UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IPSEN BIOPHARMACEUTICALS, INC.,

Plaintiff,

v.

ERIC D. HARGAN, Acting Secretary of Health and Human Services, *et al.*,[1]

Defendants.

Civil Action No. 16-cv-2372 (DLF)

MEMORANDUM OPINION

Ipsen Biopharmaceuticals, Inc. (Ipsen) brings this suit under the Administrative Procedure Act to challenge the Centers for Medicare & Medicaid Services' (CMS) interpretation of the Social Security Act—as expressed in a letter sent to Ipsen—as arbitrary, capricious, and contrary to law. Before the Court are the parties' cross-motions for summary judgment. Because the letter at issue does not qualify as final agency action, the Court will grant CMS's motion for summary judgment, deny Ipsen's motion for summary judgment, and dismiss the complaint.

I. BACKGROUND

Ipsen markets various drug products in the United States. A.R. 1. In 2007, the Food & Drug Administration (FDA) approved Ipsen's new drug application (NDA) for a product called

[1] Since the defendants filed their reply, Alex Azar has replaced Eric Hargan as the Secretary of Health and Human Services. No party has yet moved to substitute Azar for Hargan as a defendant, so the Court retains the defendants as they appear on the docket for purposes of the case name.

Somatuline Depot Injection that is used to treat acromegaly.[2] *Id.* at 1, 35–39. In 2014, after Ipsen had submitted additional user studies and proposed changes in supplemental new drug applications (sNDAs), FDA approved two supplemental applications: one that "propose[d] changes to the drug substance and drug product manufacturing processes, and to the drug product container closure system" and another that "provide[d] for a new indication" to use the drug to treat a rare type of cancer. *See id.* at 40, 76. Ipsen calls the products approved through the sNDA process Somatuline ED. *Id.* at 1.

The parties dispute whether Somatuline ED is a new drug for purposes of the Medicaid Drug Rebate Program (MDRP). The Social Security Act requires drug manufacturers to participate in the MDRP as a condition of Medicaid payment for covered outpatient drugs. *See* 42 U.S.C. § 1396r-8. As part of that program, manufacturers provide rebates to the states for sales of prescription drugs covered by Medicaid. *Id.* § 1396r-8(a)(1). The amount of those rebates is calculated using a statutorily set formula, *id.* § 1396r-8(c), and that formula uses a drug's "base date average manufacturer price" (AMP)—that is, a number reflecting the average manufacturer's price for the first full quarter after a drug enters the market—as part of the calculation. If Somatuline ED is a new drug, Ipsen can calculate and report a new base date AMP for it. If not, Ipsen must continue to use the AMP for the "old" version of Somatuline Depot Injection. *See* Def.'s Opp'n & Cross-Mot. at 1–6, Dkt. 16-1 (describing the process).

On January 7, 2015, Ipsen sent a letter to CMS—the federal agency tasked with administering the Medicaid program—expressing its view that "the Somatuline ED products should be considered 'new products' entitled to baseline AMPs separate and distinct from those

[2] Acromegaly is "a condition involving excessive growth of the hands, feet, and face as a result of excessive growth hormone production during adulthood." Pl.'s Mot. at 4, Dkt. 13.

of the correlating Somatuline Injection products." A.R. 1. The letter explained in detail why Ipsen believed Somatuline ED was entitled to its own AMP and informed CMS that "Ipsen intend[ed] to proceed with this approach absent CMS instruction to the contrary." *Id.* at 4. On July 2, 2015, CMS replied to Ipsen via email. CMS's email stated that CMS "appreciate[d]" the nature of the changes Ipsen made and "the time, effort and financial support" involved, but concluded that Ipsen's changes "d[id] not meet the criteria for the establishment of new base date AMPs for the three strengths of Somatuline ED." *Id.* at 6. CMS provided a brief analysis and concluded that "the baseline data for these three NDCs [for Somatuline ED] must be changed to reflect the original baseline data of Somatuline Depot." *Id.* On July 30, Ipsen emailed CMS and stated that it would seek review of the decision and "would continue to use its newly established base date AMP pending further review by HHS." *Id.* at 11.

On September 21, Ipsen (through counsel) sent another letter to CMS, this time requesting that CMS's Office of General Counsel review the initial determination, requesting a meeting to discuss the issue, and again arguing that its Somatuline ED products were entitled to new base date AMPs. *Id.* at 9–21. Ipsen's letter concluded that CMS "should reconsider its decision reflected in the July 2, 2015 email and should approve Ipsen's request to establish new base date AMPs for its Somatuline ED product." *Id.* at 21. On August 3, the Director of the Division of Pharmacy sent a two-page letter reiterating CMS's position and stating that CMS "maintain[ed]" that the factors Ipsen relied upon "d[id] not warrant establishment of new base date AMPs for the three strengths of Somatuline ED." *Id.* at 34. The letter stated that it was not "a final agency action or even an initial determination on a reimbursement claim." *Id.*

Ipsen filed a complaint on December 5, 2016, and now "request[s] that the Court declare that Somatuline ED is a new and different drug product from its predecessor for purposes of the

MDRP and set aside CMS's contrary determination." Pl.'s Mot. at 12, Dkt. 13. The parties have since filed cross-motions for summary judgment. Dkts. 13, 16.

II. LEGAL STANDARDS

A court grants summary judgment if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). When a plaintiff seeks review of an agency decision under the Administrative Procedure Act (APA), summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). "[T]he entire case . . . is a question of law" and the district court "sits as an appellate tribunal." *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (internal quotation marks and footnote omitted).

The Administrative Procedure Act provides that "final agency action for which there is no other adequate remedy in a court [is] subject to judicial review." 5 U.S.C. § 704. To be "final" under this provision, the action must satisfy two conditions: "First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016) (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)). Here, both parties "agree that CMS's interpretation . . . was the consummation of its decisionmaking process," as "CMS is not still considering how to respond to Ipsen's letters." Def.'s Reply at 2–3, Dkt. 20. The issue is thus whether CMS's August 3, 2016 letter is an action

by which rights or obligations have been determined, or from which legal consequences will flow.[3]

III. ANALYSIS

"The law in this area is hardly crisp." *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1027 (D.C. Cir. 2016). That is at least in part because of the "'pragmatic' and 'flexible' nature of the inquiry as a whole." *Id.* (quoting *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1279 (D.C. Cir. 2005)). As a result, there is language in Supreme Court and D.C. Circuit opinions that seemingly pulls in both directions. The Supreme Court, for example, recently characterized its 1956 decision in *Frozen Food* in terms that would seem to cut in favor of finding reviewability here:

> Although the order "had no authority except to give notice of how the [Interstate Commerce] Commission interpreted" the relevant statute, and "would have effect only if and when a particular action was brought against a particular carrier," we held that the order was nonetheless immediately reviewable. The order, we explained, "warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties."

U.S. Army Corps of Eng'rs v. Hawkes Co., 136 S. Ct. 1807, 1815 (2016) (Roberts, C.J.) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 150 (1967) and *Frozen Food Express v. United States*, 351 U.S. 40, 44 (1956)) (internal citations omitted). Yet the D.C. Circuit has stated—well after the decisions in *Abbott* and *Frozen Food*—that "the case law is clear that [courts] lack authority

[3] There is some question whether CMS was correct to concede that its letter marked the consummation of its decisionmaking process. *Cf. Southwest Airlines Co. v. Dep't of Transp.*, 832 F.3d 270, 276 (D.C. Cir. 2016) (not reaching issue "whether an agency's mere characterization of a previously issued guidance letter as open to reconsideration would suffice to render the letter non-final"); *see also id.* at 275 (noting D.C. Circuit has "found a guidance document was non-final in part because there was no indication that the agency had applied the guidance as if it bound regulated parties"); Def.'s Reply at 5, Dkt. 20 ("CMS's letter does not bind CMS to its interpretation of the statute . . . ."). But because the Court concludes that the letter here did not determine rights or obligations or occasion the flow of legal consequences, it need not address the first *Bennett* factor.

to review claims under the APA 'where an agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party.'" *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 808 (D.C. Cir. 2006) (quoting *Indep. Equip. Dealers Ass'n v. EPA*, 372 F.3d 420, 427 (D.C. Cir. 2004) (Roberts, J.)) (some internal quotation marks omitted). *But see Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 438 n.9 (D.C. Cir. 1986) ("[A]n agency may not avoid judicial review merely by choosing the form of a letter to express its definitive position on a general question of statutory interpretation."); *id.* at 436 ("Once the agency publicly articulates an unequivocal position, however, and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review."). And there is clear disagreement among sitting Justices of the Supreme Court about how to view the *Bennett* test. *Compare Hawkes*, 136 S. Ct. at 1817 (Kagan, J., concurring) (relying on "[t]he creation of [a] safe harbor[] which binds the agencies in any subsequent litigation" to satisfy *Bennett*'s second prong), *with id.* at 1818 n.* (Ginsburg, J., concurring in part and concurring in the judgment) (noting that the *Bennett* test, "contrary to Justice Kagan's suggestion, does not displace or alter the approach to finality established by [*Abbott*] and [*Frozen Food*]").

Because the relevant finality precedent lacks bright-line rules, *Rhea Lana*, 824 F.3d at 1027, the Court will look to the *holdings* of those precedents and compare them to the CMS letter in this case. That inquiry convinces the Court that CMS's August 3 letter does not stack up with other actions deemed final in this Circuit.

The facts in *Independent Equipment Dealers Association v. EPA* are strikingly similar to this case. There, a trade association wrote to EPA "seeking EPA's concurrence in its interpretation of emissions regulations pertaining to 'nonroad engines.'" 372 F.3d at 421. EPA

"replied that it did not concur in [the trade association's] proffered interpretation." *Id.* The D.C. Circuit, in an opinion by then-Judge Roberts, held that the letter failed to satisfy *Bennett*'s second prong: the letter "[c]ompell[ed] no one to do anything" and "had no binding effect whatsoever—not on the agency and not on the regulated community." *Id.* at 427. And the court cited a slew of cases in support of that proposition. *See Reliable Automatic Sprinkler Co. v. CPSC*, 324 F.3d 726, 732 (D.C. Cir. 2003) (agency action unreviewable where agency "has not yet made any determination or issued any order imposing any obligation . . . , denying any right . . . , or fixing any legal relationship"); *AT&T v. EEOC*, 270 F.3d 973, 975 (D.C. Cir. 2001) (agency action unreviewable where "an agency merely expresses its view of what the law requires of a party, even if that view is adverse to the party"); *DRG Funding Corp. v. HUD*, 76 F.3d 1212, 1214 (D.C. Cir. 1996) (agency action unreviewable where order "does not itself adversely affect complainant but only affects his rights adversely on the contingency of future administrative action" (quoting *Rochester Tel. Corp. v. United States*, 307 U.S. 125, 130 (1939) (internal quotation marks omitted))).[4]

The D.C. Circuit has also stated that "interpretative rules or statements of policy generally do not qualify" as final agency action. *Am. Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 395 (D.C. Cir. 2013). In distinguishing binding norms from statements of policy, courts look to

[4] The *Independent Equipment Dealers* court appeared to rely at least in part on its conclusion that EPA's interpretation provided nothing new. *See id.* at 426–28. Here, by contrast, Ipsen argues as part of its arbitrary and capricious challenge that CMS's interpretation "was unknown" and divorced from its prior policy. Pl.'s Mot. at 25–27, Dkt. 13; Pl.'s Reply at 24–25, Dkt. 18. CMS argues the contrary. *See* Def.'s Opp'n & Cross-Mot. at 5, 9–10, 29–30, Dkt. 16-1; Def.'s Reply at 3, Dkt. 20. But it is unclear whether the novelty of the interpretation, as opposed to its lack of practical effect, was necessary to the decision in *Independent Equipment Dealers*, and it is not obvious that *novelty* has any logical bearing on *finality*. *See Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1007 (D.C. Cir. 2014) ("If an agency action announces a *binding* change in its enforcement policy which *immediately affects* the rights and obligations of regulated parties, then the action is likely final and subject to review." (emphasis added)).

(1) whether the action imposed any rights and obligations; (2) whether the action genuinely left the agency free to exercise discretion; (3) the agency's characterization of its own action; (4) whether the action was published in the Federal Register or Code of Federal Regulations; and (5) whether the action has binding effects on private parties or on the agency. *Ctr. for Auto Safety*, 452 F.3d at 806–07. Here, (1) the letter has no independent legal effect; (2) CMS is not bound to its opinion as expressed in the letter, and may bring—or not bring—enforcement actions irrespective of the position expressed in the letter; (3) the letter itself disclaims being final agency action, and CMS has adhered to that characterization; (4) the letter was sent only to Ipsen and does not appear to have been published *anywhere*, let alone the Federal Register or Code of Federal Regulations; and (5) the letter has no *binding* effects on Ipsen, and any practical effect it may have is addressed below.

Ipsen argues that "those cases are inapposite because they deal with policy statements and interpretive rules, respectively, rather than a decision directed to a particular regulated entity that states a definitive legal position and exposes the plaintiff to adverse legal consequences." Pl.'s Reply at 7, Dkt. 18. But that response is unconvincing for a number of reasons. First, it is not clear that the limited scope of CMS's letter—essentially a one-off "directed to a particular regulated entity"—favors Ipsen. *Cf. Ctr. for Auto Safety*, 452 F.3d at 806 (publication in Federal Register or Code of Federal Regulations cuts in favor of reviewability). Second, the letter itself does not "expose[] the plaintiff to adverse legal consequences"; rather, "the scope of [Ipsen's] liability . . . remains exactly as it was before" it received the letter. *Nat'l Ass'n of Home Builders v. Norton*, 415 F.3d 8, 16 (D.C. Cir. 2005); *see also id.* at 15 (noting that "failure to comply does not change the legal burden placed on the government . . . in a suit for injunctive relief"); *AT&T*, 270 F.3d at 976 ("The Commission has not inflicted any injury upon AT&T merely by

expressing its view of the law—a view that has force only to the extent the agency can persuade a court to the same conclusion."). And third, there is clear overlap between the analyses for whether an action is a general statement of policy (as opposed to a rule) and whether that action is final. *See Ctr. for Auto Safety*, 452 F.3d at 805–11.

Finally, the D.C. Circuit has considered letters from an agency non-final even where they appear more serious than the one at issue here. In *Holistic Candlers & Consumers Association v. FDA*, the court deemed non-final fifteen "warning letters" sent from FDA to fifteen manufacturers and distributors of ear candles.[5] 664 F.3d 940, 941–42 (D.C. Cir. 2012). The letters advised that "FDA considered [the] candles to be adulterated and misbranded medical devices," instructed the recipients to "take prompt action to correct [the identified] deviations" from the law, "request[ed]" that the recipients discontinue marketing, promoting, and distributing the candles, and warned that "[f]ailure to promptly correct these deviations may result in regulatory action." *Id.* at 942. At a subsequent meeting between FDA and one of the letter recipients, FDA reiterated its position and "asserted that FDA did not intend to approve ear candles for use in the market," although the meeting did conclude with FDA inviting a response from the letter recipient. *Id.* The court held that the warning letters failed to satisfy either of *Bennett*'s two prongs, in part because the letters were FDA's method of seeking voluntary compliance, were "informal and advisory," and "d[id] not commit FDA to taking enforcement action." *Id.* at 944 (quoting FDA Manual § 4-1-1).

[5] "Ear candles are hollow tubes made of fabric soaked in beeswax or paraffin; a user places one end in his ear and sets the other on fire with an open flame." *Id.* at 941. Though the FDA apparently found their health benefits dubious, proponents claimed they could alleviate conditions ranging from sinus congestion to attention deficit disorder to vision problems. *See id.* at 942.

The cases Ipsen cites fail to demonstrate that an agency's legal opinion expressed in a letter, without more, can satisfy *Bennett*'s second prong. In *Hawkes*, EPA's jurisdictional determination denied a legal safe harbor to the company. 136 S. Ct. at 1814. But here, no matter which position CMS had taken in its response to Ipsen, Ipsen would never have had any "safe harbor." *See* Def.'s Reply at 5, Dkt. 20. In *Rhea Lana*, a letter from the Department of Labor informing a company that it was violating the law "rendered knowing any infraction in the face of such notice, and made [the company] susceptible to willfulness penalties that would not otherwise apply." 824 F.3d at 1025; *see also Sackett v. EPA*, 566 U.S. 120, 126 (2012) (compliance order final where it created legal obligation to restore property and exposed challenger to double penalties in future enforcement proceeding). But Ipsen concedes that CMS's letter does not impute any legally relevant scienter that would enhance future penalties. *See* Pl.'s Reply at 6, Dkt. 18. In *Appalachian Power Co. v. EPA*, EPA's guidance document "read[] like a ukase" and "g[ave] the States their 'marching orders,'" leading almost all States to "fall in line" and insist on compliance with the guidance for regulated entities to receive permits. 208 F.3d 1015, 1023 (D.C. Cir. 2000). But here, Ipsen does not need any such permit; it self-reports its drug-pricing data to CMS as part of the rebate program. *See* A.R. 99. And in *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111 (D.D.C. 2009), CMS denied a drugmaker's request to reclassify one of its products, which affected reimbursement rates and created a financial disincentive for providers to administer the product to Medicare beneficiaries. *Id.* at 114. But, again, Ipsen self-reports its drug-pricing data; it does not need CMS to take any action at all, and is not requesting anything other than CMS's blessing over its own practices.

Two cases—*CSI Aviation Services, Inc. v. Department of Transportation*, 637 F.3d 408 (D.C. Cir. 2011) and *Ciba-Geigy Corp.*, 801 F.2d 430—come closer, but still do not push the

letter in this case over the finality line. Those cases found a cease-and-desist letter and letters directing companies to modify their pesticide labels, respectively, final agency action for three reasons: (1) the agency took a definitive legal position concerning its statutory authority; (2) the case presented a purely legal question of statutory interpretation; and (3) the agency's letter imposed an immediate and significant practical burden. *CSI Aviation Servs.*, 637 F.3d at 412 (citing *Ciba-Geigy*, 801 F.2d at 435–37). The practical burdens in those cases were weighty. In *CSI Aviation Services*, the cease-and-desist order "cast a shadow over CSI's customer relationships, tainted almost every aspect of its long-term planning, and impaired the company's ability to fend off competitors," and the letter's "very purpose" was "to prompt CSI to shut down its operations." 637 F.3d at 413. In *Ciba-Geigy* (which predated *Bennett*), compliance would have been costly and noncompliance would have "run the risk of serious civil and criminal penalties for unlawful distribution of 'misbranded' products." 801 F.2d at 438–39; *see also Pharm. Research & Mfrs. of Am. v. HHS*, 138 F. Supp. 3d 31, 45–46 (D.D.C. 2015) (finding third factor satisfied where compliance would require pharmaceutical manufacturers to sell certain drugs at reduced prices and would directly affect day-to-day business by forcing changes to accounting systems and increasing auditing expenditures).

But these cases must be read in light of the D.C. Circuit's statement that "'[p]ractical consequences,' such as the threat of 'having to defend itself in an administrative hearing should the agency actually decide to pursue enforcement,' are insufficient to bring an agency's conduct under [courts'] purview." *Indep. Equip. Dealers*, 372 F.3d at 428 (quoting *Reliable Automatic Sprinkler Co.*, 324 F.3d at 732); *see also Ctr. for Auto Safety*, 452 F.3d at 811 ("[D]e facto compliance is not enough to establish that the guidelines have had *legal* consequences."); *Norton*, 415 F.3d at 15 ("[I]f the practical effect of the agency action is not a certain change in

the legal obligations of a party, the action is non-final for the purpose of judicial review."). The unifying principle behind these cases—as well as *Frozen Food* and the *Hawkes* Court's reading of it, *see supra*—may be the "flexible" and "pragmatic" nature of the finality inquiry. *See Rhea Lana*, 824 F.3d at 1027; *Hawkes*, 136 S. Ct. at 1815. Because of that flexibility, "whether an agency letter threatening enforcement action is subject to judicial review varies based on the circumstances." *CSI Aviation Servs.*, 637 F.3d at 414 n.2.

Here, the circumstances do not show the requisite "immediate and significant" practical burden on Ipsen. *See id.* at 412. The burden here is less significant than in cases like *Frozen Food* and other cases, where potential criminal liability existed. *See* Def.'s Opp'n & Cross-Mot. at 14, Dkt. 16-1 (listing only civil enforcement mechanisms). CMS's letter does not force Ipsen to alter its business model or day-to-day practices; in fact, the record indicates that Ipsen continued to self-report a new base date AMP for Somatuline ED even after CMS initially declined to acquiesce in Ipsen's interpretation. *See* A.R. 4, 6, 11. Compliance costs are low: Ipsen must already have reporting systems in place to report AMPs, and would simply report a different number.[6] The letter, unlike the letters in many of the cases on which Ipsen relies, does not threaten any enforcement action. The letter was not even a CMS initiative—it was simply a response to Ipsen's request that CMS acquiesce in its interpretation. *Cf. Rhea Lana*, 824 F.3d at 1028 ("Agencies routinely use such letters to warn regulated entities of potential violations before saddling them with expensive and demanding enforcement actions. Treating such reminders of regulated parties' legal obligations as final and judicially reviewable agency action

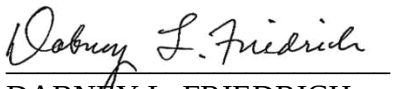
[6] True, Ipsen would presumably lose money under the rebate program if it used the AMP that CMS believes is appropriate. But in light of the case law described above, that cost does not seem to rise to the "immediate and significant" change in a company's business model that some cases have found sufficient to warrant judicial review, particularly in light of the conflicting statements in other cases.

would discourage their use, 'quickly muzzl[ing] . . . informal communications between agencies and their regulated communities . . . that are vital to the smooth operation of both government and business.'") (quoting *Indep. Equip. Dealers Ass'n*, 372 F.3d at 428).

The Court thus concludes that CMS's August 3 letter does not qualify as final agency action, and is therefore unreviewable under § 704. As a result, the Court does not reach Ipsen's substantive challenges to CMS's interpretation.

CONCLUSION

For the foregoing reasons, the Court will grant CMS's motion for summary judgment, deny Ipsen's motion for summary judgment, and dismiss the complaint for failure to state a claim.[7]



DABNEY L. FRIEDRICH
United States District Judge

Date: September 24, 2018

[7] The D.C. Circuit has sent conflicting signals about whether § 704's finality requirement is jurisdictional. *Compare DRG Funding Corp.*, 76 F.3d at 1214 ("The requirement of a final agency action has been considered jurisdictional."), *with Reliable Automatic Sprinkler Co.*, 324 F.3d at 731 (when "judicial review is sought under the APA rather than a particular statute prescribing judicial review, the requirement of final agency action is not jurisdictional"). The later-in-time case intimates that the proper method for dismissing non-final claims is for failure to state a claim. *Reliable Automatic Sprinkler Co.*, 324 F.3d at 731; *see also Holistic Candlers*, 664 F.3d at 943; *Pharm. Research & Mfrs. of Am.*, 138 F. Supp. 3d at 39 n.5 ("Although the D.C. Circuit has occasionally characterized the issue as 'jurisdictional,' it is now 'firmly established' that 'the review provisions of the APA are not jurisdictional.'" (internal citations omitted)). The Court thus follows that approach.