UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

DEL MONTE FRESH PRODUCE N.A., INC., **Plaintiff,** **v.** **UNITED STATES OF AMERICA,** **Defendant.**	**Civil Action 08-02161 (HHK)**

MEMORANDUM OPINION

Del Monte Fresh Produce N.A., Inc. ("Del Monte") brings this action against the United States of America, alleging that the U.S. Food and Drug Administration ("FDA") has engaged in an unlawful pattern and practice of delay in sampling and inspecting Del Monte's produce for import to the United States. Del Monte seeks injunctive and declaratory relief pursuant to section 706(1) of the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*. Before the Court is the motion of the United States to dismiss Del Monte's complaint [#10]. Upon consideration of the motion, the opposition thereto, and the record of this case, the Court concludes that the motion should be granted.

I. BACKGROUND

A. Statutory and Regulatory Background

1. FDA inspection of imported food

The FDA has authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, to sample and inspect, *inter alia*, food an importer seeks to bring into the United States. 21 U.S.C. § 381(a). If the FDA determines that "it appears from the examination of such

samples or otherwise" that the food "has been manufactured, processed, or packed under insanitary conditions" or is otherwise prohibited from entry under other sections of the U.S. Code, the food "shall be refused admission" to the United States. *Id.* FDA regulations provide that when the FDA requests "a sample of an article offered for import" for examination, the U.S. Bureau of Customs and Border Protection[1] "shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample." Food and Drugs, Imports and Exports, 21 C.F.R. § 1.90; *see also* 21 U.S.C. § 381(a) (requiring such notice to the importer). The owner of the article "shall hold such article and not distribute it until further notice . . . of the results of examination of the sample." 21 C.F.R. § 1.90. It is the FDA's practice to issue a "Notice of Action" alerting an importer of its decision to release a particular shipment for, or to reject it from, import.

2. Suits for agency failure to act

A party may sue under the APA if she is "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. In the context of this provision and this case, "agency action" means "final agency action" and is defined as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or *failure to act*." *Id.* §§ 704, 551(13) (emphasis added).

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[1] The relevant regulation refers generally to "the collector of customs having jurisdiction over the article." 21 C.F.R. § 1.90. The text of the Federal Food, Drug, and Cosmetic Act refers to actions to be taken by the Secretary of the Treasury and the Secretary of Health and Human Services. 21 U.S.C. § 381(a). There is no dispute that the Secretary of Homeland Security, rather than of the Treasury, currently oversees the actions of the entity now called the U.S. Bureau of Customs and Border Protection, which manages imports generally, or that the actions of the Secretary of Health and Human Services authorized by the statute, which regard monitoring of "food, drugs, devices, tobacco products, and cosmetics" in particular, 21 U.S.C. § 381(a), are delegated to the FDA.

Pursuant to section 706(1) of the APA, if a party brings a claim arising from an agency's failure to act, a court may grant relief by "compel[ling] agency action unlawfully withheld or unreasonably delayed." *Id.* § 706(1).

The Supreme Court has made clear that a claim for relief under section 706(1) is limited to challenges to the omission of (1) "a *discrete* action" that is (2) "legally *required*." *Norton v. S. Utah Wilderness Alliance* ("*SUWA*"), 542 U.S. 55, 63 (2004) (emphasis in original). The Court has further explained that "[t]he limitation to discrete agency action precludes the kind of broad programmatic attack [the Court] rejected in *Lujan v. National Wildlife Federation*" ("*Lujan*"), 497 U.S. 871 (1990), *id.*, in which it held that a party "cannot seek *wholesale* improvement of [an agency] program by court decree, rather than in the office of the Department or the halls of Congress," *Lujan*, 497 U.S. at 891 (emphasis in original).

B. Factual Background

Del Monte imports fresh produce into the United States and is therefore subject to the FDA's occasional inspection of samples of the fruits or vegetables it seeks to bring into the country. The basis of this action is Del Monte's allegation that the FDA often allows too much time to pass before completing those inspections, causing Del Monte's produce to become less fresh and therefore to lose value. As examples of this delay, Del Monte describes six instances between early 2008 and early 2009 in which the FDA requested a sample of a shipment of produce—specifically, in each instance, either bananas, cantaloupes, or plantains—and did not issue the resulting Notice of Action to Del Monte until so many days had passed—specifically, between six and eleven—that Del Monte was harmed.

Del Monte asserts in this action that "[s]ince at least 2006, FDA has engaged in, and continues to engage in, a pattern and practice of unreasonably and/or unlawfully delaying sampling, inspection, examination and release of perishable fresh produce imported or offered by Del Monte for import into the United States." Compl. ¶ 8.[2] Del Monte requests that the Court "[i]ssue an injunction compelling FDA to cease unreasonable and/or unlawful delay in sampling, inspecting, examining and releasing food that Del Monte seeks to import into the United States" and "[i]ssue a declaratory judgment declaring that FDA has engaged in a pattern or practice that constitutes agency action unlawfully withheld and/or unreasonably delayed." Compl. at 7.

II. ANALYSIS

The United States has moved for dismissal of Del Monte's complaint,[3] arguing that because Del Monte alleges a pattern and practice of unreasonable delay rather than contesting unreasonable delay in the sampling and inspection of a particular import shipment, its claims are not justiciable under the APA.[4] Specifically, the United States asserts that by bringing a "pattern

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[2] All citations herein to Del Monte's complaint refer to the Amended Complaint.

[3] The motion seeks dismissal pursuant to either Federal Rule of Civil Procedure 12(b)(1), which permits dismissal for lack of subject matter jurisdiction, or Rule 12(b)(6), which permits dismissal for failure to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(1), (6). Although the United States characterizes the argument the Court addresses below as falling under Rule 12(b)(6), it might be more properly categorized as a claim under Rule 12(b)(1). *See Blancett v. U.S. Bureau of Land Mgmt.*, 2006 WL 696050, at *3-4 (D.D.C. March 20, 2006) (discussing application of Rule 12(b)(1) to claims under the APA for an agency's failure to act); *but see SUWA*, 542 U.S. at 61-67 (discussing dismissal of claims under APA for failure to act without addressing the section of Rule 12 under which such dismissal is appropriate). The Court's reasoning does not depend on which section of Rule 12 is the basis for dismissal.

[4] The United States also presents other arguments in support of its motion to dismiss. The first argument, that the FDA's review of imported food is committed to the FDA's discretion such that judicial review is inappropriate, fails because the argument is pertinent to

and practice" claim rather than seeking relief from particular agency actions, Del Monte asks the Court to order "wholesale improvements," an action which is disallowed by the APA as interpreted by the Supreme Court in *SUWA* and *Lujan*. Def.'s Mot. to Dismiss at 28.

Del Monte responds that the agency delay of which it complains meets the requirements for judicial review because a decision by the FDA to admit, or not admit, food to the United States meets the requirements of *SUWA*: it is a final agency action required by law. Because "a single failure to act is reviewable," Del Monte argues, "it follows that a pattern and practice of many such failures also is reviewable for unreasonable delay." Pl.'s Opp'n to Def.'s Mot. to Dismiss ("Pl.'s Opp'n") at 15.

The United States has the better argument. The Supreme Court has made explicit that a court may only review an agency's failure to act, or unreasonable delay in acting, if the action not taken, or taken too late, is discrete. *SUWA*, 542 U.S. at 64. After prohibiting "programmatic attack[s]" on and "wholesale improvement" of agency programs, the Court wrote:

> The principle purpose of the APA limitations we have discussed . . . is to protect agencies from undue judicial interference with their lawful discretion, and to avoid judicial entanglement in abstract policy disagreements which courts lack both expertise and information to resolve. If courts were empowered to enter general orders compelling compliance with broad statutory mandates, they would necessarily be empowered, as well, to determine whether compliance was

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challenges to the substance of the FDA's decisions regarding the importation of particular food rather than to the amount of time that passes before the FDA makes those decisions. *Cf. SUWA*, 542 U.S. at 64 (explaining that section 706(1) "empowers a court only to compel an agency 'to perform a ministerial or non-discretionary act,' or 'to take action upon a matter, without directing *how* it shall act'" (citation omitted) (emphasis in original)). The Court need not address the United States' second argument, that Del Monte's claims are moot, because it agrees with the third, that they are not justiciable. The fourth argument the United States presents, that Del Monte's claims are barred because Del Monte failed to exhaust its administrative remedies, similarly does not require resolution because the claims are not of the type that may come before this Court regardless of their procedural history.

> achieved—which would mean that it would ultimately become the task of the supervising court, rather than the agency, to work out . . . day-to-day agency management.

Id. at 66-67. Were the Court to review Del Monte's claim, it would, as the United States argues, consider the procedures by which the FDA inspects samples and makes decisions as to their suitability for import. Such broad review of agency operations is just the sort of "entanglement" in daily management of the agency's business that the Supreme Court has instructed is inappropriate.[5]

Del Monte has emphatically and repeatedly made clear that it is bringing a "pattern and practice" claim rather than seeking relief from specific instances of unreasonable delay by the FDA. *See, e.g.*, Compl. ¶ 8 ("Th[e FDA's] pattern and practice of delay is ongoing and is reasonably expected to continue unless remedied by this Court); *id.* ¶ 10 ("Recent examples of the FDA's pattern and practice of delay include, but are not limited to, the following incidents."); Pl.'s Opp'n at 15 ("Because a single failure to act is reviewable, it follows that a pattern and practice of many such failures also is reviewable for unreasonable delay.").[6] The case Del Monte

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[5] Other courts have rejected claims for relief under section 706(1) on this ground. *See, e.g.*, *The Wilderness Soc. v. Norton*, 2005 WL 3294006, at *22 (D.D.C. Jan. 10, 2005) ("Count 42 alleges a pattern or practice in that [the agency] allegedly fails to prepare wilderness management plans for designated wilderness, as required by [statute]. The APA does not allow a suit to enforce a general statutory command. Accordingly, Count 42 will be dismissed." (internal citation to *SUWA*, 542 U.S. 55, omitted)); *Inst. for Wildlife Prot. v. Norton*, 337 F. Supp. 2d 1223, 1228-29 (W.D. Wash. 2004) (dismissing claims for lack of subject matter jurisdiction where, although plaintiffs argued that they contested not a program but "repeated, specific violations" of a statute governing agency action, plaintiffs sought general improvement of the practice that caused the agency to consistently fail to meet the relevant deadline (citing *Lujan*, 497 U.S. at 891)).

[6] Del Monte has neither suggested that its complaint can alternatively be viewed to contest the specific instances of delay it describes nor chosen to file a second amended complaint adding a count or counts seeking relief from unreasonable delay in those, or other, specific

cites to support the proposition that it may sue based on the FDA's pattern and practice rather than discrete actions, *Payne Enterprises, Inc. v. United States*, 837 F.2d 486 (D.C. Cir. 1988), does not convince the Court of plaintiff's position. *Payne Enterprises* regards the repeated denial of Freedom of Information Act requests based on the invocation of inapplicable statutory exemptions rather than delay of an action over which the agency had discretion. *Id.* at 489-91. Furthermore, insofar as the D.C. Circuit's 1988 opinion conflicts with *SUWA* and *Lujan*, the Supreme Court's more recent proclamations of the law overrule it. Therefore, Del Monte's claims are not properly before the Court.

III. CONCLUSION

For the foregoing reasons, the Court concludes that the motion to dismiss of the United States [#10] shall be granted. An appropriate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge

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instances. It does assert, however, that its claims are not moot because the specific instances of delay described in its complaint are "capable of repetition, yet evading review," Pl.'s Opp'n at 26-28, which arguably suggests that it seeks relief from those particular events. But the Court will not infer that Del Monte implicitly means to offer this alternative theory of its case. Del Monte makes this argument regarding mootness only as an alternative to the argument that a challenge to the agency's pattern and practice "does not become moot when individual instances of delay are resolved," *id.* at 25, and, as noted, it nowhere indicates explicitly that it seeks relief other than from the FDA's pattern and practice.