UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ALLERGAN, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Case No. 13-00264 (RJL)**
	)	
SYLVIA MATHEWS BURWELL, *in her official capacity as Secretary of Health and Human Services,*[1]	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

(March 30, 2016) [Dkts. ## 30, 31]

Plaintiff Allergan, Inc. ("Allergan") brought this action against the Secretary of the United States Department of Health and Human Services ("HHS") on February 28, 2013. In a single count complaint, plaintiff seeks declaratory judgment that the Secretary acted arbitrarily and capriciously or contrary to law in violation of section 10(e)(2)(A) of the Administrative Procedure Act ("APA") by interpreting sections 1847A and 1927 of the Social Security Act ("SSA") to require Allergan to disclose to HHS's Center for Medicare Services ("CMS") its proprietary "average sales price" data ("ASP") for BOTOX Cosmetic. *See* Compl. [Dkt. # 1].

Both parties moved for summary judgment under Federal Rule of Civil Procedure 56(a). Pl.'s Mot. for Summ. J. ("Pl.'s Mot.") [Dkt. # 30]; Def.'s Mot. for Summ. J.

[1] The complaint initially named Kathleen Sebelius in her official capacity as the Secretary of Health and Human Services as the defendant, who has been succeeded by the current Secretary of Health and Human Services, Sylvia Mathews Burwell.

("Def.'s Mot.") [Dkt. # 31]. Upon consideration of the pleadings, record, and relevant law, I find that defendant is entitled to summary judgment. Accordingly, defendant's motion is GRANTED and plaintiff's motion is DENIED.

BACKGROUND

A. Allergan, BOTOX, and BOTOX Cosmetic.

Allergan is a healthcare company that develops and commercializes innovative pharmaceuticals, biologics, medical devices, and over-the-counter products. Pl.'s Mem. of Points and Authorities in Supp. of its Mot. for Summ. J. ("Pl.'s Mem.") 1. The SSA defines "biologicals" as those "included (or approved for inclusion) in the United States Pharmacopoeia . . . ." 42 U.S.C. § 1395x(t)(1). Subsection 351(i)(1) of the Public Health Service Act defines a "biological product" as

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. § 262(i)(1). Absent a biologics license granted by the FDA, it is unlawful to "introduce or deliver for introduction into interstate commerce any biological product . . . ." *Id.* § 262(a)(1).

Allergan submitted a "Biologics License Application" ("BLA") to, and received a biologics license from, the Food and Drug Administration ("FDA") to market onabotulinumtoxinA, a toxin regulated by the FDA under 42 U.S.C. § 262(i). Def.'s Mem. of Points and Authorities in Supp. of Mot. for Summ. J. and in Opp'n to Pl.'s Mot.

for Summ. J. ("Def.'s Mem.") 7. Beginning in 1989, Allergan received FDA approval under that BLA to market onabotulinumtoxinA as "BOTOX" for a number of therapeutic uses. Pl.'s Mem. 2. In 2002 the FDA approved Allergan's supplement to its BLA for onabotulinumtoxinA to be marketed as "BOTOX Cosmetic" for the treatment of wrinkles ("glabellar lines"). *See id.*; Def.'s Reply Mem. in Supp. of Mot. for Summ. J. ("Def.'s Reply") 6-7 [Dkt. # 36]. The approval letter provided, in relevant part, "The Supplement to your License Application, for Botulinum Toxin Type A to include the indication of treatment of glabellar lines, has been approved. Under this approval, Botulinum Toxin type A will be *marketed and labeled* for this indication as BOTOX COSMETIC." Ltr. from Karen L. Goldenthal, M.D., HHS (Apr. 12, 2002), at 1, *available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm088278.pdf (emphasis added). OnabotulinumtoxinA is the sole active ingredient in the same formulation in both BOTOX and BOTOX Cosmetic. Pl.'s Mem. 3; Administrative Record ("A.R.") at 160. BOTOX and BOTOX Cosmetic have different packaging and labels, and Allergan develops, manages, and markets BOTOX and BOTOX Cosmetic in separate divisions of the company. Pl.'s Mem. 3; Def.'s Reply 1. Because BOTOX Cosmetic is approved only for cosmetic treatment, it is not currently eligible for payment under Medicare. Pl.'s Mem. 2-3; A.R. at 29.

Drug manufacturers like Allergan must regularly provide the FDA with lists of all drugs they manufacture, prepare, propagate, compound, or process for commercial distribution. *See* 21 U.S.C. § 360. Manufacturers report their drugs to the FDA using

National Drug Codes ("NDCs"), ten-digit numbers that indicate the labeler, product, and trade package size. *See* 21 C.F.R. § 207.35(b)(2)(i)-(ii). Depending on the dose size, BOTOX is associated with three NDCs. Def.'s Mem. 8. Similarly, BOTOX Cosmetic is associated with two. *Id.*

B. Medicare Part B Reporting Requirements.

Title XVIII of the SSA, colloquially known as the Medicare Act, establishes a federally subsidized health insurance program to be administered by the Secretary of HHS. Medicare has five parts: Part A—Hospital Insurance Benefits; Part B—Supplementary Medical Insurance Benefits; Part C—Medicare+Choice Program; Part D—Voluntary Prescription Drug Benefit Program; and Part E—Miscellaneous Provisions. *See* 42 U.S.C. § 1395 *et seq.* This case deals with Part B, a voluntary supplemental insurance program that provides coverage for various medical and healthcare services including a limited number of outpatient prescription drugs, including injectable drugs furnished incident to a physician's services. *See* 42 U.S.C. § 1395k(a). Doctors request Medicare reimbursements using Healthcare Common Procedure Codes ("HCPCs"). *See* 45 C.F.R. § 162.1002(a)(5)(i), (b)(1), (c)(1); *see also* 42 C.F.R. § 424.32. The injection of onabotulinumtoxinA has a single HCPC, J0585, which is the code assigned for that procedure. Def.'s Mem. 8-9.

With the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"), Congress altered the calculation formula for Medicare reimbursements, *see* Pub. L. No. 108-173, 117 Stat. 2065 (2003), apparently in order to avoid overcharges caused by price discrimination, *see*

H.R. Rep. No. 108-391, at 582 (2003) (Conf. Rep.) (finding drugs' average wholesale prices ("AWPs"), to which reimbursement was tied, "do not reflect the discounts that manufacturers and wholesalers customarily offer to providers and physicians" and thus "AWPs for many Medicare-covered products far exceed the acquisition cost paid by suppliers and physicians"). Under the new statute, drug manufacturers participating in Medicare must report "by National Drug Code . . . [an] average sales price ['ASP'] (as defined in [42 U.S.C. § 1395w-3a])," 42 U.S.C. § 1396r-8(b)(3)(A), for any "drug or biological for which payment may be made" under Medicare, *id.* § 1395u(o)(1). Participating manufacturers who fail to report such data are subject to a $10,000 per day late fee, and could lose their eligibility to participate in Medicare and Medicaid after ninety days. *See id.* § 1396r-8(b)(3)(C)(i); *id.* § 1396r-8(a)(1).

HHS uses the ASP data to calculate a "volume-weighted average of the average sales prices," *id.* § 1395w-3a(b)(6)(A), "for all National Drug Codes assigned to such drug or biological product," *id.* § 1395w-3a(b)(4). Medicare will reimburse 106% of the volume-weighted average price "for the billing and payment code for a drug or biological." *Id.* § 1395w-3a(b)(1). HHS is specifically instructed to determine the reimbursement amount "without regard to any special packaging, labeling, or identifiers on the dosage form or product or package . . . ." *Id.* § 1395w-3a(b)(5).

C. Allergan's Challenge to Reporting Data for BOTOX Cosmetic.

In 2004 Allergan reported the newly required ASP data for BOTOX, but not for BOTOX Cosmetic. *See* Pl.'s Mem. 4; *see also* Pl.'s Mot. Ex. 4, May 13, 2004 Baldo-Hibshman, Minawala Email [Dkt. # 30-5] (A.R. at 34). The Centers for Medicare &

Medicaid Services ("CMS")—the federal agency within HHS that, *inter alia*, administers the Medicare program—requested the missing data via email, Allergan objected, and CMS reversed its position, agreeing with Allergan that BOTOX Cosmetic was "not subject to the ASP reporting requirements." *See* Pl.'s Mem. 4; *see also* Pl.'s Mot. Ex. 5, June 14, 2004 Baldo-Hibshman, Minawala Email 2 [Dkt. # 30-6] (A.R. at 37).

Pursuant to HHS's authority to make "such regulations as may be necessary to carry out the administration" of Medicare, 42 U.S.C. § 1395hh, CMS conducted a round of notice-and-comment rulemaking in 2006. In the preamble to the final rules, CMS responded to a commenter's question as follows:

> With respect to whether a manufacturer may exclude sales for noncovered uses from its calculation of the ASP for an NDC and whether NDCs that are labeled for cosmetic or other typically noncovered use (for example, contraception) are exempt from the ASP reporting requirements, we believe the statute provides no such exclusion.

Miscellaneous Medicare Program Rules, 71 Fed. Reg. 69,624, 69,675 (Dec. 1, 2006). In response to subsequent inquiries from Allergan, Pl.'s Mot. Ex. 6, Feb. 9, 2007 Ingram-Warren Ltr. 1 [Dkt. # 30-7] (A.R. at 43), CMS told Allergan that, based on the response to the comment, Allergan was now obligated to report ASP data for BOTOX Cosmetic, Pl.'s Mot. Ex. 7, Mar. 28, 2007 Warren-Ingram Ltr. 1 [Dkt. # 30-8] (A.R. at 46). Allergan reported the data to avoid potential noncompliance penalties, Pl.'s Mot. Ex. 8, Radensky Decl. ¶¶ 2-3 [Dkt. # 30-9], but elevated the challenge in a letter to the HHS Office of General Counsel ("OGC"), Pl.'s Mot. Ex. 3, May 16, 2012 Pinkston-Shultz Ltr. 1-5 [Dkt. # 30-4] (A.R. at 28-32). After a meeting with Allergan in August 2012, CMS

responded to Allergan via email stating BOTOX Cosmetic ASP data was subject to the reporting requirement. Pl.'s Mot. Ex. 9, Nov. 7, 2012 Hoffman-Zimmerman Email 1 [Dkt. # 30-10] (A.R. at 1). CMS explained it "interpreted the term 'biological product'—as used in [42 U.S.C. § 1395w-3a(b)(4)]—to mean all iterations of a biologic under the same Biologics License Application," *id.*, and provided a link to a 2007 guidance document explaining the "multi-step process" through which CMS identifies "'biological products' subject to payment under [42 U.S.C. § 1395w-3a]," Pl.'s Mot. Ex. 10, 2007 HHS Guidance 2 [Dkt. # 30-11] (A.R. at 24). The email also referred to penalties associated with a manufacturer's failure to submit ASP data, set forth in subsection 1927(b)(3)(C) of the SSA. Pl.'s Mot. Ex. 9, Nov. 7, 2012 Hoffman-Zimmerman Email 1.

Allergan then brought this action challenging HHS's decision. *See generally* Compl. On May 15, 2015, following this Court's denial of defendant's motion to dismiss the instant case, plaintiff filed a Motion for Summary Judgment, contending that section 1927 of the SSA does not require Allergan to disclose ASP data for Botox Cosmetic. Defendant timely opposed, contending that the SSA requires Allergan to report the ASP for every National Drug Code and brand name assigned to a biological product and for which payment may be made under Medicare Part B.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 56(a), summary judgment is warranted "if the movant shows that there is no genuine dispute as to any material fact." Fed. R. Civ. P. 56(a). On a summary judgment motion challenging final agency action under the APA, the Court's review is limited to the administrative record. *See e.g.*, *Coe v.*

McHugh, 968 F. Supp. 2d 237, 239 (D.D.C. 2013). Whereas "the role of the agency [is] to resolve factual issues," the sole "function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citation and internal quotation marks omitted). The court must determine "whether the agency acted within the scope of its legal authority, . . . explained its decision, . . . relied [on facts that] have some basis in the record, and . . . considered the relevant factors." *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C. 1995). "Summary judgment is an appropriate mechanism for resolving cases involving administrative rulemaking on the record, particularly where, as here, the case turns chiefly on issues of statutory construction." *Indiv. Reference Servs. Grp., Inc. v. FTC*, 145 F. Supp. 2d 6, 22 (D.D.C. 2001), *aff'd sub nom.*, *Trans Union LLC v. FTC*, 295 F.3d 42 (D.C. Cir. 2002).

ANALYSIS

Plaintiff seeks judgment declaring the HHS Secretary acted arbitrarily and capriciously or contrary to law in violation of section 10(e)(2)(A) of the APA by interpreting sections 1847A and 1927 of the SSA to require that plaintiff report average sales price of BOTOX Cosmetic to CMS. *See generally* Compl. Specifically, plaintiff alleges the Secretary's interpretation is arbitrary and capricious or contrary to the SSA because section 1927 (1) allows the government to collect ASP data only for products covered by Medicare, and Medicare cannot pay for BOTOX Cosmetic, and (2) limits the scope of ASP reporting to drugs or biologicals for which payment amount is established under 1847A, which also is limited to products covered by Medicare. *Id.* ¶¶ 41-53.

Confronted with statutes administered by an agency, the court will first "employ traditional tools of statutory construction," *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984), to determine "whether Congress has spoken directly to the precise question at issue," *id.* at 842. This inquiry begins with the ordinary meaning of the text of the statute. *See Ransom v. FIA Card Servs., N.A.*, 562 U.S. 61, 69 (2011); *United States v. Brown*, 58 F. Supp. 3d 115, 119 (D.D.C. 2014). However, the court must examine "the words of a statute . . . in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (internal quotation marks omitted). The court may also choose to examine the legislative history, *see id.* at 147, or the purposes of the statute, *see Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1049 (D.C. Cir. 1997). If the statute is clear, "that is the end of the matter" and the court "must give effect to the unambiguously expressed intent of Congress." *Chevron*, 467 U.S. at 842-43.

If congressional intent on "the precise question at issue" is not apparent, the court will often defer to any "permissible construction of the statute" offered by the agency, *id.* at 843, even if it is inconsistent with the agency's prior interpretation, *see Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005). At this phase the court will not substitute its own judgment, *Chevron*, 467 U.S. at 844, but rather will uphold any realistic interpretation of the language and is faithful to the statutory purpose, *see GTE Serv. Corp. v. FCC*, 205 F.3d 416, 421 (D.C. Cir. 2000). This level of deference is appropriate when circumstances imply "that Congress would expect the agency to be able to speak with the force of law." *United States v. Mead Corp.*, 533 U.S. 218, 229

(2001). If the agency was not meant to speak with the force of law, the court will give the agency's position "respect," *see Christensen*, 529 U.S. at 587, and defer only in proportion to "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it the power to persuade," *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

A. Allergan Must Report All Sales of OnabotulinumtoxinA as One Biological Product.

I begin with the threshold issue of whether the statute is clear that Allergan must report all sales of onabotulinumtoxinA as one biological product. I conclude it is.[2]

Because this case requires the interpretation of a statute administered by an agency, *see* 42 U.S.C. § 1395hh, I begin my analysis at *Chevron* step one under which I must employ "traditional tools of statutory construction" to check for a clear expression of congressional intent, 467 U.S. at 843 n.9. This inquiry begins, of course, with the ordinary meaning of the text of the statute. *See Ransom*, 562 U.S. at 69. The reporting provision at issue provides that drug manufacturers participating in Medicare must report an "average sales price ['ASP'] (as defined in [42 U.S.C. § 1395w-3a]) . . . by National Drug Code," SSA § 1927 [42 U.S.C. § 1396r-8(b)(3)(A)], for any "drug or biological for which payment may be made" under Medicare, *id.* § 1395u(o)(1). In other words, a drug manufacturer must report ASP data for every NDC assigned to a biological product for which payment may be made under Medicare Part B. Allergan argues that BOTOX and

[2] Because the statute is clear, "that is the end of the matter," *Chevron*, 467 U.S. at 842, and I do not delve into legislative history or any deference due to the agency's interpretation.

BOTOX Cosmetic are two different biological products, while HHS argues they are one. Plaintiff's argument, unfortunately, is too clever by half.

Indeed, the statutes defining biologicals or biological products themselves demonstrate that BOTOX and BOTOX Cosmetic are the same biological product. Allergan notes that the SSA defines "biologicals" as those "included (or approved for inclusion) in the United States Pharmacopoeia . . . ." 42 U.S.C. § 1395x(t)(1). Although that source identifies BOTOX and BOTOX Cosmetic separately, the descriptions thereof additionally demonstrate they constitute the same biological product, even though used for different purposes. The first entry for "BOTULINUM TOXIN TYPE A" ("Parenteral-Local") lists BOTOX as the commonly used brand name. Pl.'s Opp'n Ex. 11, 1 *USP-DI* 590 (27th ed. 2007) at 4 [Dkt. # 35-1]. The other entry for "BOTULINUM TOXIN TYPE A" ("Intramuscular route") lists BOTOX and BOTOX Cosmetic as the commonly used brand names. Pl.'s Opp'n Ex. 12, 2 *USP-DI* 274 (27th ed. 2007) at 4 [Dkt. # 35-2]. The listings suggest Botulinum Toxin Type A, or onabotulinumtoxinA, is a biological product, for which BOTOX and BOTOX Cosmetic are commonly used brand names. Subsection 351(i)(1) of the Public Health Service Act defines a "biological product" as

> a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (Except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

42 U.S.C. § 262(i). It is undisputed that the toxin onabotulinumtoxinA is the *sole* active ingredient in the same formulation in both BOTOX and BOTOX Cosmetic. Pl.'s Mem. 3; A.R. at 160. Because it is the chemical composition of the product that is the basis for biological product status, not the purpose for which it will be used, the above definition comfortably supports HHS's position that BOTOX and BOTOX Cosmetic are one biological product.

To the extent the reporting statute could still permit either party's interpretation, the statutory scheme further compels the government's unitary biological product construction. The Supreme Court, of course, has directed courts to evaluate "the words of a statute . . . in their context and with a view to their place in the overall statutory scheme." *Brown & Williamson Tobacco Corp.*, 529 U.S. at 133. The longstanding FDA licensing regime for biological products informs our understanding of such products under the Medicare Modernization Act. Importantly, it is undisputed that BOTOX and BOTOX Cosmetic were approved pursuant to the same Biologics License Application ("BLA"). Beginning in 1989, the FDA approved Allergan's BLA for Botulinum Toxin Type A, or onabotulinumtoxinA, to be marketed as BOTOX for various therapeutic uses. In 2002 the FDA approved Allergan's supplement *under the same BLA* to market "BOTOX Cosmetic" for the treatment of wrinkles ("glabellar lines"). *See id.*; Def.'s Mem. 6-7 (citing Ltr. from Karen L. Goldenthal, M.D., HHS (Apr. 12, 2002), at 1, *available at* http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/ucm0882278.pdf ("Under this approval [of Allergan's Supplement to its License

Application for Botulinum Toxin Type A], Botulinum Toxin type A will be *marketed and labeled* for this indication as BOTOX COSMETIC." (emphasis added))). The FDA's approval of Botulinum Toxin Type A, or onabotulinumtoxinA, to be marketed as BOTOX and later BOTOX Cosmetic under the same BLA confirms the conclusion that they constitute one biological product.

Moreover, BOTOX and BOTOX Cosmetic constitute the same biological product notwithstanding differences between them in packaging, labeling, and identifiers. The reporting provision at issue cannot be divorced from the surrounding statutory scheme. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 133. Under the Medicare Modernization Act, manufacturers must report ASP data for biological products for which payment may be made under Medicare, SSA § 1927 ("the reporting provision"), and HHS must use that data to calculate reimbursement payment amounts, SSA § 1847A ("the reimbursement provision"). The reimbursement provision requires payment amounts to be determined based on the reported ASP data for *all* NDCs assigned to a biological product, and "without regard to any special packaging, labeling, or identifiers on the dosage form or product or package." 42 U.S.C. § 1395w-3a(b)(5). That limiting language would be superfluous if, as Allergan suggests, separate labels and prescribing information created separate biological products. *See Asiana Airlines v. FAA*, 134 F.3d 393, 398 (D.C. Cir. 1998) (noting the "cardinal principle of interpretation" requiring a court to "construct a statute so that no provision is rendered inoperative or superfluous, void or insignificant" (internal quotation marks omitted)). To the contrary, the statutory regime clearly contemplates the reported ASP data for a single biological product may be

associated with different NDCs, packaging, labeling, and identifiers, as is the case with BOTOX and BOTOX Cosmetic.

Allergan contends that BOTOX and BOTOX Cosmetic are distinct biological products, but its arguments presume the conclusion Allergan seeks to prove. It is undisputed that the reporting provision applies only to "drugs or biological products for which payment may be made" under Medicare Part B. SSA § 1927, 42 U.S.C. § 1396r-8. Because payment may not be made under Medicare for BOTOX Cosmetic, Allergan argues, it need not disclose ASP data for BOTOX Cosmetic. Pl.'s Mem. in Supp. of its Opp'n to the Gov't's Mot. for Summ. J. ("Pl.'s Opp'n") 4 [Dkt. # 35].[3] Not so fast. Section 1862(a)(10) of the SSA bars reimbursement for cosmetic *procedures*, not the use of certain brands or NDCs that are FDA-approved for cosmetic uses. 42 U.S.C. § 1395y(a)(10) (excluding expenses for "cosmetic *surgery*" (emphasis added)). OnabotulinumtoxinA is a biological product reimbursable under Medicare. *See* Def.'s Mem. 8-9 (doctors request Medicare reimbursement using HCPCs, and an injection of onabotulinumtoxinA has a single HCPC, J0585, assigned for that procedure). Because BOTOX and BOTOX Cosmetic are the same biological product reimbursable under Medicare—onabotulinumtoxinA—Allergan *must* report all ASP data for that biological product.

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[3] Plaintiff makes the same argument with regard to the reimbursement provision, section 1847A of the SSA, which applies only to "drugs and biologicals that are described in [SSA § 1842(o)(1)(C)]," which, in turn, applies only to those "drugs or biological products for which payment may be made" under Medicare Part B, 42 U.S.C. § 1395u(o)(1)(C). *See* Pl.'s Opp'n 15.

B. Allergan Challenges Final Agency Action.

The government reasserts the argument from its Motion to Dismiss that Allergan has not challenged final agency action, but fails to provide a basis for the Court to depart from its prior ruling. The government again contends that Allergan lacks a cause of action because judicial review under the APA is limited to final agency action and, in its opinion, the 2012 email from CMS that plaintiffs challenge in this suit does not constitute final agency action. *See* Def.'s Mem. 21-22. HHS previously moved to dismiss for lack of subject matter jurisdiction and failure to state a claim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). *See* Mem. Op. & Order 1, Mar. 17, 2015 [Dkt. # 23]. I denied that motion and found jurisdiction under APA § 10(c), 5 U.S.C. § 704, because Allergan's claim, concerning HHS actions pursuant to SSA § 1927(b)(3), 42 U.S.C. § 1396r-8(b)(3), was neither barred by the statutory preclusion of certain claims concerning SSA § 1847A, 42 U.S.C. § 1395w-3a, nor subject to the mandatory administrative remedies in SSA § 1847A. *Id.* at 2-5. I also found that Allergan's complaint adequately stated a claim under APA § 10(c) by challenging "final agency action" taken by HHS. *Id.* at 5-6. While I had to accept Allergan's allegations as true at the motion-to-dismiss phase, the factual record has not changed since that point and the contents of the 2012 email remain undisputed. A.R. 28-32; Ans. ¶ 37 [Dkt. # 25].

The 2012 email, in my judgment, constitutes final agency action reviewable under the APA. *See* 5 U.S.C. § 704 (limiting review to "final agency agency"). Finality requires satisfaction of two criteria: "[f]irst, the action must mark the consummation of the agency's decisionmaking process . . . [a]nd second, the action must be one by which

rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citation and internal quotation marks omitted). In other words, agency action is final when it is "definitive" and has "direct and immediate effect on the day-to-day business of the part[y] challenging the action." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986) (providing the applicable framework for analyzing the finality of pre-enforcement agency action) (internal quotation marks and alterations omitted). "Definitiveness" is satisfied when there is "no ambiguity" in the statement, nor any indication it is "subject to further agency consideration or possible modification." *Id.* at 437. The 2012 email satisfies the *Ciba-Geigy* finality requirements because it unequivocally stated the agency's position—that BOTOX Cosmetic is subject to ASP reporting obligations; did not allude to future modification—no future changes in agency policy were suggested; and required "immediate compliance" with the agency's stated position—referring to penalties. *See* Mem. Op. & Order 5-6, Mar. 17, 2015. Until the 2012 email, "Allergan ha[d] received conflicting advice from CMS" regarding whether to report ASP data for BOTOX Cosmetic, "without a clear explanation" regarding the shift in position after the notice-and-comment rulemaking in 2006. Pl.'s Mot. Ex. 3, May 16, 2012 Pinkston-Shultz Ltr. 1. The 2012 email, by comparison, was not "purely informational" and did not "restate" the position set forth in the 2006 preamble, *see Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004), but rather *commanded* immediate compliance by finally and firmly resolving the issue, providing a legal explanation for its decision, and referring to mandatory penalties should Allergan fail to comply.

CONCLUSION

For all of the foregoing reasons, the Court DENIES plaintiff's Motion for Summary Judgment and GRANTS defendant's Motion for Summary Judgment. An Order consistent with this decision accompanies this Memorandum Opinion.

RICHARD J. LEON
United States District Judge