

Exhibit 1

21-2426

Magellan Technology, Inc. v. United States Food and Drug Administration

1 UNITED STATES COURT OF APPEALS
2 FOR THE SECOND CIRCUIT

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5 August Term 2022

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7 Argued: February 6, 2023

8 Decided: June 16, 2023

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10 No. 21-2426

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13 MAGELLAN TECHNOLOGY, INC.,

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15 *Petitioner,*

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17 *v.*

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19 UNITED STATES FOOD AND DRUG ADMINISTRATION,

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21 *Respondent.*

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25 On Petition for Review of a Final Marketing Denial Order
26 by the Food and Drug Administration

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29 Before: JACOBS, PÉREZ, and MERRIAM, *Circuit Judges.*

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31 Petitioner Magellan Technology, Inc. (“Magellan”), the distributor of
32 various electronic nicotine delivery systems (“ENDS”) products, petitions for
33 review of a marketing denial order issued by Respondent, the United States Food
34 and Drug Administration (the “FDA”). In September 2021, the FDA denied
35 Magellan’s premarket tobacco application, concluding that the application lacked

1 sufficient evidence to demonstrate that the marketing of Magellan’s flavored
2 ENDS products was appropriate for the protection of the public health. Because
3 we conclude that the FDA’s denial of Magellan’s application did not violate the
4 Administrative Procedure Act and was well within the FDA’s statutory authority
5 under the Family Smoking Prevention and Tobacco Control Act, we deny
6 Magellan’s petition.

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13
14 MYRNA PÉREZ, *Circuit Judge:*

15 This case concerns the United States Food and Drug Administration’s
16 (the “FDA”) efforts to regulate electronic nicotine delivery systems (“ENDS”)
17 products, more commonly known as e-cigarettes. ENDS are a relatively new type
18 of tobacco product that deliver aerosolized liquid containing nicotine derived
19 from tobacco (“e-liquids”) when a user inhales. They have rapidly become
20 popular—especially among young people, who have overwhelmingly adopted
21 flavored ENDS products as their tobacco products of choice.

1 Magellan Technology, Inc. (“Magellan”) distributes ENDS products,
2 including replaceable cartridges,¹ also known as “pods.” Magellan’s pods contain
3 e-liquids at four different nicotine strengths in fruit and dessert flavors—
4 “Mango,” “Pretzel Graham,” and “Blue Razz” —as well as tobacco and menthol
5 flavors. The FDA differentiates between e-liquids in fruit and dessert flavors
6 (“flavored ENDS products” or “flavored pods”) and e-liquids in tobacco and
7 menthol flavors. *See* Joint App’x at 84.

8 Magellan sought authorization from the FDA to market its ENDS products
9 under the Family Smoking Prevention and Tobacco Control Act (the “TCA”),
10 Pub. L. No. 111-31, 123 Stat. 1776 (2009). The FDA denied Magellan’s premarket
11 tobacco application (“PMTA”) with respect to its flavored pods, finding
12 insufficient evidence showing that marketing the pods would be appropriate for
13 the protection of the public health, a finding that requires denial of a PMTA under
14 the TCA. *See* 21 U.S.C. § 387j(c)(2)(A). Magellan now petitions for review. It
15 argues that the FDA’s denial of its PMTA was arbitrary and capricious because (1)
16 the FDA departed from its stated standard of review without providing notice to

¹ A cartridge is a “small, enclosed unit . . . designed to fit within or operate as part of an electronic nicotine delivery system” that “holds liquid that is to be aerosolized through product use.” Joint App’x at 83.

1 or considering the reliance interests of applicants; and (2) despite previously
2 emphasizing the potential importance of marketing plans to its PMTA assessment,
3 the FDA failed to consider Magellan's. Magellan also argues that the FDA
4 exceeded its statutory authority by requiring applicants to demonstrate that their
5 flavored ENDS products are more effective than tobacco-flavored products at
6 promoting cessation or switching from combustible cigarettes to ENDS products.
7 For the reasons stated herein, we uphold the FDA's decision and deny Magellan's
8 petition.

9 I. Background

10 A. Statutory Framework

11 In enacting the TCA in 2009, Congress found that the use of tobacco
12 products was "the foremost preventable cause of premature death in America"
13 and, in particular, that youth use "is a pediatric disease of considerable
14 proportions." TCA §§ 2(1), (13), 123 Stat. at 1777. To combat the public's use of
15 and dependence on tobacco, the TCA "provide[s] authority to the Food and Drug
16 Administration to regulate tobacco products under the Federal Food, Drug, and
17 Cosmetic Act . . . , by recognizing it as the primary Federal regulatory authority
18 with respect to the manufacture, marketing, and distribution of tobacco products."
19 *Id.* § 3(1), 123 Stat. at 1781.

1 The TCA requires the FDA’s premarket review of “new tobacco products”
2 (defined in 21 U.S.C. § 387j(a)(1) as, inter alia, tobacco products not commercially
3 marketed in the United States as of February 15, 2007).² *Id.* § 387j(a)(2).
4 Accordingly, unless an exemption applies, a manufacturer must submit a PMTA
5 and obtain premarket authorization from the FDA to introduce a new tobacco
6 product into interstate commerce. *Id.* §§ 387j(a)(1)–(2), (c)(1)(A)(i). As relevant
7 here, to obtain FDA approval, an applicant must show that allowing its tobacco
8 product to be marketed would be “appropriate for the public health”
9 (“Appropriate”). *Id.* § 387j(c)(2)(A).

10 In determining whether the marketing of a tobacco product is Appropriate,
11 the FDA considers the “risks and benefits to the population as a whole, including
12 users and nonusers of the tobacco product.” *Id.* § 387j(c)(4). The FDA must take
13 into account “the increased or decreased likelihood that existing users of tobacco
14 products will stop using such products; and . . . the increased or decreased
15 likelihood that those who do not use tobacco products will start using such
16 products.” *Id.* §§ 387j(c)(4)(A)–(B). Thus, the FDA must weigh the potential

² The TCA “grandfathered tobacco products on the market as of February 15, 2007, excusing them from the premarket authorization requirement.” *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 13 (D.C. Cir. 2022) (citing 21 U.S.C. § 387j(a)(1)).

1 benefits of the new tobacco product in promoting smoking cessation against the
2 risks of the product contributing to smoking initiation. *See Avail Vapor, LLC v.*
3 *FDA*, 55 F.4th 409, 414 (4th Cir. 2022). The FDA bases this finding on “well-
4 controlled investigations” or other “exist[ing] valid scientific evidence . . . which
5 is sufficient to evaluate the tobacco product.” 21 U.S.C. §§ 387j(c)(5)(A)–(B).

6 **B. Regulatory Framework**

7 The TCA also empowers the FDA to deem “tobacco products” as being
8 subject to the TCA’s requirements. *Id.* § 387a(b). In 2016, the FDA issued a rule
9 deeming all tobacco products to be subject to the requirements of the Federal Food,
10 Drug, and Cosmetic Act, as modified by the TCA. *See Deeming Tobacco Products*
11 *To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the*
12 *Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and*
13 *Distribution of Tobacco Products and Required Warning Statements for Tobacco*
14 *Products*, 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) (codified at 21 C.F.R. §§ 1100,
15 1140, 1143).

16 The “Deeming Rule” applied to tobacco products, including ENDS
17 products, which were brought to market after Congress passed the TCA. The
18 practical effect of the Deeming Rule was that ENDS products already on the
19 market could no longer be sold legally without the FDA’s approval, as they were

1 now subject to the TCA's premarket authorization requirement. *See* Joint App'x
2 at 78. Instead of requiring ENDS applicants to recall their newly deemed tobacco
3 products, however, the FDA permitted them to continue marketing their products
4 pending review. The deadline for submission of PMTAs for all deemed tobacco
5 products was September 9, 2020.

6 **C. The FDA's Pre-Deadline Preparation**

7 In anticipation of the application deadline, the FDA published several
8 nonbinding guidance documents aimed at helping ENDS applicants prepare their
9 PMTAs. Relevant here, the FDA issued one such document in June 2019 (the "June
10 2019 Guidance"), which was intended to "assist applicants in submitting an ENDS
11 PMTA that could support a showing that the marketing of a new tobacco product
12 would be [Appropriate]." Joint App'x at 211. To that end, the FDA explained that,
13 as part of its consideration, it would review the "health risks associated with
14 changes in tobacco product use behavior (e.g., initiation, switching, dual use,
15 cessation)" and recommended that applicants compare their products with other
16 products in relevant categories. *Id.* at 212–13.

17 The June 2019 Guidance also outlined what could be considered sufficient
18 scientific evidence demonstrating that an ENDS product was Appropriate. The
19 FDA acknowledged that "[g]iven the relatively new entrance of ENDS on the U.S.

1 market, . . . limited data may exist from scientific studies and analyses.” *Id.* at 211.
2 As a result, the FDA would not limit its review to “well-controlled investigations,”
3 such as clinical randomized control trials (“RCTs”) and longitudinal cohort studies
4 but would consider other valid scientific evidence as well. *Id.* The FDA cautioned,
5 however, that “[n]onclinical studies alone are generally not sufficient to support a
6 determination that permitting the marketing of a tobacco product would be
7 [Appropriate].” *Id.*

8 The FDA also issued internal guidance (that was promptly superseded)
9 detailing how it intended to manage the PMTA review process. Central to
10 Magellan’s claims is the FDA’s July 2021 internal memorandum (the “July 2021
11 Memorandum”). The July 2021 Memorandum laid out the FDA’s plan “to take
12 final action on as many [non-tobacco flavored ENDS product] applications as
13 possible by September 10, 2021.” *Id.* at 46. Specifically, it stated that the FDA
14 would engage in a preliminary “fatal flaw review” of the non-tobacco-flavored
15 ENDS PMTAs not yet in the substantive scientific review phase. The FDA would
16 review these submissions for “fatal flaw[s],” which it identified as the absence of
17 an RCT or a longitudinal cohort study. *Id.* at 46–47. “[A]ny application lacking
18 this evidence w[ould] likely receive a marketing denial order” *Id.* at 47.

1 The July 2021 Memorandum was superseded by another internal
2 memorandum (the “August 2021 Memorandum”). *Id.* at 58–59. The August 2021
3 Memorandum stated that, in addition to RCTs and longitudinal cohort studies, the
4 FDA would also consider evidence from other study types, provided that those
5 studies “could reliably and robustly assess behavior change (product switching or
6 cigarette reduction) over time, comparing users of flavored products with those of
7 tobacco-flavored products.” *Id.* at 59 n.ix.

8 **D. Procedural History**

9 Magellan submitted a PMTA for various ENDS products, including its
10 flavored pods (“Mango,” “Pretzel Graham,” and “Blue Razz”), on September 8,
11 2020, which was after the FDA issued the June 2019 Guidance, but before it
12 internally circulated the July 2021 Memorandum.

13 To demonstrate that its ENDS products were Appropriate, Magellan
14 submitted four nonclinical studies: (1) a focus group of only two dozen subjects,
15 in which participants were asked about their perceptions of and intentions for
16 ENDS products generally, and about the packaging and marketing of Magellan’s
17 specific products; (2) a two-week online diary study that examined the behavior
18 of only twenty users of Magellan ENDS products, of whom eighteen completed
19 the study; (3) a “human factors stud[y]” involving only fifteen participants that

1 aimed to measure consumer comprehension of product labeling and instructions
2 for Magellan's products; and (4) an online cross-sectional perception and intent
3 survey of 400 current smokers and 1,002 nonsmokers.

4 Notably, none of Magellan's studies robustly "evaluat[ed] the effects of the
5 ENDS on users, including effects on initiation, switching behavior, cessation, and
6 dual use; and on nonusers' initiation of the product," as the June 2019 Guidance
7 recommended. Joint App'x at 237. Three of Magellan's four studies included no
8 more than two dozen participants. The diary study—the only study that
9 documented actual ENDS usage—was completed by just eighteen participants
10 over a two-week period. Although it reflected some participants' intent to use
11 ENDS products to quit smoking combustible cigarettes, it did not measure the
12 actual effectiveness of Magellan's products at promoting cessation. The focus
13 group study and online survey similarly focused on participants' intent with
14 respect to ENDS products rather than outcomes.

15 As part of its PMTA, Magellan also submitted a marketing plan outlining
16 its strategy to restrict youth access to its products and to limit youth exposure to

1 its marketing, as well as a systematic literature review that summarized scientific
2 data about the use of ENDS products.

3 On September 8, 2021, the FDA issued a Marketing Denial Order (an
4 “MDO”) to Magellan for its flavored pods.³ The FDA concluded that Magellan’s
5 PMTAs “lack[ed] sufficient evidence demonstrating that [its] flavored ENDS will
6 provide a benefit to adult users that would be adequate to outweigh the risks to
7 youth.” *Id.* at 7. Specifically, the FDA determined that Magellan had not shown
8 the comparative efficacy of its flavored ENDS products over tobacco-flavored
9 ENDS products in helping smokers completely switch to ENDS products or stop
10 smoking altogether.

11 Because the FDA found Magellan’s evidence to be “insufficient,” it did not
12 proceed “to assess other aspects of the[] application[.]” *Id.* at 8. After the FDA
13 issued the MDO, Magellan timely petitioned this Court for review.

14 II. Standard of Review

15 The TCA incorporates by reference the standard of review established by
16 the Administrative Procedure Act (the “APA”). *See* 21 U.S.C. § 3871(b) (citing
17 5 U.S.C. § 706(2)(A)). Under the APA, we must “hold unlawful and set aside

³ As of the date of Magellan’s opening brief, the FDA had not issued marketing decisions for Magellan’s tobacco- and menthol-flavored pods.

1 agency action, findings, and conclusions found to be . . . arbitrary, capricious, an
2 abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A).
3 Agency action is “arbitrary and capricious if the agency has relied on factors which
4 Congress has not intended it to consider, entirely failed to consider an important
5 aspect of the problem, offered an explanation for its decision that runs counter to
6 the evidence before the agency, or is so implausible that it could not be ascribed to
7 a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n*
8 *of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

9 “Under the arbitrary-and-capricious standard, judicial review of agency
10 action is necessarily narrow. A reviewing court may not itself weigh the evidence
11 or substitute its judgment for that of the agency.” *Islander E. Pipeline Co. v.*
12 *McCarthy*, 525 F.3d 141, 150 (2d Cir. 2008) (citations omitted); *see also FCC v.*
13 *Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) (“A court simply ensures that
14 the agency has acted within a zone of reasonableness and, in particular, has
15 reasonably considered the relevant issues and reasonably explained the
16 decision.”).

17 Judicial review of agency action incorporates the APA’s prejudicial error
18 rule. *See* 5 U.S.C. § 706. Under the prejudicial error rule, a court will not disturb

1 an agency's decision if it determines that the outcome of the agency action would
2 be the same absent agency error. See *Nat'l Ass'n of Home Builders v. Defs. of Wildlife*,
3 551 U.S. 644, 659–60 (2007) (“In administrative law, as in federal civil and criminal
4 litigation, there is a harmless error rule.” (quoting *PDK Lab'ys Inc. v. U.S. Drug*
5 *Enft Admin.*, 362 F.3d 786, 799 (D.C. Cir. 2004))); see also *Green Island Power Auth. v.*
6 *FERC*, 577 F.3d 148, 165 (2d Cir. 2009) (“[W]e will not disturb [agency action] if we
7 can determine that the outcome . . . w[ould] be the same absent [agency] error.”).
8 “[T]he burden of showing that an error is harmful normally falls upon the party
9 attacking the agency's determination.” *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009).

10 III. Discussion

11 12 A. Magellan's Challenge to the FDA's Standard of Review

13 Contrary to Magellan's claims, the FDA did not apply a new standard of
14 review in evaluating Magellan's PMTA. Therefore the FDA was not obligated to
15 notify Magellan or consider its reliance interests, as it would be if the FDA had
16 applied a new standard of review.

17 When an agency changes course, it must provide notice, *FCC v.*
18 *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (“An agency may not . . . depart
19 from a prior policy *sub silentio* or simply disregard rules that are still on the

1 books.”), and consider the reliance interests of the governed parties, *Dep’t of*
2 *Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (where an
3 agency policy has engendered a reliance interest among the governed, the agency
4 must be “cognizant” of that fact and take potential reliance interests “into account”
5 (quotation marks omitted)).

6 But here the record shows that the FDA never changed its position: that it
7 might accept evidence other than long-term studies to demonstrate that an ENDS
8 product was Appropriate *if* that evidence had sufficient scientific underpinnings.
9 Consistent with its position, the FDA considered Magellan’s weak scientific
10 evidence and found it insufficient to support an Appropriate finding.

11 In support of its argument, Magellan points to a statement in the June 2019
12 Guidance that the FDA did not “expect that applicants will need to conduct long-
13 term studies to support an application”; but this out-of-context fragment does very
14 little to help Magellan. Joint App’x at 212. There is no dispute that the June 2019
15 Guidance contemplated that evidence besides long-term studies *might* be
16 sufficient, but it did not guarantee that other scientific evidence *would be* sufficient.
17 *See Prohibition Juice Co. v. FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022) (“The FDA did not
18 reverse course. . . . The text of the FDA’s 2019 Guidance makes that clear.”). The

1 June 2019 Guidance consistently used conditional language when describing
2 acceptable evidence (as set out in the margin⁴). It also cautioned that “[n]onclinical
3 studies alone are generally not sufficient to support a determination that
4 permitting the marketing of a tobacco product would be [Appropriate].” Joint
5 App’x at 211.

6 According to Magellan, the July 2021 Memorandum heightened the
7 standard of review by saying that the FDA would conduct a “fatal flaw” analysis
8 for the absence of an RCT or longitudinal cohort study. However, the July 2021
9 Memorandum was circulated internally and superseded before Magellan received
10 its MDO. *See Avail Vapor*, 55 F.4th at 424 (reasoning that “internal documents [are]
11 unlikely to create reliance interests” and the July 2021 Memorandum was
12 “rescinded . . . or superseded” by the time the FDA issued its MDO).

⁴ Specifically, the June 2019 Guidance states:

- Other evidence might be acceptable if “it is valid scientific evidence sufficient to demonstrate that the marketing of a product would be [Appropriate].” Joint App’x at 211.
- “[I]n some cases, it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies.” *Id.* at 245.
- “In cases where a product has not yet been sufficiently reviewed, new nonclinical and clinical studies may be necessary to support a marketing order.” *Id.*
- “[P]ublished literature reviews . . . or reports may be acceptable to support a PMTA, but are considered a less robust form of support” *Id.* at 246.

1 Nor does the record support Magellan’s contention that the FDA
2 surreptitiously applied the July 2021 Memorandum’s “fatal flaw” analysis to
3 Magellan’s PMTA notwithstanding that the July 2021 Memorandum was
4 superseded shortly after its internal circulation. Instead, the record shows that the
5 FDA considered Magellan’s evidence and found it insufficient. Specifically, the
6 FDA’s Technical Project Lead (“TPL”), a document Magellan received with the
7 MDO, identified deficiencies in the evidence Magellan submitted, which led the
8 FDA to conclude that Magellan’s evidence was “not adequate” to support an
9 Appropriate finding. Joint App’x at 38. This analysis would have been
10 unnecessary had the FDA engaged in a fatal flaw review because the FDA could
11 have denied the application solely on the grounds that it lacked an RCT or
12 longitudinal cohort study.

13 Given that the FDA did not impose a new evidentiary standard on
14 Magellan, the FDA did not need to provide notice or consider its reliance interests.
15 We therefore conclude that the FDA did not act arbitrarily or capriciously. *See*
16 *Prohibition Juice*, 45 F.4th at 20–21; *see also Avail Vapor*, 55 F.4th at 422; *Liquid Labs*
17 *LLC v. FDA*, 52 F.4th 533, 539–42 (3d Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553,

1 559–60 (7th Cir. 2022), *cert. denied*, No. 22-708, 2023 WL 3440578, at *1 (U.S. May 15,
2 2023).

3 **B. Magellan’s Challenge to the FDA’s Failure to Consider Its**
4 **Marketing Plan**

5 Even assuming that the FDA’s decision not to evaluate Magellan’s
6 marketing plan as part of its PMTA review was error, any such error was harmless
7 because it did not affect the outcome of the FDA’s review.⁵

8 As previously stated, agency action is arbitrary and capricious when the
9 agency “entirely failed to consider an important aspect of the problem,” *State Farm*,
10 463 U.S. at 43, or when the decision did not include “a consideration of the relevant
11 factors,” *id.* (quotation marks omitted). In Magellan’s TPL, the FDA noted that
12 evidence regarding risk to youth “would . . . be evaluated to determine that the
13 totality of the evidence supports a marketing authorization” and that such an
14 assessment would “include[] evaluating the appropriateness of the proposed
15 marketing plan.” Joint App’x at 35. However, in the same document, the FDA
16 stated that “for the sake of efficiency,” it had “not evaluated any marketing plan[]

⁵Magellan also argues that the FDA’s failure to consider its other evidence—its four studies and literature review—was arbitrary and capricious. But as discussed above, the FDA did consider this evidence and concluded that it was “not sufficiently strong to support the benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette reduction based on flavor type to enable comparisons between tobacco and other flavors.” Joint App’x at 38.

1 submitted with the[] application[]." *Id.* at 35 n.xix. Given that the FDA itself
2 identified the marketing plan as a relevant factor to its determination of whether
3 Magellan's flavored pods would be marketed, it was likely error that the FDA did
4 not review the marketing plan. *See Green Island Power Auth.*, 577 F.3d at 158.

5 The potential error, however, did not affect the outcome of the FDA's review
6 of Magellan's PMTA because there is no indication that the marketing plan would
7 have made up for the PMTA's other defects. *See Shinseki*, 556 U.S. at 406; *see also*
8 *Green Island Power Auth.*, 577 F.3d at 165. According to Magellan, the focus of its
9 marketing plan was to "limit[] youth access and exposure" to ENDS products and
10 marketing material principally through the implementation of various age
11 verification provisions. Pet'r's Br. at 37–38. But the FDA had previously stated
12 that similar age verification strategies "would not be sufficient to address youth
13 use of [ENDS] products." Joint App'x at 118. Magellan does not explain how its
14 marketing strategies differ from the similar measures the FDA had uniformly
15 rejected or why conditions had changed such that the measures would now be
16 effective. Thus, Magellan has not shown that the FDA would have reached a
17 different result had it reviewed Magellan's marketing plan. *See Bechtel v. Admin.*
18 *Rev. Bd., U.S. Dep't of Lab.*, 710 F.3d 443, 449 (2d Cir. 2013) (finding legal error

1 immaterial where petitioner’s failure to establish a needed element was a sufficient
2 reason to rule against his claim); *see also Prohibition Juice*, 45 F.4th at 25 (“Where a
3 petitioner had ample opportunity yet failed to show that an agency error harmed
4 it, vacatur and remand to give the agency an opportunity to fix the error is
5 unwarranted.”); *Liquid Labs*, 52 F.4th at 543 (“The FDA’s decision to decline to
6 review [petitioner’s] marketing plan does not change the result because there is no
7 indication the plan would have made up for the deficiencies the FDA identified in
8 [petitioner’s] applications.”). Accordingly, any error was harmless.

9 **C. Magellan’s Challenges to the FDA’s Statutory Authority**

10 The FDA was well within its statutory authority to impose on applicants a
11 comparative efficacy requirement—the requirement that applicants demonstrate
12 their flavored ENDS products are more effective than tobacco-flavored products
13 at promoting cessation or switching from combustible cigarettes to ENDS
14 products.

15 The TCA expressly contemplates a comparative analysis among tobacco
16 products in the context of evaluating whether the products are Appropriate. The
17 TCA states that PMTAs must include “full reports of all information . . . concerning
18 investigations which have been made to show the health risks of such tobacco
19 product and *whether such tobacco product presents less risk than other tobacco products.*”

1 21 U.S.C. § 387j(b)(1)(A) (emphasis added). The TCA also requires that the FDA
2 deny PMTAs where “there is a lack of a showing that permitting such tobacco
3 product to be marketed would be [Appropriate].” *Id.* § 387j(c)(2)(A).

4 Because the TCA instructs the FDA to consider this type of comparative
5 evidence, we conclude that the FDA was well within its authority to require
6 applicants to submit it. *See Prohibition Juice*, 45 F.4th at 19 (“[T]he [TCA] not only
7 allows but expressly instructs the FDA to consider evidence regarding just the
8 comparison that the manufacturers say the FDA lacks statutory authority to
9 make.”); *Avail Vapor*, 55 F.4th at 427 (“The TCA explicitly contemplates that FDA
10 must embark on a comparative inquiry before allowing any marketing of a new
11 tobacco product.”). Finally, we also reject the argument that the comparative
12 efficacy requirement would lead to irrational results.⁶

⁶ First, Magellan contends that by requiring applicants to demonstrate their flavored ENDS products are more effective than tobacco-flavored products at promoting cessation or switching from combustible cigarettes to ENDS products, the FDA more rigorously regulates flavored ENDS products, and this is irrational. But this is not irrational. The FDA found that flavored ENDS products pose a much greater risk of youth uptake than tobacco and menthol-flavored ENDS products do. Given the greater risk, it is appropriate that flavored ENDS products are subject to higher standards than their tobacco and menthol-flavored counterparts. Second, Magellan argues that the comparative efficacy requirement leads to flavored ENDS products being regulated more rigorously than nicotine replacement therapy drugs and modified risk tobacco products. This is demonstrably false. These more heavily regulated tobacco products are subject to entirely distinct statutory provisions, which renders the evidentiary standards different and Magellan’s contrast inapposite. At bottom, we need not consider these arguments at all because the TCA expressly empowers the FDA to perform the comparative analysis with which Magellan takes issue.

1

* * *

2

For the foregoing reasons, we **DENY** Magellan’s petition for review.⁷

⁷ In denying Magellan’s petition for review, we join the majority of our sister circuits who have considered these issues. *See Avail Vapor*, 55 F.4th at 428; *Liquid Labs*, 52 F.4th at 545; *Gripum*, 47 F.4th at 561; *Prohibition Juice*, 45 F.4th at 26.