 5 U.S.C. § 706(1), this Court should hold unlawful and set aside Import Alert #22-03 and enjoin its enforcement or implementation.

70. Under 28 U.S.C. § 2201, this Court should declare that Import Alert #22-03 is an unlawful and invalid final agency action because it violated the procedures required by 5 U.S.C. § 553.

Prayer for Relief

Plaintiff respectfully requests the Court to grant the following relief:

I. Set aside Import Alert #22-03;

II. Permanently enjoin FDA from enforcing or otherwise effectuating Import Alert #22-03;

III. Issue a declaratory judgment declaring that Import Alert #22-03 is unlawful; and

IV. Award such other relief as this Court deems just and proper.

Respectfully submitted,

/s/ Daniel G. Jarcho

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