UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY,	:	
	:	
Plaintiff,	:	Civil Action No.: 14-00267 (RC)
	:	
v.	:	Re Document No.: 17
	:	
SYLVIA BURWELL, *in her official capacity as Secretary of U.S. Department of Health and Human Services, et al.*,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION

DENYING PLAINTIFF'S MOTION FOR ATTORNEYS' FEES AND COSTS

I. INTRODUCTION

In this action, the Center for Food Safety ("CFS") seeks from the U.S. Food and Drug Administration ("FDA"), the Secretary of Health and Human Services, and the Commissioner of Food and Drugs (collectively, the "Defendants") an award of attorneys' fees and costs incurred in litigating its claims under the Administrative Procedure Act ("APA"), *see* 5 U.S.C. §§ 500 *et seq*. CFS contends that, pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412(d)(1)(A), it is entitled to reasonable attorneys' fees and costs because it was the "prevailing party" in the litigation and because the Defendants' position was not "substantially justified." The Defendants dispute both contentions. Because the Court concludes that the Defendants' position was substantially justified, the Court denies CFS's motion for attorneys' fees and costs.

II. FACTUAL BACKGROUND

In 1958, Congress enacted the Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act, *see* 21 U.S.C. §§ 301 *et seq.* ("FFDCA"), requiring food manufacturers to submit to FDA evidence demonstrating the safety of food additives before FDA approves the additives for use in the marketplace. *See generally* Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,938–39 (proposed Apr. 17, 1997) (to be codified at 21 C.F.R. § 170.36). Under this amendment, "food additive" is defined to exclude substances "generally recognized . . . to be safe under the conditions of [their] intended use," which are often referred to as "GRAS" substances. 21 U.S.C. § 321(s) (2009). Accordingly, if food manufacturers determine independently that their substances are GRAS for a particular use, they are permitted to bring these substances to the marketplace without FDA's approval and without even notifying FDA. *See* 62 Fed. Reg. at 18,939; Am. Compl. 7; Mem. Supp. Defs.' Mot. Dismiss 12. In the late 1960s, however, after new scientific information came to light that cast doubt on a substance that FDA had previously considered GRAS for its intended use, FDA promulgated regulations establishing a "petition affirmation process" by which food manufacturers could voluntarily petition FDA for "official recognition" of their substance's GRAS status. *See* 21 C.F.R. § 170.30–35; 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) 5 (2010) [hereinafter "GAO Report"]; Am. Compl. 7; Mem. Supp. Defs.' Mot. Dismiss 7. As part of this voluntary process, food manufacturers would submit scientific data as part of their initial petition. *See* 21 C.F.R. § 170.35 (2011). FDA would then proceed by comprehensively reviewing this scientific data, publishing a notice in the Federal Register for

comment, and drafting an explanation of FDA's GRAS determination. GAO Report at 5–6; Am. Compl. 8; Mem. Supp. Defs.' Mot. Dismiss 8.

In 1997, claiming that the previous GRAS "petition affirmation process" was too cumbersome for both food manufacturers and the agency, FDA issued a proposed rule (the "Proposed Rule") changing this voluntary procedure to permit food companies to merely "notify" FDA of their GRAS determinations. *See* 62 Fed. Reg. at 18,938–41. Under the Proposed Rule, FDA no longer conducts a comprehensive scientific investigation of submitted data or "affirms" the GRAS status of a substance. GAO Report at 6; Am. Compl. 9; Mem. Supp. Defs.' Mot. Dismiss 9. Instead, once FDA reviews a company's GRAS notice, it sends the company a letter with one of three notifications: 1) FDA has "no questions" about the company's independent GRAS determination; 2) the company's GRAS notice does not provide a sufficient basis for a GRAS determination; or 3) FDA has ceased to evaluate the GRAS notice at the company's request. GAO Report at 6. FDA stresses that these letters are nonbinding and do not constitute a legal or factual determination that a substance is or is not GRAS. *See* Defs.' Resp. to Pl.'s Mot. Att'y Fees 2, ECF No. 18.

In the Proposed Rule, FDA also announced an interim policy (the "Interim Policy") permitting food manufacturers to submit GRAS notices under the process described in the Proposed Rule until FDA finalizes any rule based on the proposal. *See* 62 Fed. Reg. at 18,954–55. Since 1997, FDA has operated under the Interim Policy, though FDA has sought comments during two different time periods. *See id.* at 18,954; Substances Generally Recognized as Safe, 75 Fed. Reg. 81,536, 81,536 (Dec. 28, 2010). FDA has neither responded to any of the comments nor issued a final rule. *See* Am. Compl. 2; Mem. Supp. Defs.' Mot. Dismiss 11–12.

In February 2014, CFS brought this action against the Defendants. *See generally* Compl. The amended complaint alleged that FDA's failure to adopt a final rule or respond to commenters after seventeen years "deprive[s] the public of the vital procedural rights afforded by the [APA]."[1] Am. Compl. 2. Because of the long delay in finalizing the Proposed Rule and because FDA currently operates under the Interim Policy, CFS argued that the Proposed Rule "constitutes final agency action within the meaning" of 5 U.S.C. § 704, and is thus subject to judicial review. Am. Compl. 22. After finding that FDA's action meets this threshold test, the Court, CFS argued, should "hold unlawful and set aside" the Proposed Rule under § 706(2)(A) as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or, in the alternative, under § 706(2)(D) as "without observance of procedure required by law." *Id.*; *see also* 5 U.S.C. § 553(c) (requiring agencies to "give interested parties an opportunity to participate" in rulemaking). Accordingly, in its prayer for relief, CFS requested that the Court vacate the Proposed Rule and declare that the Defendants had violated and continue to violate the APA "by failing to respond to comments and properly promulgate a final GRAS rule." Am. Compl. 23.

In response, the Defendants filed a motion to dismiss, arguing that CFS lacked standing to sue, that the Proposed Rule and the Interim Policy are not final agency action and are thus not subject to judicial review, and that CFS's challenge was barred by the statute of limitations. *See generally* Mem. Supp. Defs.' Mot. Dismiss. The parties later agreed, however, that resolution of this matter without further litigation was in their best interest. *See* Consent Decree, ECF No. 15. Upon agreement between CFS and the Defendants, the Court issued a Consent Decree on

[1] CFS also addressed the Proposed Rule and the Interim Policy directly, arguing that the framework results in the sale and distribution of potentially dangerous substances improperly classified as GRAS. *See generally* Am. Compl. These arguments are not relevant to the Court's analysis, and hence are not addressed herein.

October 20, 2014, requiring FDA to finalize the Proposed Rule and submit the final rule to the Federal Register for publication no later than August 31, 2016. *Id.* at 2. The Court may grant FDA an extension of this deadline only if 1) the Court obtains the written consent of both CFS and FDA, or 2) FDA files a motion that the Court finds successfully demonstrates "good cause and/or exceptional circumstances warranting the extension." *Id.* at 2-3. In that same Consent Decree, CFS agreed to release all of its claims in the case. *Id.* at 5.

Now before the Court is CFS's motion for attorneys' fees and costs under the Equal Access to Justice Act. *See* Pl.'s Mot. Att'y Fees, ECF No. 17. The motion is now fully briefed and ripe for decision.

III. ANALYSIS

A. Equal Access to Justice Act

The Equal Access to Justice Act ("EAJA") allows a plaintiff "to obtain expenses in litigation against the federal government" under certain circumstances. *Select Milk Producers, Inc. v. Johanns*, 400 F.3d 939, 941 (D.C. Cir. 2005); *see also Nong v. Reno*, 28 F. Supp. 2d 27, 29 (D.D.C. 1998) (citing EAJA). The EAJA provides in pertinent part:

> [A] court shall award to a *prevailing party* other than the United States fees and other expenses . . . incurred by that party in any civil action . . . , unless the court finds that the position of the United States was *substantially justified* or that special circumstances make an award unjust.

28 U.S.C. § 2412(d)(1)(A) (emphasis added). Accordingly, eligibility for attorneys' fees, costs, and expenses under the EAJA "requires the claimant to meet four conditions: (1) that the claimant be a 'prevailing party'; (2) that the government's position was not 'substantially justified'; (3) that no 'special circumstances make an award unjust'; and, (4) that pursuant to 28 U.S.C. § 2412(d)(2)(B), plaintiffs satisfy all of the EAJA's threshold eligibility requirements."

Ass'n of Am. Physicians & Surgeons, Inc. v. U.S. Food & Drug Admin., 391 F. Supp. 2d 171, 175 (D.D.C. 2005) (citing *Comm'r, INS v. Jean*, 496 U.S. 154, 158 (1990)). Here, the parties do not dispute that CFS is an eligible claimant under the third and fourth conditions above. *See generally* Pl.'s Mot. Att'y Fees; Defs.' Resp. Rather, they disagree as to whether CFS was a "prevailing party" and whether the Defendants' position was "substantially justified." *See id.*

For the reasons given below, the Court concludes that although CFS was a prevailing party in the underlying litigation, the Defendants' position was substantially justified, thus precluding CFS from eligibility for attorneys' fees under the EAJA.

B. Prevailing Party

The term "prevailing party" is a "legal term of art" whose meaning the Supreme Court elucidated in *Buckhannon Board and Care Home, Inc. v. West Virginia Department of Health and Human Resources*, 532 U.S. 598 (2001). The *Buckhannon* Court held that a prevailing party "is one who has been awarded some relief by the court." 532 U.S. at 603. Prevailing party status requires "a court-ordered change in the legal relationship between the plaintiff and the defendant." *Id.* at 604 (internal alterations, quotation marks, and citation omitted). This change can result from "judgments on the merits" or "settlement agreements enforced through a consent decree." *Buckhannon*, 532 U.S. at 604. By the same token, the Court rejected the so-called "catalyst theory," under which a plaintiff can qualify as a prevailing party if his lawsuit merely brings about the result desired. *Id.* at 605. A defendant's "voluntary change in conduct," the Court explained, "lacks the necessary judicial *imprimatur*." *Id.* The lawsuit thus must be resolved by virtue of "what the court ordered," not "what the defendant did" voluntarily, in order

for the plaintiff to be a prevailing party under the EAJA. *Thomas v. Nat'l Sci. Found.*, 330 F.3d 486, 492 (D.C. Cir. 2003) (citing *Buckhannon*, 532 U.S. at 605).

In *Thomas v. National Science Foundation*, the D.C. Circuit distilled a three-part test from *Buckhannon* for an EAJA prevailing party analysis. *Id.* at 492–93. First, there must be a "court-ordered change in the legal relationship between the plaintiff and the defendant." *Id.* (internal alteration, citations, and quotation marks omitted). Second, the judgment must be in favor of the party seeking the fees. *Id.* at 493. Third, the judicial pronouncement must be accompanied by "judicial relief." *Id.* (emphasis and citation omitted)

These factors indicate that the "judicial *imprimatur*" the *Buckhannon* Court required is not satisfied by a judicial pronouncement of any kind; instead, the court's ruling must "change the legal relationship between the parties in a way" that affords the plaintiff the relief sought in the lawsuit. *Id.* As a result of judicial action, then, the plaintiff must receive "a substantial part of what plaintiff asked the court for in the first place." *Role Models Am., Inc. v. Brownlee*, 353 F.3d 962, 966 (D.C. Cir. 2004) (citation omitted). At the same time, however, a plaintiff need not prevail on the "central issue" in the litigation to be a prevailing party under the EAJA; it is sufficient for a party to prevail on an "important matter" in the course of litigation, even when that party "does not prevail on all issues." *Tex. State Teachers Ass'n v. Garland Indep. Sch. Dist.*, 489 U.S. 782, 790 (1989) (internal citations omitted).

Applying these principles, the Court concludes that CFS was a prevailing party in its suit against the Defendants. All three factors in the *Thomas* test are satisfied here. First, the Consent Decree effects a "change in the legal relationship between" CFS and the Defendants. *Thomas*, 330 F.3d at 492. This case does not involve a mere "[p]rivate settlemen[t]" which this court has no jurisdiction to enforce. *Buckhannon*, 532 U.S. at 604 n.7. Rather, the "terms of the [parties']

agreement are incorporated" into the Consent Decree. *Id.*; *see also* Consent Decree 1–2. Furthermore, the Consent Decree imposes an obligation upon FDA to finalize the Proposed Rule by a specified date, and subjects any potential extension of this deadline to the Court's oversight. Consent Decree 2–3. Indeed, unless the Court finds that such an extension is otherwise justified, CFS itself must consent to an extension by written agreement; it did not have this legal relationship with FDA prior to the Court's issuance of the Consent Decree. *See id.*

Under *Thomas's* second and third prongs, too, CFS was a prevailing party because the Consent Decree is "in favor of" CFS and accords it concrete "relief." *Thomas*, 330 F.3d at 493. Specifically, the Consent Decree directs FDA to complete the long-pending rulemaking whose delay led, at least in part, to CFS's decision to bring suit in the first place. *See* Consent Decree 1–2. That CFS sought this relief is evident from the fact that throughout its complaint, CFS contends that FDA's alleged failure to abide by APA requirements has caused CFS injury that can be remedied with a final rule promulgated through proper procedures. *See* Am. Compl. 2 ("By indefinitely operating under a proposed rule in lieu of promulgating a final rule, FDA has deprived the public of the vital procedural rights afforded by the Administrative Procedure Act."); *id.* at 3 (requesting that the Court vacate the Proposed Rule "unless and until FDA *properly promulgates a new GRAS rule* in accordance with APA requirements" (emphasis added)); *id.* at 11 (stating that FDA's failure to finalize the Proposed Rule or respond to comments is "[p]articularly alarming" and "[c]ontrary to the requirements of the APA"); *id.* at 21–22 ("Had FDA considered and responded to comments on the proposed rule prior to implementing it, potentially unsafe substances . . . may have been denied GRAS status."); *id.* at 23 (arguing that CFS is "adversely affected" by the alleged failure of FDA to abide by the APA). Indeed, CFS's prayer for relief makes clear that at least one of the outcomes that CFS hoped to

achieve in bringing suit was the issuance of a properly promulgated final rule, as the Court mandated in the Consent Decree. *See id.* at 23 (requesting that the Court vacate the Proposed Rule "until Defendants properly promulgate a final GRAS rule.").

The Defendants, however, relying on *Buckhannon*, contend that the third prong of the *Thomas* test is not satisfied because CFS has received *none* of the relief it sought in the complaint. *See Buckhannon*, 532 U.S. at 603–04 ("Our respect for ordinary language requires that a plaintiff receive at least some relief on the merits of his claim before he can be said to prevail." (internal alterations, citation, and quotation marks omitted)); Defs.' Resp. at 11–14.[2] While the Defendants are correct that CFS's assertion in its motion that it "sought one fundamental result: a properly-promulgated, final GRAS rule," Pl.'s Mot. Att'y Fees 7, is not supported by its complaint, the Court, for the aforementioned reasons, disagrees with the Defendants' argument that CFS did not seek this result at all.[3] To be sure, the Consent Decree does not grant CFS all of the items it requested in its prayer for relief. *See* Am. Compl. 23. The Consent Decree does, however, accord CFS concrete "judicial relief," *Thomas*, 330 F.3d at 493, on an "important matter," *Tex. State Teachers Ass'n*, 489 U.S. at 790, and such relief is sufficient to establish prevailing party status for purposes of the EAJA. Moreover, this case is

[2] The Defendants argue that because the Consent Decree neither vacates the Proposed Rule nor issues any declarations that the Defendants violated the APA, both of which CFS requested in its prayer for relief, CFS has not received "a substantial part of what [it] asked the court for in the first place." *Role Models*, 353 F.3d at 966 (citation omitted); *see also* Defs.' Resp. 3–4. Additionally, though the Defendants acknowledge that parties receiving only partial relief can be considered "prevailing parties" under the EAJA, the Defendants maintain that because CFS did not request the relief that the Consent Decree actually grants – an order requiring FDA to finalize the Proposed Rule – CFS has not received even part of what it sought. *See* Defs.' Resp. 6.

[3] The Defendants also argue that the "relief awarded in the Consent Decree" reveals a "fundamental flaw" in CFS's cause of action. Defs.' Resp. at 3–4. Because the Consent Decree requires the FDA to finalize the Proposed Rule, the Defendants contend, CFS's original cause of action based on a "theory that the proposed rule was 'final agency action'" is necessarily flawed. *Id.* The Court makes no finding as to this matter or any matter in the litigation that preceded the settlement of the parties' claims in the Consent Decree.

distinguishable from a preliminary injunction that "merely preserve[s] the *status quo* pending final adjudication of the case," *Thomas*, 330 F.3d at 493, because CFS has obtained "something of value in the real world," *see Envtl. Def. Fund, Inc. v. Reilly*, 1 F.3d 1254, 1257 (D.C. Cir. 1993) ("In the real world of the APA, an opportunity for comment . . . is not to be denigrated."). Even if the Defendants question the "degree of the plaintiff's success," this bears on "the size of a reasonable fee, not [the] eligibility for a fee award at all." *Tex. State Teachers Ass'n*, 489 U.S. at 790 (emphasis omitted); *see also Farrar v. Hobby*, 506 U.S. 103, 114 (1992) ("[T]he prevailing party inquiry does not turn on the magnitude of the relief obtained."). Before the Consent Decree, FDA relied on the Proposed Rule while it contemplated a final rule for seventeen years with no end in sight. After the Consent Decree, FDA not only has committed to issuing a final rule by a date certain, but such commitment also brings to an end the operation of the Proposed Rule that Plaintiff claimed was illegal. Although Plaintiff requested that the Proposed Rule be vacated in the interim, achieving the near-term death of the Proposed Rule's operation rather than its immediate demise is a matter of the "degree of the plaintiff's success," not whether it prevailed on an "important matter." *Tex. State Teachers Ass'n*, 489 U.S. at 790.

The Court accordingly holds that because the Consent Decree effects a "change in the legal relationship" between the parties, favors CFS, and offers it relief, CFS is a "prevailing party" under the EAJA. *See* 28 U.S.C. § 2412(d)(1)(A); *Thomas*, 330 F.3d at 492–93.

C. Substantial Justification

A prevailing party is entitled to attorneys' fees under the EAJA unless the government can demonstrate that its "position" was "substantially justified." *See* 28 U.S.C. § 2412(d)(1)(A); *Halverson v. Slater*, 206 F.3d 1205, 1208 (D.C. Cir. 2000) (stating that after a reviewing court

finds a plaintiff to be a prevailing party, the burden shifts to the United States to demonstrate that its position was substantially justified). "The Supreme Court has held that the term 'substantially justified' means 'justified in substance or in the main—that is, justified to a degree that could satisfy a reasonable person.'" *Ass'n of Am. Physicians & Surgeons, Inc.* 391 F. Supp. 2d at 176 (citing *Jean*, 496 U.S. at 158 n.6) (internal quotation marks omitted). This does not mean that the government's position must have been correct to be substantially justified, but rather that "a reasonable person could think it correct." *Pierce v. Underwood*, 487 U.S. 552, 566 n.2 (1988). Hence, although the substantial justification inquiry "differs from the merits determination," the merits may nonetheless be "quite relevant" to the Court's decision. *F.J. Vollmer Co., Inc. v. Magaw*, 102 F.3d 591, 595 (D.C. Cir. 1996).

Further, the government's "position" for purposes of the inquiry includes both its litigation position and the underlying action that gave rise to the litigation. *Jacobs v. Schiffer*, 204 F.3d 259, 263 (D.C. Cir. 2000); *see also Hill v. Gould*, 555 F.3d 1003, 1006 (D.C. Cir. 2009) ("[T]he underlying agency action and the legal arguments in defense of the action [must have] a reasonable basis both in law and fact." (internal quotation marks and citation omitted)). The Court is not to review the different elements of the government's position separately, but instead as an inclusive whole. *See Bennett v. Castro*, 74 F. Supp. 3d 382, 393 (D.D.C. 2014) (citing *Jean*, 496 U.S. at 158–59). Nonetheless, the "relevant 'position' of the government is that which corresponds to the claim or aspect of the case on which the private party prevailed." *Jacobs*, 204 F.3d at 264.

As the Court has already concluded, CFS was a prevailing party in the underlying litigation because it obtained procedural relief through a Consent Decree that requires FDA to finalize the Proposed Rule. *See supra* Part III.B. Accordingly, to substantially justify its

litigation position, the Defendants must establish a "reasonable basis both in law and fact," *Hill*, 555 F.3d at 1006, for their argument that the Proposed Rule and the Interim Policy are not final action and are thus not subject to judicial review, *see* Mem. Supp. Defs.' Mot. Dismiss 28–34, as well as for their argument that CFS was barred by the statute of limitations, *see id.* at 34–38, because the relief that CFS obtained "corresponds" to these "aspect[s] of the case," *Jacobs*, 204 F.3d at 264. Similarly, the Defendants must substantially justify their pre-litigation position — that is, FDA's failure to finalize the Proposed Rule and its simultaneous use of the framework outlined in the Proposed Rule through the Interim Policy.[4] *See Hill*, 555 F.3d at 1006.

Because both parties agree that CFS's statutory cause of action under 5 U.S.C. §§ 702–06 depended upon the premise that the Proposed Rule and the Interim Policy "constitut[e] final agency action," *see* Defs.' Resp. 14; Pl.'s Reply 10, the Court's substantial justification inquiry turns on the definition of this term. Agency action must meet two requirements to be considered final: first, it must be the "consummation of the agency's decisionmaking process," and second, it must "determine rights or obligations or impose legal consequences." *State of West Virginia v. Envtl. Prot. Agency (In re Murray Energy Corp.)*, 788 F.3d 330, 334 (D.C. Cir. 2015) (internal alterations and quotation marks omitted) (citing *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)); *see also Sackett v. Envtl. Prot. Agency*, 132 S. Ct. 1367, 1371–72 (2012). Further, finality is a threshold question because § 704 "limits causes of action under the APA to final agency action." *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 188 (D.C. Cir. 2006) (internal alterations and

[4] Even if the Defendants were justified in their threshold argument that CFS did not have standing in this suit, this position was secondary to the Defendants' substantive arguments in the underlying litigation. Because the Court's substantial justification inquiry "operates as a one-time threshold for fee eligibility," and the EAJA "favors treating a case as an inclusive whole, rather than as atomized line-items," *Jean*, 496 U.S. at 160–62, the Court considers the Defendants' substantive argument as a whole rather than separately addressing individual arguments herein.

citations omitted). Thus, if agency action is not final, "the action is not reviewable" under the APA. *Fund for Animals, Inc. v. U.S. Bureau of Land Mgmt.*, 460 F.3d 13, 18 (D.C. Cir. 2006) (citation omitted).

Applying this two-part test, the Court concludes that the Defendants were substantially justified in their litigation argument that the Proposed Rule is not final agency action. As the Defendants note, proposed rules are generally not subject to judicial review because they do not constitute final action. *See In re Murray Energy Corp.*, 788 F.3d at 333–34; *see also Las Brisas Energy Ctr., LLC v. Envtl. Prot. Agency*, No. 12-1248, 2012 WL 10939210, at *1 (D.C. Cir. Dec. 13. 2012) (per curiam). Because agencies often substantially revise proposed rules in their final form, they do not represent a "consummation of the agency's decisionmaking process." *Bennett*, 520 U.S. at 177–78; *see also Action on Smoking & Health v. Dep't of Labor*, 28 F.3d 162, 165 (D.C. Cir. 1994) (stating that "[t]he comments that the agency receives during the notice and comment period may persuade the agency" that it should revise its rule). Indeed, FDA argues repeatedly that the Proposed Rule is still a "work in progress" that FDA is planning to finalize in the future. Defs.' Mot Dismiss 28–33; *see also* GAO Report at 38 ("FDA agreed with our fourth recommendation that it finalize its GRAS proposal. The agency indicated that it anticipates reopening the comment period prior to issuance of a final rule."). Moreover, proposed rulemaking does not "determine rights or obligations or impose legal consequences." *In re Murray Energy Corp.*, 788 F.3d at 334; *Action on Smoking & Health*, 28 F.3d at 165 ("Agency action is final when it 'imposes an obligation, denies a right, or fixes some legal relationship.'" (citation omitted)). Consequently, the Defendants' argument that the Proposed Rule does not have a "binding legal effect on either the submitter or the agency" and is not an action "by which

rights or obligations are determined or from which legal consequences flow" was substantially justified. *See* Mem. Supp. Defs.' Mot. Dismiss 31; Defs.' Resp. 12.

Whether the Defendants were substantially justified in their argument that the Interim Policy, on the other hand, is final agency action is a closer question. Unlike the Proposed Rule, the Interim Policy is not "tentative in nature and . . . subject to further consideration and modification," *see* Mem. Supp. Defs.' Mot. Dismiss 29, because it went into effect when first published in 1997, *see* 62 Fed. Reg. at 18,954–55, and FDA has not further considered it, *see* 75 Fed. Reg. at 81,536–43 (requesting comments on changes to the Proposed Rule but proposing no changes to FDA's policy during the interim period before the Proposed Rule is finalized). Accordingly, the Interim Policy constitutes the "consummation of the agency's decisionmaking process" under *Spear's* first prong. *Spear*, 520 U.S. at 177–78. On the other hand, under *Spear's* second prong, agency actions of an "informal and advisory" nature that request voluntary compliance do not impose "legal consequences" or determine "rights or obligations" because they neither require action from private parties nor "commit [the agency] to taking enforcement action." *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944–45 (D.C. Cir. 2012) (internal citations omitted) (holding that an FDA warning letter requesting an ear candle manufacturer to voluntarily remove ear candles from the marketplace or potentially face regulatory action was not final agency action); *see also Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 11–12, 14 (D.C. Cir. 2005) (holding that a Fish and Wildlife Service Protocol that outlined recommendations for detecting the endangered Quino butterfly was not final agency action because it did not establish a binding norm, but rather served as a recommendation); *Reliable Automatic Sprinkler Co., Inc. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731–33 (D.C. Cir. 2003) (holding that a Consumer Product Safety Commission

letter requesting a sprinkler head manufacturer to undertake voluntary corrective action was not final agency action). At the same time, however, an agency action that "effectively amends a prior legislative rule" that was previously published in the Code of Federal Regulations is a legislative rule that agencies must promulgate through the notice-and-comment process in the APA before it becomes effective. *Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993); *see also CropLife Am. v. Envtl. Prot. Agency*, 329 F.3d 876, 884 (D.C. Cir. 2003) (holding that an EPA directive must be promulgated through notice-and-comment procedures because it "effect[ed] a dramatic change in the agency's established regulatory regime"). Because the Interim Policy is a voluntary program but also "effectively amends" a prior program published in the Code of Federal Regulations, it has elements of both of these types of agency action.

Even if the Interim Policy is final agency action, however, APA actions are subject to a catch-all statute of limitations of six years. *See* 28 U.S.C. § 2401(a) ("[E]very 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"); *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1094 (D.C. Cir. 1996) (explaining that the APA "carries a six-year statute of limitations"); *P & V Enters. v. U.S. Army Corps of Engineers*, 466 F. Supp. 2d 134, 143 (D.D.C. 2006) ("[F]acial challenges to agency regulations, like any other civil action filed against the United States, are subject to § 2401(a)'s six-year limitations period."). Hence, because CFS's right of action would have first accrued when the Interim Policy became effective in 1997, the Defendants' argument that CFS's 2014 challenge was time-barred was substantially justified.[5]

[5] CFS argues that FDA's reopening of the comment period in 2010 "opened the issue up anew" and reset the statute of limitations. *See* Pl.'s Reply 12 (citing *Pub. Citizen v. Nuclear Regulatory Comm'n*, 901 F.2d 147, 150 (D.C. Cir. 1990)). Indeed, under the D.C. Circuit's "reopening"

As a result, the Court need not determine separately whether or not the Interim Policy constitutes final agency action. Rather, examining the Defendants' litigation argument as an inclusive whole, as the Court must do in this inquiry, *see Jean*, 496 U.S. at 160–62, the Court concludes that the Defendants' litigation position was substantially justified.

To be sure, the Defendants' litigation position was not necessarily "correct," [6] *see Pierce*, 487 U.S. at 566 n.2, but for purposes of this substantial justification inquiry, the Court has no occasion to determine whether the Defendants "had the better arguments," *Hill*, 555 F.3d at 1007. Rather, it is sufficient that the Defendants' argument had a reasonable basis both in law and fact. *See id.* As in *Hill*, the Defendants' position did not "suffer from the defects common to positions that are not substantially justified" because it was not "flatly at odds with the controlling case law,"[7] and FDA did not "press [its] position in the face of an unbroken line of

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doctrine, "the time period for seeking judicial review begins anew" when a later proceeding "explicitly or implicitly shows that the agency actually reconsidered the rule." *Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 141 (D.C. Cir. 1998) (citing *Pub. Citizen*, 901 F.2d at 150). Moreover, "[a]n explicit invitation to comment on a previously settled matter . . . is usually sufficient to [e]ffect a reopening." *Id.* at 142. While FDA did, however, explicitly reconsider and invite comment on many different facets of the *Proposed Rule* in 2010, FDA did not reconsider its decision to *operate* under the Proposed Rule through the *Interim Policy*. *See* 75 Fed. Reg. at 81,536–43. As such, the Defendants' argument that CFS's challenge was untimely had a "reasonable basis both in law and fact," *Hill*, 555 F.3d at 1006, and was thus substantially justified.

[6] Invoking 5 U.S.C. § 555(b), CFS also asserts that FDA failed to "conclude matters within a reasonable time." *See* 5 U.S.C. § 555(b) ("[W]ithin a reasonable time, each agency shall proceed to conclude a matter presented to it."); Pl.'s Mot. Att'y Fees 9–10. To the extent that CFS is asserting in its motion for attorneys' fees a theory of "unreasonable delay" under 5 U.S.C. § 706(1), however, the Defendants correctly point out that CFS did not allege this theory in its complaint. *See* Am. Compl.; Defs.' Resp. 14. As such, because CFS did not assert this theory, it is not one upon which CFS prevailed in the underlying litigation, and is thus not relevant to the Court's substantial justification inquiry. *See Jacobs*, 204 F.3d at 264 (explaining that only "aspect[s] of the case on which the private party prevailed" are relevant to the court's substantial justification inquiry).

[7] CFS contends that the Defendants' argument that the Proposed Rule is not final agency action "is flatly contrary to the APA and controlling case law." Pl.'s Mot. Att'y Fees 9. CFS fails, however, to cite any case law supporting this proposition. *See id.*

authority." *Id.* at 1007–1008 (internal citations and quotation marks omitted). Instead, the Defendants' litigation position was substantially justified because it cited authority that is "justified to a degree that could satisfy a reasonable person." *Pierce*, 487 U.S. at 565.

Additionally, the government bears the burden of demonstrating that its pre-litigation position was substantially justified. *See Jacobs*, 204 F.3d at 263 (discussing the definition of the government's "position" in a substantial justification inquiry). CFS points out that the Defendants attempt to justify FDA's long delay in finalizing the Proposed Rule by using only a one-sentence statement and a brief footnote claiming that FDA has been focused on "several more critical public health programs and initiatives." Defs.' Resp. 13; Pl.'s Reply 8–9. FDA's justification is indeed thin. But if the Defendants' litigation position that the Proposed Rule and the Interim Policy were not final agency action was substantially justified, its logic demands that so too was the underlying agency action at the root of the initial litigation. *See Fund for Animals, Inc.*, 460 F.3d at 18 (stating that courts may not review agency actions that are not final). As such, the Court declines in a fee dispute to review an underlying action that, according to the Defendants' substantially justified litigation position, the Court could not have reviewed at all in the first place. Instead, treating the Defendants' litigation and pre-litigation positions as an inclusive whole, as the Court must do under the EAJA, *see Jean*, 496 U.S. at 160–162, the Court holds that the Defendants' overall "position" was substantially justified because the Defendants' argument that the Proposed Rule and the Interim Policy are not final agency action subject to judicial review, and that CFS's challenge was barred by the statute of limitations, "had a reasonable basis in law and fact," supported by a significant body of case law, that a "reasonable person could think. . . correct." *Pierce*, 487 U.S. at 566 n.2; *see also Hill*, 555 F.3d at 1006.

IV. CONCLUSION

In an EAJA action, the Court cannot award a plaintiff attorneys' fees if the government's position in the original litigation was substantially justified. *See* 28 U.S.C. § 2412(d)(1)(A). Because the Court holds that the Defendants' position was substantially justified, CFS's motion for attorneys' fees and costs (ECF No. 17) is **DENIED**.[8] An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: September 4, 2015

RUDOLPH CONTRERAS
United States District Judge

[8] Because the EAJA's two-prong test is not satisfied, the Court does not reach the question of whether the amount of fees and costs that CFS requests is reasonable. *See Role Models*, 353 F.3d at 968–75 (analyzing whether plaintiff's requested fee amount was reasonable).