UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY, Plaintiff, v. KATHLEEN SEBELIUS, SECRETARY OF U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and MARGARET A. HAMBURG, COMMISSIONER OF U.S. FOOD AND DRUG ADMINISTRATION, Defendants.	)	Case No. 1:14-cv-267-RC

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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INTRODUCTION

In this suit, Plaintiff, the Center for Food Safety ("CFS"), asks this Court to take the highly unusual step of vacating a *proposed* rule issued by the Food and Drug Administration ("FDA"), on the ground that FDA issued and implemented the proposal without following the notice and comment requirements of the Administrative Procedure Act ("APA"). The challenged proposal sets forth a voluntary program whereby a food manufacturer[1] may notify FDA that it has independently determined that a use of a food ingredient is generally recognized as safe ("GRAS") for its intended use in food and provide the agency with certain information about that determination. Nothing in the Federal Food, Drug, and Cosmetic Act ("FDCA") requires a manufacturer to give FDA any notice prior to marketing a GRAS food ingredient. Under the proposed rule, if a manufacturer chooses to provide such notice, FDA would review it and issue a non-binding response advising whether the agency has questions about the manufacturer's determination. The agency solicited comments on the proposed rule in two different comment periods and has not yet issued a final rule. Under an interim policy announced in the proposed rule, FDA invited manufacturers to submit notices of their independent determinations for review under the framework of the proposed rule during the period between issuance of the proposal and any final rule based on the proposal.

Although Plaintiff notes that years have passed since the issuance of the proposal and acknowledges, as it must, that FDA has not actually "promulgate[d] a final rule," (First Am. Compl. ¶ 1), Plaintiff does not seek relief under 5 U.S.C. § 706(1), the mechanism Congress provided for compelling agency action that has been "unreasonably delayed" or "unlawfully

[1] For simplicity, we refer to manufacturers submitting notifications under the proposed rule; however, under the proposed rule, such notifications could be submitted by any person. Substances Generally Recognized as Safe; Proposed Rule, 62 Fed. Reg. 18,938, 18,960 (Apr. 17, 1997).

withheld." Instead, Plaintiff argues that the proposed rule is final agency action because it "went into effect" upon publication in 1997 and asks this Court to vacate the proposed rule.

Plaintiff's First Amended Complaint ("Complaint") should be dismissed for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted.

Plaintiff lacks standing because the procedural injuries attributed to Defendants' alleged issuance and implementation of a rule without notice and comment do not by themselves establish that Plaintiff has suffered the requisite concrete and particularized injury. Although Plaintiff also alleges that its members have suffered an additional substantive injury, increased risk of harm to health and safety from potentially unsafe substances, the Complaint identifies no member of CFS who has actually suffered this clearly speculative injury. More importantly, even if Plaintiff could show that its members have suffered a cognizable injury, it still lacks standing because the challenged agency action did not cause the alleged injury and any such injury would not be redressed by the requested relief.

Even if Plaintiff has standing, the Complaint fails to state a claim under the APA, 5 U.S.C. § 706(2)(A), because the APA clearly limits review to *final* agency action. The challenged agency action is only a *proposed* rule, which, by definition, does not represent FDA's final determination with respect to the matters addressed in the proposal. Indeed, while FDA could adopt the proposal, it also remains possible, until FDA makes a final determination, that the agency could choose not to adopt the proposal or to alter it substantially even in ways that address Plaintiff's alleged concerns. Because the proposed rule (which sets forth a wholly voluntary notification program) is tentative and interlocutory rather than the end result of a completed decisionmaking process, it is not subject to judicial review. Finality is also lacking here because neither the proposed rule nor the agency's responses to notices that have been

voluntarily submitted under the interim policy have binding legal effect on FDA or anyone else. For both of these reasons, Plaintiff's claim must be dismissed for failure to state a claim under the APA.

If this Court accepts Plaintiff's argument that the proposed rule constitutes final agency action, then this suit still must be dismissed because Plaintiff's claim would be time-barred by 28 U.S.C. § 2401(a), which provides a six-year statute of limitations for actions under the APA. The cause of action alleged here, the alleged procedural defect of issuing a rule without notice and comment, accrued, under Plaintiff's theory of this case, in 1997 because the challenged proposed rule "went into effect indefinitely upon publication of notice in the Federal Register." *See* First. Am. Compl. ¶ 66. Thus, even if FDA's proposal were viewed as final, the time for challenging FDA's failure to respond to comments received on the proposed rule has passed, and the Court, accordingly, lacks jurisdiction to hear Plaintiff's claim.

STATUTORY AND REGULATORY FRAMEWORK

The 1958 Food Additives Amendment to the FDCA

In 1958, Congress enacted the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 85-929, 72 Stat. 1784. The 1958 amendment requires that, before a new additive may be used in food, FDA must approve its use. The 1958 amendment defined the terms "food additive" (21 U.S.C. 321(s)) and "unsafe food additive" (21 U.S.C. § 348(a)), established a premarket approval process for food additives (21 U.S.C. § 348(b) through (g)), and amended the food adulteration provisions of the FDCA to deem adulterated any food that is, or bears or contains, any food additive that is unsafe within the meaning of 21 U.S.C. § 348 (*see* 21 U.S.C. § 342(a)(2)(C)).

The term "food additive" means "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." 21 U.S.C. § 321(s). The statute excludes certain specific types of substances[2] from this broad definition as well as any substance that is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use." *Id.*.

Under the 1958 amendment, a substance that is generally recognized as safe ("GRAS") for a particular use may be marketed for that use without agency review and approval. First Am. Compl. ¶ 28. The creation of this GRAS exclusion reflected Congress's determination that many substances intentionally added to food do not need premarket review by FDA to ensure their safety, either because their safety has been established by a long history of use in food or because their safety has been established by information about the substances that is generally available to, and accepted by, qualified scientists. 62 Fed. Reg. at 18,938-39. Many substances (such as vinegar, vegetable oil, baking powder, and many spices, flavors, gums, and preservatives) are lawfully marketed without going through the premarket approval process for food additives based on this GRAS exclusion to the food additive definition.

The FDCA permits a food manufacturer to make an independent determination that the use of a substance for a particular purpose is GRAS. This is sometimes referred to as a self-determination of GRAS status. A manufacturer that makes a self-determination of GRAS status is not required to seek FDA's agreement with that determination or the agency's permission to

[2] *See generally* 21 U.S.C. § 321(s) (excluding, for example, pesticide chemical residues in or on a raw agricultural commodity or processed food, color additives, and new animal drugs).

market the substance. *See* First Am. Compl. ¶ 28 ("A substance that is GRAS for a particular use may be marketed for that use without the formal FDA review and premarket approval required for other food additives."). Indeed, food manufacturers are not required to notify FDA that they have made a self-determination of the GRAS status of a substance, and, in fact, many do not. *See* U.S. Gov't Accountability Office, GAO-10-246, Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to be Generally Recognized as Safe (GRAS) (2010) (hereinafter "GAO Report") (FDA "does not review many of the substances added to food that manufacturers determine to be [GRAS] under the conditions of their intended use"); *see also id.* at 12 (describing an international food marketer that makes about five GRAS determinations a year without notifying FDA); First Am. Compl. ¶ 52. It is for this reason that FDA refers to GRAS notification as a voluntary program.

When a substance is not GRAS for a particular use and is not otherwise excluded from the definition of "food additive" in 21 U.S.C. § 321(s), the substance is a food additive for that use and is subject to a premarket approval requirement.[3] Thus, if FDA does not agree with an independent GRAS determination that the use of a substance is GRAS, the government can initiate an enforcement action to stop distribution of the food substance and foods containing that

[3] The food additive petition process is set forth in 21 U.S.C. § 348(b) through (g) and 21 C.F.R. § 171.1. Safe conditions of use for two of the substances highlighted in Plaintiff's Complaint, allyl isothiocyanate (i.e., the main chemical component of volatile oil of mustard) and olestra were first established through approval of those substances as food additives, prior to publication of the proposed rule. *See* 29 Fed. Reg. 14,624 (Oct. 27, 1964) and 21 C.F.R. § 172.515 (previously 21 C.F.R. § 121.1164) (mustard oil) and 61 Fed. Reg. 3,171 (Jan. 30, 1996) and 21 C.F.R. § 172.867; Declaration of Michael M. Landa ¶ 16a&b (attached hereto as Exhibit A).

Defendants submit the attached declaration in support of their argument that Plaintiff lacks standing. The Court may consider such materials in ruling on challenges to its subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1). *Herbert v. Nat'l Academy of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992). The declaration also includes information regarding FDA's timing goal for clearing the final rule in FDA, which is offered solely as background.

substance on the grounds that such foods are or contain an unlawful food additive. *See* 21 U.S.C. § 348(a) (deeming a food additive to be unsafe if the particular use of the food additive is not the subject of a regulation prescribing the conditions under which it can be safely used or an exclusion); 21 U.S.C. § 342(a)(2)(C) (deeming a food to be adulterated if it contains an unsafe food additive); 21 U.S.C. § 331(a)-(c)&(k) (prohibiting distribution of adulterated food).

The GRAS List

Shortly after the passage of the 1958 amendment to the FDCA, FDA published a list of food substances that, when used for the purposes indicated and in accordance with current good manufacturing practice, are GRAS. *See* Substances that are Generally Recognized as Safe, 24 Fed. Reg. 9,368 (Nov. 20, 1959). FDA later added to this "GRAS List" in subsequent rulemakings. *See* Substances Generally Recognized as Safe; Spices, Seasonings, Flavorings, Essential Oils, Oleoresins, and Natural Extractives, 25 Fed. Reg. 404 (Jan. 19, 1960); Substances that are Generally Recognized as Safe, 26 Fed. Reg. 3,991 (May 9, 1961). However, the GRAS list is not a comprehensive listing of all substances that are GRAS for their intended use. *See* 21 § C.F.R. 182.1(a).

In 1970, FDA announced that it was undertaking a comprehensive study of the substances on the GRAS List in order to "evaluate by current standards the available safety information regarding each item on the list." Food Additives; Eligibility of Substances for Classification as Generally Recognized as Safe in Food, 35 Fed. Reg. 18,623 (Dec. 8, 1970). The agency explained that it intended to "repromulgate each item in a new GRAS list or in a food additive regulation or in an interim food additive regulation pending completion of additional toxicity experiments." *Id.*

At the same time, FDA also proposed criteria to establish whether these food substances should be listed as GRAS, clarify the differences between GRAS status and food additive status, and describe the procedures being used to conduct the review of food substances. 35 Fed. Reg. at 18,623-24. These criteria were later incorporated into agency regulations and, after further modification, are presently found at 21 C.F.R. § 170.30. *See* 35 Fed. Reg. at 18,623; Eligibility of Substances for Classification as Generally Recognized as Safe in Food, 36 Fed. Reg. 12,093 (June 25, 1971); General Recognition of Safety and Prior Sanctions for Food Ingredients; Notice of Proposed Rulemaking, 39 Fed. Reg. 34,194 (Sept. 23, 1974). The final regulations (ultimately codified in 21 C.F.R. § 170.30) distinguish a determination of GRAS status through scientific procedures (scientific procedures GRAS determination; current § 170.30(b)) from a determination of GRAS status through experience based on common use in food (common use GRAS determination; current § 170.30(c)). *See* General Recognition of Safety and Prior Sanctions for Food Ingredients, 41 Fed. Reg. 53,600 (Dec. 7, 1976).

The GRAS Affirmation Petition Process

Because the agency's re-review of the substances on the GRAS List was not intended to cover all GRAS substances, FDA established a procedure through which an interested person can petition the Commissioner to review the GRAS status of a substance, or the agency may do so on its own initiative. GRAS and Food Additive Status; Proposed Procedures for Affirmation and Determination, 37 Fed. Reg. 6,207 (Mar. 25, 1972); *see also* GRAS and Food Additive Status Procedures, 37 Fed. Reg. 25,705 (Dec. 2, 1972). This voluntary administrative process provided a mechanism for "official recognition of lawfully made GRAS determinations." 62 Fed. Reg. at 18,941; *see* 21 C.F.R. § 170.35. No statute or regulation required FDA to establish or maintain

the GRAS affirmation petition process, and the petition process, like the notification process, is voluntary.

The procedures set forth in section 170.35 involve a resource-intensive rulemaking process, in which FDA would publish a notice in the Federal Register that a petition had been filed and request comments; conduct a comprehensive review of the petition's data and information as well as the comments received, in an effort to determine whether the evidence established that the substance was GRAS for the use set forth in the petition; and draft a detailed explanation of the GRAS determination for publication of a final rule in the Federal Register. 21 C.F.R. § 170.35(c). The use was then codified in the Code of Federal Regulations, *see, e.g.,* 21 C.F.R. Part 184, and if FDA later determines that changes are needed, the agency must go through a similar rulemaking process. In "many cases," companies that submitted GRAS petitions for FDA's review "began to market their products based on FDA's filing of their petition and well before FDA reached a decision on the GRAS status of the petitioned use." GAO Report at 60 (Appx IV: Comments from the FDA).

The GRAS Notification Process and the Interim Policy

FDA came to believe that the resource-intensive GRAS affirmation petition process was not only draining agency resources but also deterring "many persons from petitioning the agency to affirm their independent GRAS determinations." 62 Fed. Reg. at 18,941. As a result, in 1997, FDA published the proposed rule that is the subject of this litigation. There were two elements to the proposal. First, FDA proposed to revise 21 C.F.R. §§ 170.3(h) and 170.30 "to clarify when use of a substance is exempt from the [FDCA's] premarket approval requirements because such use is GRAS." 62 Fed. Reg. at 18,941.

Second, FDA proposed to replace the GRAS affirmation petition process set forth in 21 C.F.R. § 170.35(c) with a notification procedure in proposed § 170.36. In the proposed procedure, a person could notify FDA that he/she had determined that a particular use of a substance is GRAS. 62 Fed. Reg. at 18,941. This notification would include a "GRAS exemption claim" that would provide specific information about a GRAS determination in a consistent format, including a concise description of the substance that is the subject of the notice ("the notified substance"), the applicable conditions of use, and the basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food) and would be dated and signed by the person submitting the notice. In addition to the GRAS exemption claim, the notice would include detailed information about the identity and properties of the notified substance and a detailed discussion of the basis for the notifier's GRAS determination. *Id.* at 18,941.

FDA explained that, under the proposed notification procedure, the agency intended to evaluate whether the notice provides a sufficient basis for a GRAS determination, but the agency did "not intend to conduct its own detailed evaluation of the data that the notifier relies on . . . ." *Id.* Instead, the agency would determine "whether information in the notice or otherwise available to FDA raises issues that lead the agency to question whether use of the substance is GRAS." *Id.*[4] FDA cautioned that, because it would not "receive the detailed data and information that" supported the notifier's self-determination, the agency's response to a GRAS notice would not reflect a determination that the agency agrees the use of the substance is GRAS. *Id.* at 18,950-51. Moreover, as long as the company had self-determined that the substance is

[4] Over time, FDA developed three categories of response letters, which generally stated either that FDA has no questions, that the notice does not provide a basis for a GRAS determination, or that at the notifier's request, FDA ceased to evaluate the notice. GAO Report at 9 Table 1; First Am. Compl. ¶ 38.

GRAS, it would not automatically be prohibited from marketing the substance, even if FDA reviewed a GRAS notice for that substance and found that it "does not provide a sufficient basis for a GRAS determination." GAO Report at 9. In addition, even when the agency initially responds that it has no questions about a particular notified substance, under the proposed rule, the agency remains free to revisit the issue. Specifically, FDA explained that if it receives additional information raising questions about the safety of the notified substance, "FDA may subsequently advise the notifier and other interested parties of those questions." 62 Fed. Reg. at 18,951. If appropriate, FDA may also publish a notice in the Federal Register determining that the substance is not GRAS and consider enforcement action to remove a product that is an unapproved food additive from the market. *Id.*

FDA tentatively concluded that the proposed notification procedure has several advantages over the GRAS affirmation petition process. In particular, because "the proposed notice is simpler than a GRAS affirmation petition," FDA posited that manufacturers may have "an incentive . . . to inform FDA of their GRAS determinations," which "would result in increased agency awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances." *Id*. at 18,941. Also, the switch to the notification process would eliminate the resource-intensive rulemaking associated with the GRAS affirmation petitions, which would in turn allow FDA to redirect resources in several important ways. Specifically, FDA could redirect its resources to (1) addressing "questions about GRAS status that are a priority with respect to public health protection"; (2) preparing "documents that would provide the industry with guidance on certain food safety issues for complex substances (e.g., macroingredients or biological polymers, such as proteins, carbohydrates, and fats and

oils)"; and (3) performing the agency's "statutorily mandated task of reviewing food and color additive petitions." *Id.* at 18,941. Thus, FDA explained:

> [T]he substitution of the proposed notification procedure for the current GRAS petition process would not adversely affect the public health because the agency would be replacing one voluntary administrative process with a different voluntary administrative procedure that would utilize FDA's resources more effectively and efficiently. Under both the current and the proposed procedures, a manufacturer may market a substance that the manufacturer determines is GRAS without informing the agency or, if the agency is so informed, while the agency is reviewing that information. Thus, from a legal and regulatory perspective, this substitution is neutral.

Id. at 18,941-42.

In the proposed rule, FDA also announced an interim policy for how the agency would address GRAS notices during the period between publication of the proposed rule and issuance of any final rule based on the proposal. FDA invited persons who made a GRAS determination that a particular use of a substance is GRAS to notify the agency of those determinations under the framework in the proposed rule. *Id.* at 18,954. The agency said that it "would administer the notices" as described in proposed 21 C.F.R. § 170.36(d)-(f), but would not consider itself bound by the timeframe set out in the proposal. 62 Fed. Reg. at 18,954. FDA further explained that it would "determine whether its experience in administering" notices submitted in the interim period "suggests modifications to the proposed procedure" are necessary. *Id.* The agency also stated that persons who had submitted GRAS affirmation petitions could amend their pending petitions to GRAS notices. *Id.* at 18,954-55.

Comment Period Reopened in 2010

As FDA worked to develop a final rule based on the proposal, the agency determined that it should first reopen the comment period not only to update comments received on the entire rule due to the length of time that had passed since the proposal was published in 1997, but also

to solicit input on specific questions raised by the agency's experience in reviewing voluntarily submitted GRAS notices under the interim policy. Substances Generally Recognized As Safe; Reopening of the Comment Period, 75 Fed. Reg. 81,536 (Dec. 28, 2010). Between February 1, 1999 and December 31, 2009, FDA received approximately 26 GRAS notices per year about substances intended for use in human food.[5] *Id.* at 81,537.[6] Thus, FDA explained that, through its "experience with GRAS notices during the interim period," comments that were received on the proposal, and recommendations made by the Government Accountability Office,[7] the agency had "identified a number of issues" in the proposed rule that "may require further clarification." *Id.* at 81,537. As a result, the agency solicited input on more than a dozen specific issues, ranging from issues related to the proposed changes to the definitions in 21 C.F.R. §§ 170.3(h) and 170.30, to the GRAS notification procedure and the effect of the proposed notification procedure on existing GRAS petitions. *See generally id.* at 81,537-43. The comment period was reopened until March 28, 2011. *Id.* at 81,536.

FDA's efforts to respond to comments received on the proposed rule and complete the rulemaking process have been delayed based on other higher public health priorities, including the agency's effort to implement the Food Safety and Modernization Act of 2010 ("FSMA"), Pub. L. No. 111-353, 124 Stat. 3885 (2011), which requires the agency to issue more than seven rules, and various labeling and food ingredient initiatives. *See* Landa Declaration ¶¶ 13-15. Nevertheless, the process of preparing a final rule based on the proposed rule is already

[5] FDA's Center for Veterinary Medicine (CVM) established a pilot notification program for receiving and reviewing GRAS notifications for ingredients in animal food in 2010. Substances Generally Recognized as Safe Added to Food for Animals; Notice of Pilot Program 75 Fed. Reg. 31,800 (June 4, 2010).

[6] By comparison, FDA received on average eight GRAS affirmation petitions per year. *See* Landa Decl. ¶ 11.

[7] *See* GAO Report at 34-35.

underway. Although it is not feasible for FDA to predict with certainty when the final rule will publish, the agency has set a goal of clearing the rule in FDA not later than July 2016. *Id.* ¶ 15.

STANDARD OF REVIEW

Defendants, the Secretary of Health and Human Services and the Commissioner of Food and Drugs, move to dismiss Plaintiff's Complaint under Rule 12(b)(1) of the Federal Rules of Civil Procedure for lack of subject matter jurisdiction because Plaintiff lacks standing and because Plaintiff's claim is time-barred by 28 U.S.C. § 2401(a). Defendants also move to dismiss the Complaint under Rule 12(b)(6) because the agency action Plaintiff seeks to challenge is not "final agency action," and therefore Plaintiff has failed to state a claim under the APA.

In ruling on a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), the court must construe a plaintiff's complaint liberally, giving it the benefit of all favorable inferences that can be drawn from the alleged facts. *See Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). Notwithstanding these favorable inferences, the plaintiff bears the burden of proving that the court has subject matter jurisdiction to hear the case. *See Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); *see U.S. Ecology, Inc. v. DOI*, 231 F.3d 20, 24 (D.C. Cir. 2000). A court has an "affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). For this reason, the factual allegations in a plaintiff's complaint "'will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim.'" *Id*. at 13-14 (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1350 (2d ed. 1990)). In deciding a 12(b)(1) motion, a court need not limit itself to the allegations of the complaint, and it may consider such materials

outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction in the case. *Id.* at 14; *see Herbert v. Nat'l Acad. Of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992).

When ruling on a Rule 12(b)(6) motion to dismiss, a court must assume the veracity of all "well-pleaded factual allegations" in the complaint, but need not accept as true "'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)). Nor should the court accept "legal conclusions cast in the form of factual allegations." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994).

ARGUMENT

I. The Complaint Should be Dismissed Because Plaintiff Lacks Standing

Before the Court may exercise jurisdiction, it must assure itself that CFS has met the requirements for standing under Article III of the Constitution. *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Florida Audubon Soc'y* v. *Bentsen*, 94 F.3d 658, 661 (D.C. Cir. 1996) (en banc). The "irreducible constitutional minimum of standing" requires a plaintiff to demonstrate that it has "personally . . . suffered" an "actual or threatened injury" that may be "fairly . . . traced" to the challenged action, and will "likely [] be redressed by a favorable decision" by the court. *Lujan*, 504 U.S. at 560; *Florida Audubon*, 94 F.3d at 661; *Int'l Bhd. of Teamsters* v. *Transp. Sec. Admin.*, 429 F.3d 1130, 1133-34 (D.C. Cir. 2005). These three requirements "ensure[] that a litigant alleges such a personal stake in the outcome of the controversy as to warrant [*its*] invocation of federal-court jurisdiction." *Chamber of Commerce* v. *EPA*, 642 F.3d 192, 199 (D.C. Cir. 2011) (internal quotation marks omitted). Plaintiff bears the burden of establishing each of these elements, and the absence of any one of them defeats standing. *Lujan*, 504 U.S. at 561.

To satisfy the injury requirement, "the plaintiff must have suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (internal quotation marks, citations, and footnote omitted). A "concrete" injury is one that is "direct, real, and palpable – not abstract." *Pub. Citizen, Inc.* v. *Nat'l Highway Traffic Safety Admin.*, 489 F.3d 1279, 1292 (D.C. Cir. 2007). To be "particularized," the alleged injury must be "personal, individual, distinct, and differentiated – not generalized or undifferentiated." *Id.* An injury is "actual or imminent" only if it has already occurred or is "certainly impending and immediate – not remote, speculative, conjectural, or hypothetical." *Id.* at 1293.

In addition to these constitutional requirements, the Supreme Court has articulated a "set of prudential principles that bear on the question of standing" and limit courts from exercising judicial power under certain circumstances. *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 474 (1982). These principles include that a plaintiff cannot rest his claim to standing on the rights and interests of third-parties. *Id.*; *see also Lujan*, 504 U.S. at 562. Nevertheless, an organization may have standing to assert the claims of its members, even where the organization itself has suffered no injury from the challenged activity, under a theory of "associational standing," provided that "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Nat'l Ass'n of Home Builders v. EPA*, 667 F.3d 6, 12 (D.C. Cir. 2011) (internal citations and quotation marks omitted); *Int'l Bhd. of Teamsters*, 429 F.3d at 1135.

Plaintiff has not alleged an injury that is caused by the proposed rule or that would be redressed by a favorable decision by this Court. Unable to show injury-in-fact, causation, or redressability, Plaintiff cannot maintain this action.

A. Plaintiff Has Not Alleged A Particularized or Concrete Injury-in-Fact to It or Any Identified Members of its Organization

Plaintiff attempts to show that it has standing to bring this action by alleging injuries to its own procedural due process rights and those of a third party, as well as injuries based on speculation about potential risks to the health and safety of unidentified individual members of CFS. *See* First Am. Compl. ¶¶ 65-70. For the reasons shown below, Plaintiff has not satisfied the requirements of standing for any of these alleged injuries.

1. Plaintiff's Claimed Procedural Injuries Do Not Support Standing

Plaintiff alleges two procedural injuries, neither of which is sufficient to confer standing. Plaintiff first claims that its interests and "procedural due process rights" are "adversely affected by FDA's decision to implement a rule without following the notice-and-comment rulemaking procedures mandated by the APA." First Am. Compl. ¶ 66. It is well established, however, that "deprivation of a procedural right without some concrete interest that is affected by the deprivation -- a procedural right *in vacuo* -- is insufficient to create Article III standing." *Summers v. Earth Island Inst*., 555 U.S. 488, 496 (2009); *Food and Water Watch v. EPA*, Civ. No. 12-1639, 2013 U.S. Dist. LEXIS 174430 *24 n.7 (Dec. 13, 2013); *see New York Reg'l Interconnect, Inc. v. FERC*, 634 F.3d 581, 587 (D.C. Cir. 2011) (the "omission of a procedural requirement does not, by itself, give a party standing to sue.") (citing *Ctr. for Biological Diversity v. U.S. Dep't of Interior*, 563 F.3d 466, 479 (D.C. Cir. 2009)). Instead, even where a plaintiff has alleged a procedural defect, he or she must show the procedural injury "impair[s] a separate concrete interest." *See Lujan*, 504 U.S. at 572; *Int'l Bhd. of Teamsters*, 429 F.3d at

1135 ("mere inability to comment effectively or fully, in and of itself, does not establish an actual injury," and plaintiff still must "show it has itself suffered personal and particularized injury.") (internal quotation omitted); *Fla. Audubon*, 94 F.3d at 664-65 ("[A] prospective plaintiff must demonstrate that the defendant caused the particularized injury, and not just the alleged procedural violation."). Plaintiff has not alleged an impairment to its concrete interests, and thus its conclusory allegation of harm based on a violation of procedural due process does not establish standing.

Plaintiff's second procedural claim fares no better. Plaintiff claims that *its* "procedural due process rights" are "adversely affected by Defendants' failure to respond" to comments that were submitted to FDA during the 1997 comment period by another organization, the International Center for Technology Assessment (ICTA),[8] which Plaintiff terms its "programmatic predecessor." First Am. Compl. ¶ 47. As with its first claim of procedural injury, this allegation fails to show how FDA's alleged failure to respond to ICTA's comments causes a concrete injury to Plaintiff.[9] Indeed, Plaintiff does not define "programmatic predecessor," and the term bears no meaning in any search of federal case law.

Nor can Plaintiff litigate this case to redress alleged injuries to ICTA. Plaintiff's attempt to establish an injury based on Defendants' alleged failure to respond to another organization's comments fails the long-established prudential limitation on standing that "plaintiff generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties." *Valley Forge*, 454 U.S. at 474 (rejecting suit for lack of

[8] ICTA is another non-profit organization, which was founded in 1994 and remains in existence today. *See* http://www.icta.org/about/ (last viewed Apr. 19, 2014).

[9] CFS has never submitted any comments, either during the 1997 comment period or during the more recent 2010-2011 comment period, even though it was founded in 1997, First Am. Compl. ¶ 13.

standing where organization sought to raise the rights of taxpayers); *see also Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 12 (2004) (the "prudential dimensions of the standing doctrine" include "'the general prohibition on a litigant's raising another person's legal rights . . . .'") (quoting *Allen v. Wright*, 468 U.S. 737, 751 (1984)).[10]

2. Plaintiff Cannot Establish an Injury based on Speculative Claims About Increased Risk to Health of Unidentified Members

In addition to its flawed claims of procedural injury, Plaintiff claims its members have "purchased or consumed substances allowed to be used in food under the proposed rule that may pose serious risks to human health." First. Am. Compl. ¶ 68. This alleged injury cannot support standing because Plaintiff has failed to identify a single member of its association who has suffered the alleged injury and, in any event, the claimed injury is too speculative to satisfy the injury-in-fact requirement.

As noted above, an association has standing to sue on behalf of its members only if, *inter alia*, "at least one of its members would have standing to sue in his own right." *Chamber of Commerce*, 642 F.3d at 199 (citing *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002)). Although Plaintiff alleges as injury that its members are at increased "risk of harm to . . . health and safety" as a result of "purchas[ing] and consum[ing] substances allowed to be used in food under the proposed rule," First Am. Compl. ¶ 68, Plaintiff fails to identify any specific members "who have suffered the requisite harm." *Chamber of Commerce*, 642 F.3d at 199-200.

When an organization "claims associational standing, it is not enough to aver that unidentified members have been injured." *Id.* Instead, to establish standing, Plaintiff must

[10] Plaintiff has not alleged that there is any "hindrance" to ICTA's ability to protect is own interests. *See Rumber v. District of Columbia*, 595 F.3d 1298, 1301 (D.C. Cir. 2010) ("A plaintiff must ordinarily assert his own legal interests, rather than those of third parties. A plaintiff may assert the rights of a third party only when there is some hindrance to the third party's ability to protect his or her own interests") (internal citations and quotations omitted).

specifically "identify members who have suffered the requisite harm." *Id*. at 199 (quoting *Summers*¸ 555 U.S. at 499); *Am. Chemistry Council v. Dep't of Transp*., 468 F.3d 810, 820 (D.C. Cir. 2006) ("an organization bringing a claim based on associational standing must show that at least one specifically-identified member has suffered an injury-in-fact. . . . At the very least, the identity of the party suffering an injury in fact must be firmly established."). Because Plaintiff fails to identify a single member who has allegedly suffered any injury purportedly caused by the proposed rule, the Complaint should be dismissed. *See Chamber of Commerce*, 642 F.3d at 200 ("Because the Chamber has not identified a single member who was or would be injured by EPA's waiver decision, it lacks standing to raise this challenge."); *see also Am. Chemistry Council.*, 468 F.3d at 820 (requiring organization asserting associational standing to show at least one "specifically-identified member has suffered an injury-in-fact").

Even if an allegedly injured CFS member were identified, the alleged injury is, by Plaintiff's own terms, speculative:

> The proposed rule has allowed or expanded the use of *potentially* unsafe substances in the market, thereby *increasing the risk of* harm to the health and safety of Plaintiff's members. Plaintiff's members have purchased or consumed substances allowed to be used in food under the proposed rule that *may pose* serious risks to human health.

First Am. Compl. ¶ 68 (emphasis added); *see also id.* ¶ 69 ("potentially unsafe substances"); *id.* ¶ 14 ("potentially harmful substances"). Injury is not sufficiently imminent or concrete where a plaintiff can "only aver that any significant adverse effects . . . *may* occur at some point in the future." *Ctr. for Biological Diversity v. Dep't of Interior*, 563 F.3d 466, 478 (D.C. Cir. 2009) (rejecting as insufficient alleged injury that "climate change might occur" as a result of the challenged agency action). Rather, the D.C. Circuit has "allowed standing" based on increased risk of harm "'when there was at least *both* (i) a *substantially* increased risk of harm and (ii) a

substantial probability of harm with that increase taken into account.'" *Public Citizen Inc. v. Nat'l Highway Traffic Safety Admin.*, 513 F.3d 234, 237 (D.C. Cir. 2008) (quoting *Public Citizen, Inc. v. Nat'l Highway Traffic Safety Admin*, 489 F.3d at 1295) (emphasis in original). The Complaint's allegations of *potential* risks that the food substances *may* pose does not satisfy the injury-in-fact requirement.

Moreover, even if Plaintiff were to identify a member who suffered an injury in the past, that claim cannot support the requested injunctive relief because Plaintiff has not "establish[ed] a real and immediate threat that the harm-producing conduct will recur." *Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (stating that "a plaintiff who seeks prospective injunctive relief cannot establish standing based on past harm alone"). For any members who have actually suffered an injury, Plaintiff must show that the injury will recur in order to have standing. *See NB ex rel. Peacock v. D.C.*, 682 F.3d 77, 82 (D.C. Cir. 2012) ("Because plaintiffs seek only forward-looking injunctive and declaratory relief, past injuries alone are insufficient to establish standing and plaintiffs must show that they suffer an ongoing injury or face an immediate threat of injury.") (citations omitted).

Because Plaintiff has not alleged an injury-in-fact, its Complaint should be dismissed.

B. Plaintiff Lacks Standing Because The Proposed Rule Does Not Cause the Alleged Injuries From Consumption of Food Substances

Even assuming that Plaintiff is able to identify specific members of its organization who allegedly have suffered an actual or certainly impending injury, the Complaint should be dismissed because Plaintiff is unable to meet its burden to show that this alleged injury "fairly can be traced to the challenged action of the defendant[s], and [is] not injury that results from the independent action of some third party not before the court." *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41 (1976); *see also Allen*, 468 U.S. at 757. The challenged agency action—

failure to adhere to the APA's notice and comment rulemaking requirement in announcing the proposed rule—did not cause the alleged injuries because the proposed rule did not "allow" the substances Plaintiff identifies (volatile oil of mustard, olestra, and mycoprotein) or any other substance, to enter into the market.[11]

In an effort to substantiate its theory of causation, plaintiff repeatedly misstates the proposed rule's function as "allowing" products to be marketed or "exempting" them from regulation as food additives. *See, e.g.,* First Am. Compl ¶ 65 ("continued operation under the proposed rule[] . . . allows hundreds of GRAS substances to be placed in food"); *id.* ¶ 3 (the proposed rule "exempts substances from food additive regulations"); *id.* ¶ 6 ("two GRAS notifications submitted under the proposed rule . . . have expanded the ranges of GRAS uses of Olestra"); *id.* p.17 (referring to "Uses Approved as GRAS Under the Proposed Rule"); *see also id.* ¶¶ 1, 4, 6-7, 38, 62, 68-69. This is simply incorrect.

The GRAS notification program announced in the proposed rule does not allow or authorize food substances to enter the food supply. As discussed *supra* at 5-6, under the FDCA any entity may determine that a use of a substance is GRAS and sell the substance in food without notifying, much less obtaining approval from, FDA. The FDCA does not require that FDA be notified of such a determination through a GRAS notice (or any other notice) to the agency, and a substance that is GRAS for a particular use is excluded from the definition of "food additive" and therefore does not require premarket approval by FDA. For those who choose to participate, as discussed *supra* at 9-10, the GRAS notification program announced in

[11] In fact, as noted *supra*, volatile oil of mustard and olestra were marketed for certain uses before the proposed rule was published in 1997. *See* First Am. Compl. ¶ 6 ("Olestra was originally approved by FDA as a food additive in 1996 for limited use in savory snacks such as corn chips."); 21 C.F.R. § 182.20 (listing mustard oil as generally recognized as safe) (cited in FDA Response Letter to GRAS Notice No. GRN 000133 (Jan. 5, 2004) and referenced in First Am. Compl. fn 10). Landa Decl. ¶ 16a&b.

the proposed rule serves as a voluntary mechanism for manufacturers and other third parties to submit to FDA information regarding their own independent determinations that a substance is GRAS for a particular use. Even if a manufacturer chooses to submit a GRAS notice to the agency, it need not await the agency's response to market the substance. After reviewing the GRAS notice, FDA informs the manufacturer whether the agency has questions about the manufacturer's self-determination.

Contrary to Plaintiff's assertions (*e.g.*, First Am. Compl. ¶ 38), a "no questions" response letter does not mean that FDA has "allowed" the substance to be used in food or "exempted" it from the definition of "food additive." *See* 62 Fed. Reg. at 18,952; *Id.* at 18,950-51 (cautioning that because the agency would not "receive the detailed data and information that" supported the notifier's self-determination, the agency's response to a GRAS notice would not reflect a determination that the agency agrees the use of the substance is GRAS). The "no questions" letters make this point clear, stating that FDA "*has not . . . made its own determination* regarding the GRAS status of the subject use" and reminding the manufacturer of its "continuing responsibility . . . to ensure that food ingredients" it "markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements." *See, e.g.,* FDA Response to GRAS Notice No. GRN 000180 (March 16, 2006) (cited in First Am. Compl. ¶ 55 n.10 and *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm154629.htm) (emphasis added); FDA Response to GRAS Notice No. GRN 000227 (olestra) (cited in First Am. Compl. ¶ 62 and n.23 and *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm153886.htm). Even Plaintiff acknowledges that under the GRAS notification program outlined in the

proposed rule "FDA no longer affirms whether or not a substance's use is GRAS at all . . . ." First Am. Compl. ¶ 38.

In short, despite Plaintiff mischaracterizing the proposed rule, it does not serve a gatekeeping function that authorizes use of food substances. Manufacturers distribute their food substances based on their own independent determinations that those substances are GRAS for the uses at issue, not because the proposed rule "allows" their distribution. As a result, even assuming *arguendo* that Plaintiff could show its members have an actual or impending injury from consumption of potentially harmful substances in food, that injury was caused by the decisions of manufacturers to distribute food containing those ingredients. Plaintiff cannot show that this injury "fairly can be traced to the challenged action of the defendant[s], and [is] not injury that results from the independent action of some third party not before the court." *Simon*, 426 U.S. at 41-42; *see Lujan*, 504 U.S. at 562 (finding that standing is "substantially more difficult" to establish when injury arises from a non-party). Because the alleged injury is not caused by the challenged agency action, Plaintiff lacks standing.

C. Vacating the Proposed Rule Would Not Redress the Alleged Injury

Plaintiff also fails to satisfy the redressability requirement of standing. Plaintiff must show that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 561 (quotation marks omitted). Where, as here, the plaintiff "is not the object of an alleged government action or inaction," it is "ordinarily 'substantially more difficult' to establish" standing because redressability, like causation, frequently turns on the actions of "independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict." *Id.* at 562 (quoting *Allen,* 468 U.S. at 758 and *ASARCO, Inc. v. Kadish*, 490 U.S. 605, 615 (1989)

(opinion of Kennedy, J.)). As a result, Plaintiff bears the burden "of adduc[ing] facts showing that those [third-party] choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.*

To remedy its alleged injury (i.e., potential risk of harm to its members from purchasing and consuming volatile oil of mustard, olestra, mycoprotein, and other allegedly "potentially unsafe" food substances that are marketed under the GRAS exclusion), Plaintiff requests that the Court declare that the proposed rule was issued in violation of the APA, vacate the proposed rule, "reinstat[e]" the GRAS affirmation process (discussed *supra* at 8-9),[12] and issue such other injunctive relief as the Court deems necessary. First Am. Compl. at 23. The requested relief would not redress the alleged injury because the GRAS affirmation petition process, like the GRAS notification process, is a voluntary program, not a mandatory system of premarket approval, and because redress of the alleged injury would depend on the independent choices of third parties (i.e., those who market the substances). Plaintiff cannot meet its burden of showing that independent actors will make choices "in such manner as to . . . permit redressability of [its alleged] injury," *Lujan*, 504 U.S. at 562, and thus its Complaint should be dismissed. *See Nat'l Wrestling Coaches Ass'n v. Dept. of Educ.*, 366 F.3d 930, 938 (D.C. Cir. 2004) (affirming

[12] Although Plaintiff asks this Court to issue an order "reinstating the GRAS rule previously in force," the regulation setting forth the GRAS affirmation process has not been withdrawn and remains in the Code of Federal Regulations. FDA has proposed to withdraw portions of 21 C.F.R. § 170.35 as part of the proposed rule challenged here. *See* 62 Fed. Reg. at 18,945. As discussed *supra* at 11-12, FDA explained that it was proposing to eliminate the GRAS affirmation process "in order to increase effectiveness and efficiency" and that it would "not continue to commit resources to review of a GRAS affirmation petition" during the interim period between publication of the proposed rule and issuance of any final rule based on the proposal. *Id.* at 18,954-55. Thus, the relief that Plaintiff is actually seeking is an order compelling FDA to devote considerable resources to a program that the agency found to be inefficient and was under no obligation to establish.

dismissal of suit where plaintiffs failed to show that third parties would behave in a specific manner if requested relief was granted).

Plaintiff's theory of redressability requires the following chain of events to occur: (1) a manufacturer of a potentially unsafe food substance that nevertheless believes its food substance is GRAS will opt to prepare and submit a GRAS affirmation petition to FDA; (2) FDA will determine that the substance is not GRAS for the use described in the petition; and (3) either the manufacturer will voluntarily decide to refrain from marketing the substance *or* FDA will recommend enforcement action to the Department of Justice, which will agree to file and then prevail in such an enforcement action. We address each of these issues in turn.

It is pure speculation that a manufacturer would submit a GRAS affirmation petition to FDA for review for any given substance. Plaintiff candidly admits that what it really wants FDA to establish is a mandatory premarket approval system for GRAS determinations: "CFS and its members believe it is imperative that FDA promotes a responsible approach to the *approval* of substances as GRAS and *require* a thorough, independent review and analysis of all scientific evidence prior to *granting* GRAS status to any substance." First Am. Compl. ¶ 17 (emphasis added). The GRAS affirmation petition process Plaintiff asks this Court to reinstate is not such a system.[13]

As described *supra* at 8-9, the GRAS affirmation petition process, like the GRAS notification process, was a *voluntary* administrative process that provided a mechanism for "official recognition of lawfully made GRAS determinations." *See* 62 Fed. Reg. at 18,941; 21 C.F.R. § 170.35. It involved a "resource-intensive rulemaking process." 62 Fed. Reg. at 18,941.

[13] In fact, in "many cases," companies that submitted GRAS petitions for FDA's review "began to market their products based on FDA's filing of their petition and well before FDA reached a decision on the GRAS status of the petitioned use." GAO Report at 55 (Appx IV: Comments from the FDA).

Because the GRAS affirmation petition process was both burdensome and often lengthy,[14] Plaintiff cannot show that it is "likely" manufacturers of substances like volatile oil of mustard, olestra, mycoprotein, or any other substance would avail themselves of it. *See* 62 Fed. Reg. at 18,941 (FDA believes the GRAS affirmation petition process actually "deters many persons from petitioning the agency to affirm their independent GRAS determinations").[15] Indeed, there is little incentive for manufacturers to do so.

Plaintiff's inability to show that it is "likely" a given manufacturer would submit a GRAS affirmation petition is illustrated by the agency's experience with the two programs. One of the specific advantages FDA identified in announcing the GRAS notification process in the proposed rule was that it would "provide an incentive for manufacturers to inform FDA of their GRAS determinations," "result[ing] in increased agency awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances." 62 Fed. Reg. at 18,941.

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[14] *See* P. Gaynor, R. Bonnette, E. Garcia, Jr., L. Kahl, and L. Valerio, Jr., FDA's Approach to the GRAS Provision: A History of Processes (Apr. 2006), *available at* http://www.fda.gov/food/ingredientspackaginglabeling/gras/ucm094040.htm ("In general, industry-sponsored GRAS affirmation petitions completed" after 1990 took more than 72 months, whereas the mean time to respond to GRAS notices completed between 1998 and 2005 was 162 days); *see also* 62 Fed. Reg. 18,958 ("The proposed notification procedure will come to closure more quickly and generate less uncertainty than the GRAS petition process because the notification procedure is based on a 90-day review period rather than on the open-ended review period of the GRAS petition process. In some cases, the GRAS petition process involves a number of iterative steps in which FDA asks for and receives additional supporting information.").

[15] This is particularly true with respect to volatile oil of mustard, olestra, and mycoprotein. FDA has established safe conditions of use for olestra and volatile oil of mustard for specific uses through the food additive petition process. *See* 21 C.F.R. §§ 172.515, 172.867. Landa Decl. ¶ 16a&b. FDA also has responded with "no questions" letters for all three substances for particular uses, under the GRAS notification program. First Am. Compl. ¶¶ 55, 62-63. It is pure speculation whether, if this Court "reinstated" the GRAS affirmation process, the manufacturers of any of these substances would choose to revisit, via the GRAS affirmation petition process, the GRAS status for any use that was already described in a GRAS notification, or whether they would submit GRAS affirmation petitions if they later conclude their substances are GRAS for additional uses.

This proved correct. In the twelve-year period preceding publication of the proposed rule (*i.e.*, 1987 to 1996), FDA received a total of fewer than 100 GRAS affirmation petitions, averaging about 8 petitions per year. Landa Decl. ¶ 11. But in the twelve-year period following publication of the proposed rule (*i.e.*, 1998 through 2009), FDA filed a total of 310 GRAS notices, averaging approximately 26 per year. *See* 75 Fed. Reg. at 81,537. Therefore, reverting to the GRAS affirmation process would actually make it *less likely* that manufacturers would submit any information at all to FDA regarding substances they have determined are GRAS for a particular use. *See Lujan*, 504 U.S. at 561 (noting the general rule that "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision") (internal quotation marks omitted).

The second and third actions in Plaintiff's chain of events for redress of its injury likewise involve speculation. What conclusion FDA would reach about a hypothetical GRAS affirmation petition is, of course, pure speculation.[16] If, hypothetically, the agency concludes that a given substance is not GRAS, then removal of the substance from the market is not automatic. What happens next depends in part on the choices of third parties. The manufacturer may or may not voluntarily decide to refrain from marketing the substance. If not, even assuming FDA concludes that removal of the substance from the market is a sufficiently high enforcement priority to warrant action, the agency can only *recommend* enforcement action to the Department of Justice, because actions to enforce the FDCA under 21 U.S.C. §§ 332, 333, & 334, are brought in the name of the United States, 21 U.S.C. § 337(a). DOJ would then have to complete its own review of the matter to determine whether to file an enforcement action, and it

[16] It is also possible that the substance could instead be approved as a food additive, even if it cannot qualify as GRAS for the use at issue. In that event, the substance might still be approved under the food additive petition process and enter the market as a food additive—as olestra and volatile oil of mustard did. *See* Landa Decl. ¶ 16a&b; First Am. Compl. ¶ 16.

"may or may not accept [FDA's] recommendation." *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-99 (1950).

"Redressability must be satisfied *now* to establish jurisdiction." *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438, 442 (D.C. Cir. 1999) (rejecting appellant's claims on standing grounds because redressability could only be accomplished through two contingent steps) (emphasis in original). In order for Plaintiff to establish that the alleged injury is redressable by the requested relief, it would have to show that third parties (e.g., manufacturers) would likely take a specific course of action, and that the agency, in response, would likely take two specific courses of action. Plaintiff's theory depends upon a combination of at least three hypothetical events, and as a result, it lacks standing. *See id.* at 441-42; *see also St. John's United Church of Christ v. FAA*, 520 F.3d 460, 463 (D.C. Cir. 2008) (finding no standing where petitioners' complained-of injuries would not be redressed by the requested relief: "[I]t is entirely conjectural whether nonagency activity that affects [petitioners] will be altered or affected by the agency activity they seek to overturn.") (quoting *Lujan*, 504 U.S. at 571).

For all of these reasons, Plaintiff does not have standing to bring this suit, and its Complaint should be dismissed.

II. The Proposed Rule Is Not Final Agency Action and Therefore Is Not Subject to Judicial Review

Even if CFS could meet the standing requirements, its claim would still fail as a matter of law. The APA limits judicial review to "final" agency action for which there is no other adequate remedy in court. 5 U.S.C. § 704. Thus, finality is a threshold question that determines whether judicial review is available. *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006). To satisfy the APA's finality requirement, two conditions must be present. First, "the action must mark the consummation of the agency's decision-making

process," and "must not be of a merely tentative or interlocutory nature." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal quotation marks and citation omitted). Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 178 (internal citation and quotation omitted); *see Holistic Candlers and Consumers Ass'n v. FDA*, 664 F.3d 940, 943 (D.C. Cir. 2012).

The finality requirement in 5 U.S.C. § 704 reflects the strong interest in postponing judicial review when an agency's position is, as here, still tentative. Permitting challenge only to "final" agency action "conserves both judicial and administrative resources to allow the required agency deliberative process to take place before judicial review is undertaken." *Reliable Automatic Sprinkler v. CPSC*, 324 F.3d 726, 733 (D.C. Cir. 2003).

The proposed rule satisfies neither of the conditions that must be present for agency action to be considered "final."

A. The Proposed Rule Does Not Reflect the Consummation of the Agency's Decisionmaking Process

Plaintiff cannot show that the proposed rule marks the "consummation" of the agency's decisionmaking process. A *proposed* rule, by definition, is tentative in nature and is subject to further consideration and modification. FDA remains free to choose not to adopt the proposal or to substantially revise it—and indeed may revise it in a way that addresses Plaintiff's alleged concerns. If the agency chooses to issue a final rule based on the proposal, the agency will do so only after considering the public comments it has received.

Plaintiff's suggestion that FDA has treated the proposed rule as "final" is not correct. The agency has always understood the *proposed* rule to be just that. The agency solicited comments on the proposal when it was published, and received and reviewed voluntarily submitted GRAS notices as an "interim" approach for the period between issuance of the

proposed rule and any final rule based on the proposal. 62 Fed. Reg. at 18,954. The agency described its plan to use experience in administering GRAS notices to determine whether modifications to the proposed notification procedure were needed. *Id.*; *see also* First Am. Comp. ¶ 39 (alleging that FDA "created an option for manufacturers needing additional guidance to request consultation with FDA 'because such consultation may identify sections of the proposed procedure that may require clarification in any final rule based on the proposal.'") (citing 62 Fed. Reg. at 18,955). Moreover, in 2010, FDA made clear that the proposed rule remained a work in progress, explaining that the agency had identified a number of issues within the scope of the proposed rule that may require further clarification. 75 Fed. Reg. at 81,537. The agency requested comments on the entire 1997 proposed rule but also solicited comments on more than a dozen specific issues. *Id*. FDA assured that before it would issue any final rule, the agency also would consider any comments that were received prior to the reopening of the comment period, even if submitted after the initial comment period closed on July 16, 1997. *Id.* Clearly, in FDA's view, this proposal is not final.

In addition, FDA has expressed its intent to finalize the rule. In response to an inquiry from the Government Accountability Office in 2009, FDA explained: "FDA agrees with GAO's recommendation to finalize the GRAS proposal on a timeframe that is in keeping with FDA's other public health and rulemaking priorities." GAO Report at 65 (Appx. IV: Comments from FDA) (stating that the agency anticipated reopening the comment period prior to the issuance of a final rule, which it did in December 2010).

In short, FDA has not taken a definitive legal position with respect to the issues in the proposed rule, and the proposal remains subject to further consideration and modification. *Compare Alaska Dept. of Envtl. Conservation v. EPA*, 540 U.S. 461, 483 (2004) (EPA's decision

was "final" because the agency had stated its final position on the issue) *with Florida Power & Light Co. v. EPA*, 145 F.3d 1414, 1418-19 (D.C. Cir. 1998) ("that EPA is still in the process of clarifying the scope of its own corrective action authority is evidenced by the fact that it has yet to promulgate final rules on many of the issues addressed in the . . . proposed rule"). Because FDA is in the middle of a process that has not reached its end, the proposed rule does not represent the consummation of the decisionmaking process and cannot be challenged as "final agency action."[17]

B. Legal Consequences Do Not Flow from the Proposed Rule and It Does Not Determine Rights and Obligations

Even if Plaintiff could show that the proposed rule marks the consummation of FDA's decisionmaking process, this suit still must be dismissed because Plaintiff cannot show that the proposed rule determines rights or obligations or that legal consequences flow from it. *Bennett*, 520 U.S. at 178. The GRAS notification program is voluntary: FDA did not have to create it and no one is required to participate. Moreover, even when a GRAS notice is submitted to and reviewed by the agency, FDA's response has no binding legal effect on either the submitter or the agency. Because the proposed rule does not "impose[] an obligation, den[y] a right, or fix[]

[17] Courts have held in a variety of contexts that proposed rules have no binding legal effect and are not final actions. *See, e.g., United States v. Springer*, 354 F.3d 772, 776 (8th Cir. 2004) (a "major purpose of formal rulemaking is to ensure that agencies gather as much relevant information as possible before promulgating final rules that will have the force and effect of law. For this reason, an agency that exercises its discretion to propose a rule has no duty to promulgate its proposal as a final rule. Thus, it is well-settled that proposed regulations . . . have no legal effect.") (internal quotation omitted); *Center for Law & Educ. v. U.S. Dep't of Educ.*, 209 F. Supp. 2d 102, 111 (D.D.C. 2002) ("[i]t is the final rule which will mark the consummation of the agency's decisonmaking process and set forth the agency's definitive position") (internal quotations omitted); *Nat'l Wildlife Fed. v. Mosbacher*, 1989 U.S. Dist. LEXIS 9748 (D.D.C. Aug. 14, 1989) ("The substance of the Secretary's new proposed regulation is not properly before the Court, as there is obviously no 'final' agency action for the Court to review."); *Blackfeet Nat'l Bank v. Rubin*, 890 F. Supp. 48, 54 (D.D.C. 1995) ("Based on the fact that the proposed regulations are just that - proposed - the Court finds that there has been no final agency decision within the meaning of the APA.").

some legal relationship," it does not represent "final" agency action under the APA. *Reliable Automatic Sprinkler*, 324 F.3d at 731.

The GRAS notification process does not satisfy the second prong of the test for final agency action because it is entirely voluntary for both FDA and the participants. As discussed *supra* at 5-6, if a manufacturer independently determines that a substance is GRAS for a particular use, the manufacturer can market the substance not only without first seeking FDA's review and approval but also without even informing the agency of its determination. 62 Fed. Reg. at 18,942; *see also* First Am. Compl. ¶ 28 ("A substance that is GRAS for a particular use may be marketed for that use without the formal FDA review and premarket approval required for other food additives."). And, the statute does not require FDA to establish *any kind of a process*, let alone a particular type of process, by which manufacturers can "check in" with the agency before acting on their independent GRAS determinations.[18] Thus, the GRAS affirmation petition process FDA established in the 1970s was entirely voluntary for both FDA and industry, and the GRAS notification program set forth in the proposed rule simply proposes to replace one voluntary program with another. The proposed rule therefore does not impose any obligations on FDA or industry.

Moreover, as discussed *supra* at 22-23, FDA's responses to the GRAS notices it receives and reviews under the proposed rule and interim policy have no binding effect on FDA or industry, and no legal consequences flow from them. If FDA reviews a voluntarily-submitted GRAS notice and issues a letter indicating that it has "no questions" about the notice, FDA's letter does not represent an agency decision on the GRAS status of that substance. 62 Fed. Reg.

[18] By comparison, the statute provides a process for petitioning the agency to issue a regulation prescribing the conditions under which a food additive (i.e., a substance that is not GRAS) may be safely used. *See* 21 U.S.C. § 348(b). In addition, the statute was amended in 1997 to provide a notification process for food contact substances. *See* 21 U.S.C. § 348(h).

at 18,952; *Id.* at 18,950-51 (cautioning that because the agency would not "receive the detailed data and information that" supported the notifier's self-determination, the agency's response to a GRAS notice would not reflect a determination that the agency agrees the use of the substance is GRAS); *see also* First Am. Compl. ¶ 38 ("FDA no longer affirms whether or not a substance's use is GRAS at all . . . ."); FDA Response to GRAS Notice No. GRN 000180 (March 16, 2006) (cited in First Am. Compl. ¶ 55 n.10 and *available at* http://www.fda.gov/Food/Ingredients PackagingLabeling /GRAS/NoticeInventory/ucm1.htm) (FDA's "no questions" letter for volatile oil of mustard cautions "[t]he agency has not, however, made its own determination regarding the GRAS status of the subject use of VOM. As always, it is the continuing responsibility of Mitsubishi to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.").

Nor does a "no questions" response preclude FDA from later questioning whether the substance at issue is truly GRAS. Thus, if FDA receives additional information raising questions about the safety of the notified substance, "FDA may subsequently advise the notifier and other interested parties of those questions," and take such other action as the agency deems appropriate. 62 Fed. Reg. at 18,951 (explaining that FDA may publish a notice in the Federal Register determining that the substance is not GRAS, and consider enforcement action to remove a product that is an unapproved food additive from the market).

Similarly, even if FDA concludes that the GRAS notice does not provide a sufficient basis for a GRAS determination, FDA's "insufficient basis" response does not constitute a legally binding determination that automatically prohibits the manufacturer from marketing a substance that the manufacturer has independently determined to be GRAS. 62 Fed. Reg. at 18,951; *see also* GAO Report at 9 (as long as the company has self-determined that the substance

is GRAS, it may market the substance, even if FDA reviewed a GRAS notice for that substance and found that it "does not provide a sufficient basis for a GRAS determination.").[19] Because the challenged agency action is not one by which rights or obligations are determined or from which legal consequences flow, it is not final agency action and cannot be challenged under the APA. Accordingly, Plaintiff's Complaint must be dismissed for failure to state a claim.

C. Plaintiff's Challenge to the Proposed Rule is a Procedural Attack that Is Barred by the Statute of Limitations

Because the proposed rule is not final, it is not subject to judicial review for the reasons discussed above. If, however, the Court accepts Plaintiff's characterization of the proposed rule as final agency action, then the time for challenging the proposed rule as procedurally defective based on FDA's alleged failure to respond to comments on the proposal has passed. Because Plaintiff's claim was filed well beyond the six-year statute of limitations in 28 U.S.C. § 2401(a), it must be dismissed for lack of subject matter jurisdiction.

The United States enjoys sovereign immunity, and thus Congress can set the conditions under which the United States may be sued. *United States v. Mitchell*, 463 U.S. 206, 212 (1983) ("It is axiomatic that the United States may not be sued without its consent and that the existence of consent is a prerequisite for jurisdiction."). One such condition is a statute of limitations.

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[19] As noted *supra* at 21-22, Plaintiff attempts to elide this defect in its claim by repeatedly mischaracterizing the GRAS notification program as "allowing" products to be marketed or "exempting" them from regulation as a food additive. These statements are legal conclusions, not allegations of fact that must be presumed to be true for purposes of this motion. *Kowal*, 16 F.3d at 1276 (court should not accept "legal conclusions cast in the form of factual allegations."). They also are incorrect legal conclusions for the reasons stated above. Moreover, to the extent Plaintiff intends these statements as allegations regarding the *practical* consequence of FDA's review of GRAS notices, they still cannot show that there has been final agency action by FDA. *Holistic Candlers*, 664 F.3d 944 n.5 ("the law is clear that 'practical consequences . . . are insufficient to bring an agency's conduct under our purview'") (quoting *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 428 (D.C. Cir. 2004)); *Reliable Automatic Sprinkler*, 324 F.3d at 732 (where agency action had no legal consequence, court refused to find the action "final" based on practical consequences).

Plaintiff's APA claims are governed by the "catch-all" statute of limitations set forth in 28 U.S.C. § 2401(a), which provides, "Except as provided by the Contract Disputes Act of 1978, every civil action commenced against the United States shall be barred unless the complaint is filed within six years after the right of action first accrues . . . ." *See Harris v. FAA*, 353 F.3d 1006, 1009 (D.C. Cir. 2004) ("Unless another statute prescribes otherwise, a suit challenging final agency action pursuant to section 704 must be commenced within six years after the right of action first accrues. 28 U.S.C. §2401(a)"); *Wong v. Doar*, 571 F.3d 247, 262-63 (2d Cir. 2009) (applying § 2401(a) to APA challenge); *Cedars-Sinai Med. Ctr. v. Shalala*, 177 F.3d 1126 (9th Cir. 1999) (same). Failure to file an action within section 2401(a)'s limitations period deprives a court of jurisdiction. *Muwekma Ohlone Tribe v. Salazar*, 708 F.3d 209, 218 (D.C. Cir. 2013) ("The court lacks subject matter jurisdiction to hear a claim barred by section 2401(a).").

Plaintiff attacks the proposed rule on procedural grounds. "[I]n a procedural challenge, it is the manner in which the regulation was adopted which is in issue; the content or substance of the regulation is irrelevant." *Utu Utu Gwaitu Paiute Tribe v. Dept. of Interior*, 766 F. Supp. 842, 844 (E.D. Cal. 1991) (citing *Sierra Club v. Penfold*, 857 F.2d 1307, 1315 (9th Cir. 1988)). Here, the crux of Plaintiff's complaint is that FDA issued the proposed rule in 1997 and, as set forth in the interim policy announced in the preamble to the proposed rule, immediately began to operate under it without responding to the comments received on the proposal. *See* First Am. Compl. ¶¶ 1-2, 76-79. Plaintiff alleges the proposed rule "constitutes final agency action within the meaning of the APA, 5 U.S.C. §§ 551(13), 704" that violates the APA because the "public did not have an opportunity to comment on the rule before it went into effect as required by 5 U.S.C. § 553." First Am. Compl. ¶¶ 76-77; *see id.* ¶ 8 ("This Court should declare that FDA has violated the APA by operating under a proposed rule that did not undergo the rulemaking

procedures required by the APA."); ¶ 67 ("CFS's programmatic predecessor, ICTA, submitted comments to FDA during the 1997 comment period. The interests of Plaintiff and its procedural due process rights are adversely affected by Defendants' failure to respond to its comments and the comments of others, as required by the APA.").

Where, as here, the cause of action is based on claimed procedural error in the promulgation of a regulation, final agency action occurs upon issuance of the regulation. *Wong*, 571 F.3d at 262-63 (§ 2401(a) barred challenge for failure to issue regulation in accordance with APA's notice and comment requirement; statute of limitations began to run when regulation was issued); *Cedars-Sinai Med. Ctr. v. Shalala*, 177 F.3d at 1129 (procedural claim that agency failed to adhere to notice-and-comment rulemaking provisions of APA was barred by six-year statute of limitations applicable to actions for judicial review of agency regulations and cause of action accrued "on the issuance of the rule"); *JEM Broad. Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) ("We have held unequivocally that when a party complains of an agency's failure to provide notice and comment prior to acting, it is that failure which causes 'injury'; and interested parties are 'aggrieved' by the order promulgating the rules. Moreover, the failure to provide notice and comment is a ground for complaint that is or should be fully known to all interested parties at the time the rules are promulgated.") (internal citation omitted); *Ala. v. Shalala*, 124 F. Supp. 2d 1250, 1270 (M.D. Ala. 2000) (claim of procedural deficiency in promulgating OMB Circular accrued when the Circular was published in Federal Register; APA challenge to its application in action to disallow costs paid to Alabama by federal government was barred by statute of limitations); *see Utu Utu Gwaitu Paiute Tribe*, 766 F. Supp. at 844 (charges that an administrative agency failed to comply with the notice and comment provisions of the APA are a common procedural challenge to an administrative regulation, and are therefore barred if raised

more than six years after publication of the rule) (citing *Chem. Waste Mgmt. v. EPA*, 869 F.2d 1526, 1529 (D.C. Cir. 1989)); *see also Harris v. FAA*, 353 F.3d 1006 (D.C. Cir. 2004) (claim that FAA recruitment notice was arbitrary was time-barred six years after publication in the Federal Register); *Dunn-McCampbell Royalty Interest, Inc. v. Nat'l Park Serv.*, 112 F.3d 1283 (5th Cir. 1997) (on facial challenge to federal agency's regulation, limitations period begins to run when agency publishes regulation in Federal Register).

Plaintiff's allegations make plain that its cause of action accrued in 1997 when it alleges FDA began operating under the proposed rule without first responding to comments received on the proposal. Plaintiff contends that "FDA's proposed rule went into effect indefinitely *upon publication of notice in the Federal Register*," First Am. Compl. ¶ 77 (emphasis added), and "FDA began operating under its proposed GRAS rule *at the time the proposed rule was published*," *id.* ¶ 2 (emphasis added). Plaintiff emphasizes that "Contrary to the requirements of the APA, 5 U.S.C. § 553, the agency *put the proposed rule into place upon publication of the notice of proposed rulemaking, before the public was able to provide comment* and before the agency considered such comments and finalized the rule." *Id.* ¶ *44* (emphasis added); *see also id.* ¶ 66 ("FDA's proposed rule *went into effect indefinitely upon publication of notice in the Federal Register, prior to public comment*. The interests of Plaintiff and its procedural due process rights are adversely affected by FDA's decision to implement a rule without following the notice-and-comment rulemaking procedures mandated by the APA.") (emphasis added); *id.* ¶ 39 ("As part of the notice of proposed rulemaking, FDA announced an 'interim' notification process that would be used 'between the time of publication of this proposal and any final rule based on this proposal.' 62 Fed. Reg. at 18,954.").

In short, Plaintiff cannot argue that the proposed rule is final, yet escape the consequences of finality. The proposed rule is not final for all of the reasons discussed above, *supra* at 29-34. But if Plaintiff persuades this Court that FDA's proposed rule is, in fact, a "final" rule subject to review under the APA, then Plaintiff's attack on the procedural genesis of the regulation accrued in 1997 and was time barred nearly a decade before this suit was filed. *See* Plaintiff's First Amended Complaint should therefore be dismissed for lack of subject matter jurisdiction.

CONCLUSION

For all of the reasons set forth above, Plaintiff's First Amended Complaint should be dismissed.

Respectfully submitted,

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