United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued January 25, 2023 Decided August 29, 2023

No. 22-1076

FONTEM US, LLC,
PETITIONER

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
RESPONDENT

Consolidated with 23-1021

On Petitions for Review of an Order
of the Food and Drug Administration

Andrew D. Prins argued the cause for petitioner. With him on the briefs were *Philip J. Perry* and *Jacob Rush*.

Garrett Coyle, Trial Attorney, U.S. Department of Justice, argued the cause for respondent. With him on the brief were *Brian M. Boynton*, Principal Deputy Assistant Attorney General, and *Samuel R. Bagenstos*, General Counsel, U.S. Department of Health and Human Services.

Before: RAO and WALKER, *Circuit Judges*, and GINSBURG, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* RAO.

RAO, *Circuit Judge*: This case concerns the scope of the Food and Drug Administration's authority to regulate the marketing of new tobacco products under the Tobacco Control Act. After the FDA promulgated regulations applying the Act to vaping products, Fontem US, LLC, submitted numerous applications to market its flavored and unflavored vaping products. The FDA denied all of them, concluding Fontem had not shown its products were "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). Fontem petitions for review, arguing the denial was unlawful.

We agree with Fontem in part. As to Fontem's flavored products, the FDA reasonably found a lack of evidence that the benefits of such products to adult smokers sufficiently outweighed the potential risks to young non-smokers. As to Fontem's unflavored products, however, the FDA acted unlawfully by failing to engage in the holistic public health analysis required by the statute. The agency did not take into account the potential benefits of unflavored products or weigh those benefits against risks to the public health.

Accordingly, we deny the petition for review as to Fontem's flavored products and grant the petition for review with respect to the unflavored products.

I.

A.

In 2009, Congress authorized the FDA to regulate new tobacco products. Family Smoking Prevention and Tobacco

Control Act ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1776 (codified at 21 U.S.C. § 387 *et seq.*). The Tobacco Control Act sets out a highly detailed framework governing the FDA's regulatory authority. For instance, the agency may impose "tobacco product standards" that govern the ingredients or properties of tobacco products, *see* 21 U.S.C. § 387g; it may restrict the sale and distribution of tobacco products, *see id.* § 387f(d)(1); and it may prescribe regulations governing the manufacturing of these products, *see id.* § 387f(e). Each of these regulatory avenues is governed by distinct and detailed procedural requirements, which are discussed below.

The Act also provides that all new tobacco products—those not commercially marketed in the United States prior to February 2007—must be approved by the FDA before being marketed to the public. *See id.* § 387j. The agency must deny an application to market a new tobacco product if it makes one of four findings: (1) "there is a lack of a showing" that marketing the product is "appropriate for the protection of the public health"; (2) the manufacturing of the product does not conform to manufacturing regulations promulgated by the agency; (3) the proposed labeling of the product is "false or misleading"; or (4) the product does not conform to a "tobacco product standard" promulgated by the agency. *Id.* § 387j(c)(2). The Act further details the necessary factors for determining a product is not shown to be "appropriate for the protection of the public health" and the type of investigations and evidence the FDA must consider before making such a finding. *Id.* § 387j(c)(4).

The Act initially did not apply to "electronic nicotine delivery systems," colloquially known as vaping products. *See id.* § 387a(b) (providing the statute applies to "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"). These devices utilize solutions containing nicotine.

When activated, the device heats the solution, vaporizing it and allowing the user to inhale the aerosolized liquid. Some vaping products have the same flavor as more traditional tobacco products—menthol or tobacco—and are referred to as "unflavored." Other "flavored" vaping products have a taste reminiscent of fruits or desserts.

Under the Tobacco Control Act, the FDA may by regulation subject "any product made or derived from tobacco … intended for human consumption" to the provisions of the statute.[1] 21 U.S.C. §§ 321(rr)(1), 387a(b). In 2016, the agency invoked this authority to deem vaping products subject to the Act. *See* 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) ("Deeming Rule"). As a result of this Deeming Rule, manufacturers of vaping products were required to secure premarketing approval from the FDA unless the product in question had been marketed prior to 2007.

After issuing the Deeming Rule and following litigation, the FDA required applications for approval of vaping products to be submitted by September 2020. *See* Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market Without Premarket Authorization (Revised); Guidance for Industry; Availability, 85 Fed. Reg. 23,973, 23,974 (Apr. 30, 2020); *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 472 (D. Md. 2019). At no point, however, did the FDA use its regulatory authority to promulgate tobacco product standards or manufacturing regulations. And while the agency issued preliminary guidance in 2019, that guidance did not crystallize into a final rule until

[1] Last year, the Act was amended to make explicit that products "containing nicotine from any source" may qualify as tobacco products. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, div. P., § 111(a)(1), 136 Stat. 49, 789.

well after manufacturers were required to submit applications. *See* Premarket Tobacco Product Applications and Recordkeeping Requirements, 86 Fed. Reg. 55,300 (Oct. 5, 2021).

B.

Fontem began marketing vaping products in 2009 and therefore had to secure premarketing approval for these products. Fontem applied to the agency in April 2020 to market a variety of its vaping products, both flavored and unflavored.

The FDA responded with a deficiency letter, making twenty-two requests for additional information. Although Fontem responded to each of these requests, the agency denied all of Fontem's applications on April 8, 2022. The agency's denial decision rested entirely on the finding that Fontem had not sufficiently demonstrated that permitting its products to be marketed would be "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A).

In support of this conclusion, the agency identified six deficiencies in Fontem's applications:

- Fontem failed to provide sufficient information about the safety of its products, such as the quantities of various compounds "at the maximum allowable coil temperature" (Deficiency 1);
- Fontem failed to provide sufficient information about the "puffing regimens" used to determine "toxicant yields" and about "aerosol temperature measurements" (Deficiency 2);
- Fontem failed to provide the agency with certain information relating to the manufacturing and stability of its products, including details about the laboratories

Fontem employed (Deficiency 3) and about the "microbiological stability" of Fontem's vaping devices (Deficiency 4);

- As to its flavored products, Fontem failed to show such products would be sufficiently beneficial to adults to offset their attractiveness to youth (Deficiency 5);
- Certain files relied upon by Fontem did not include adequate information (Deficiency 6).

On May 6, 2022, Fontem filed a petition for review of the marketing denial order. *See* 21 U.S.C. § 387*l*(a)(1). On June 6, 2022, Fontem also submitted an administrative appeal, seeking supervisory review of the order. Following the agency's denial of that appeal, Fontem filed a second petition for review on January 23, 2023.

II.

At the outset, the government maintains we lack jurisdiction over Fontem's first petition because, once Fontem filed an administrative appeal, the FDA's denial order was not final and therefore not reviewable. By contrast, the government views Fontem's second petition as properly before this court. We disagree with both propositions.[2]

The Tobacco Control Act permits "any person adversely affected" by the "denial of an application under section 387j(c)" to petition for judicial review within 30 days of the denial. 21 U.S.C. § 387*l*(a)(1). The FDA's order, issued on April 8, 2022, denied Fontem's section 387j(c) application, and

[2] *Circuit Judge* GINSBURG would hold that, because, as Fontem points out, one of its petitions for review is necessarily timely, we need not decide which one. *See Collins v. Nat'l Transp. Safety Bd.*, 351 F.3d 1246, 1250 (D.C. Cir. 2003).

Fontem filed its initial petition for review within 30 days of that order, on May 6, 2022. We have jurisdiction over that petition for review. Conversely, Fontem's second petition for review was filed long after the 30-day time period had ended, on January 23, 2023. The petition was therefore untimely and we cannot review it.

Fontem's administrative "appeal" does not affect our jurisdiction. To begin with, the "denial of an application" is a sufficient basis for this court's jurisdiction. *Id.* § 387*l*(a)(1)(B). The Act includes no requirement of finality. Nor is such a finality requirement imposed by the APA, which provides that "[a]gency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review." 5 U.S.C. § 704. A denial order is "made reviewable" by the Tobacco Control Act, and therefore the APA imposes no additional finality requirement.

Furthermore, Congress did not explicitly provide for agency rehearing of marketing denial orders in the Tobacco Control Act. Instead, administrative review of orders is set forth in FDA regulations that specify an informal and unstructured process by which "[a] decision of an FDA employee … is subject to review by the employee's supervisor" at "the request of an interested person outside the agency." 21 C.F.R. § 10.75(a). Nothing in the Act or the regulations suggests this informal process for reviewing employee "decisions" limits applicants' ability to petition for review of marketing denial orders. In order to secure judicial review, Fontem simply had to file within 30 days of the order.

The government argues this court has previously held in other contexts that administrative rehearing requests render an underlying order unreviewable. The cases cited by the government, however, involve statutes with jurisdictional

finality requirements. For instance, this court has held that we lack jurisdiction over petitions filed under the Hobbs Act when the petitioner has concurrently requested agency rehearing because the Hobbs Act grants this court jurisdiction only over "final orders." 28 U.S.C. § 2342(1); *see also, e.g.*, *Flat Wireless, LLC v. FCC*, 944 F.3d 927, 933 (D.C. Cir. 2019). Similarly, we have held that finality concerns preclude our review of petitions brought under the Federal Power Act that coincide with requests for rehearing before the Federal Energy Regulatory Commission. *See Clifton Power Corp. v. FERC*, 294 F.3d 108, 110 (D.C. Cir. 2002) (explaining that this court may review only final orders under the Federal Power Act). Unlike these other statutes, the Tobacco Control Act does not contain a finality requirement; rather, it provides for judicial review over a defined class of orders, including the denial order at issue here.

In this statutory and regulatory context, the government's position—that judicial review of a denial order is available only after the FDA also denies a supervisory appeal—would create uncertainty for litigants and pose serious challenges for judicial administration. Under the government's theory, a supervisory appeal would toll the Act's 30-day timeline to file a petition for judicial review until the appeal is denied. But in the absence of any governing time limits, parties could circumvent the 30-day statutory limit for judicial review by filing a belated supervisory appeal. Alternatively, as government counsel conceded at oral argument, the FDA could delay judicial review by failing to act on an appeal. Nothing in the Tobacco Control Act suggests the availability of judicial review turns on such informal and open-ended regulatory appeals controlled exclusively by the agency.

Under the Tobacco Control Act, when a party files for review within 30 days of a marketing denial order, that order is

immediately reviewable regardless of any administrative appeals the party may file. We thus have jurisdiction over Fontem's initial petition. Fontem's second petition, however, is untimely because it was filed over eight months after the 30-day time period expired.[3]

III.

Fontem argues the FDA's denial of its vaping product applications was unlawful. We first consider the denial of Fontem's flavored products and conclude the FDA reasonably found Fontem failed to show marketing these products would be appropriate for the protection of public health.

A.

The Tobacco Control Act structures the FDA's review of premarketing applications by providing four distinct grounds under which the agency may deny such applications. In denying Fontem's flavored products, the FDA invoked only the first ground: whether "there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). While public health standing alone may be a capacious concept, the Act specifies the basis for such a finding. The FDA must determine:

[3] Because Fontem's initial petition is properly before this court, and the second petition raises the same substantive arguments, the untimeliness of the second petition does not alter the scope of our review.

> the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Id. § 387j(c)(4). In addition, when determining whether an applicant has demonstrated that marketing of a tobacco product is appropriate for the protection of public health, the FDA "shall, when appropriate" rely on "well-controlled investigations," which may include expert "clinical investigations." *Id.* § 387j(c)(5)(A). The Secretary may also authorize the use of other types of evidence. *Id.* § 387j(c)(5)(B).

To deny an application on public health grounds, the FDA must make a single predictive judgment whether a given tobacco product, on balance, will benefit the public as a whole. The Act explicitly requires the FDA to consider *both* "the risks and benefits" of the product. *Id.* § 387j(c)(4). Moreover, the public health inquiry looks to the overall effect of a product for the "population as a whole," *id.*, which means the agency should generally be concerned with the most epidemiologically significant factors associated with approving the marketing of a new product. As part of this determination, the agency must balance the benefits of transitioning existing smokers to the product against the costs of inducing non-smokers to take up smoking. *Id.* § 387j(c)(4)(A), (B). This requirement is bolstered by the information applicants must provide, which includes "full reports of all information … concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product

presents less risk than other tobacco products." *Id.* § 387j(b)(1)(A). Weighing the relative risks of new tobacco products will often be central to the public health analysis given the reality that there are both many smokers who wish to stop smoking and many individuals who do not presently consume tobacco products at all. The Act requires the FDA to undertake a holistic analysis directed at the overall effect a product will have on the public health.

B.

The FDA lawfully concluded Fontem had not shown its flavored products were appropriate for the protection of the public health. In Deficiency 5, the agency explained that because flavored products "have significant appeal to youth and are associated with youth initiation of such products," Fontem would have to provide "robust and reliable evidence … regarding the magnitude of the potential benefit to adult smokers." Such benefits may come from switching to vaping or cigarette reduction over time. In the agency's judgment, the primary study Fontem conducted did not show flavored products had any added benefit for adult smokers relative to unflavored products. The FDA concluded that Fontem failed to show the benefits of its flavored products to adult smokers outweighed the substantial risks of flavored products to youth.

We recently found it reasonable for the FDA to determine that "flavored products present greater risks than other tobacco products, based on a robust array of literature showing the dangers those products pose of hooking new users, especially youth." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 19 (D.C. Cir. 2022). The FDA applied the same determination when denying Fontem's applications for flavored products. The FDA considered the extent to which flavored products might help

adult smokers quit or reduce smoking, compared with the possibility that such products may encourage young non-smokers to take up smoking. By weighing the public health benefits against the public health risks based on the record before it, the agency's analysis was consistent with the statutory requirements and with the balance we approved in *Prohibition Juice*.

Fontem raises three arguments in response. First, Fontem argues the FDA impermissibly altered its standards between the initial deficiency letter and the denial order. Fontem suggests the deficiency letter merely required Fontem to show a "likelihood" that flavored products increase switching by adult smokers, while the subsequent denial order required Fontem to show the benefits of its flavored products "outweigh the risk to youth" by some unspecified magnitude.

Fontem's distinction amounts to splitting hairs. In the deficiency letter, the FDA required Fontem to show its flavored products "increase[] the likelihood of complete switching among adult smokers … while minimizing initiation, particularly by youth." In its denial order, the agency explained Fontem failed to show its products "have a potential to benefit adult smokers … that would outweigh the risk to youth." These statements simply recast the statutory tradeoff required by the Act—whether "the increased or decreased likelihood that existing users of tobacco products will stop using such products" outweighs "the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4)(A)–(B). While the FDA may have used different words in the deficiency letter and the denial order, the underlying public health analysis was the same.

Next, Fontem argues the FDA's denial unlawfully imposed "device access restrictions"[4] for flavored products, and that such restrictions may be imposed only pursuant to a tobacco product standard. Fontem maintains any access restrictions must comply with the procedural requirements for promulgating tobacco product standards, and the agency cannot use a public health finding as a backdoor to circumvent those requirements. Fontem's argument relies on a footnote in which the FDA indicated that measures short of device access restrictions "cannot mitigate the substantial risk to youth" from flavored products. But in context, this footnote does not categorically mandate device access restrictions; it merely suggests that certain mitigation measures cannot substitute for evidence demonstrating that flavored products benefit adult smokers. Indeed, in that same paragraph the FDA indicated that high-quality evidence such as randomized trials could justify approval of Fontem's flavored products. The agency simply concluded Fontem had not produced the necessary evidence.

Finally, Fontem contends that even if the findings in Deficiency 5 were lawful, that deficiency was not an independent basis for the FDA's denial decision, and therefore the denial can be upheld only if every other deficiency is also lawful. We disagree. "When an agency relies on multiple grounds for its decision, some of which are invalid, we may nonetheless sustain the decision as long as one is valid and the agency would clearly have acted on that ground even if the other were unavailable." *Casino Airlines, Inc. v. Nat'l Transp. Safety Bd.*, 439 F.3d 715, 717 (D.C. Cir. 2006) (cleaned up).

---

[4] As explained in the FDA's technical review of Fontem's applications, device access restrictions are "technologies that require adult user identification by fingerprint or other biometric parameters in order to unlock and use a tobacco product."

The reasoning provided in Deficiency 5 is sufficient to support the denial of Fontem's flavored products. The FDA concluded Fontem had failed to provide "sufficient evidence demonstrating that" the flavored products "have a potential to benefit adult smokers, who switch completely or significantly reduce their cigarette use, that would outweigh the risk to youth." The explanation makes clear the agency understood Deficiency 5 to be a sufficient basis for denying approval of Fontem's flavored products. The FDA focused on the question central to the public health inquiry—whether Fontem had shown the "increased or decreased likelihood that existing users of tobacco products will stop using such products" outweighs the "increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4)(A)–(B). Having answered that critical question in the negative, the agency had a sufficient basis for denying Fontem's products.

The FDA adequately explained its finding that Fontem had failed to show that marketing its flavored products would be appropriate for the protection of the public health. Accordingly, we deny Fontem's petition as to these products.

IV.

With respect to Fontem's unflavored products, the FDA also denied Fontem's applications on the public health ground. While the FDA identified multiple "deficiencies," it failed to analyze the tradeoffs necessary to make a public health finding. Nor did the agency explain how the specific deficiencies relate to its overall conclusion that Fontem failed to demonstrate its unflavored products were appropriate for the protection of public health. The agency's denial therefore failed to comport with the requirements of the Tobacco Control Act.

In denying Fontem's unflavored products, the FDA relies solely on the public health ground. The FDA could have promulgated regulations imposing consistent requirements on the composition and manufacturing of tobacco products. Had the agency done so, Fontem's failure to meet those standards would be an independent and sufficient ground for denying the applications, regardless of the overall public health consequences of Fontem's products. But the agency has not exercised its regulatory authority. Because the FDA has chosen to proceed application by application under the public health ground, it must undertake the holistic inquiry required by the statute. We hold that the agency failed to engage in the necessary analysis with respect to Fontem's unflavored products.

A.

As described above, to deny a product on the basis of public health, the FDA must make an all-things-considered judgment that a given tobacco product has not been shown to be appropriate for the protection of the public health. By its nature, such a judgment may validly incorporate a range of factors but, at the same time, it is not unlimited in scope. The agency's review is limited to the public health consequences of the tobacco product, which "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." 21 U.S.C. § 387j(c)(4).

Other provisions of the Tobacco Control Act confirm that the public health inquiry requires the FDA to engage in a high-level balancing test as to the overall public health consequences of the product at issue. The Act provides specific grants of regulatory authority to the agency to promulgate tobacco product standards and manufacturing regulations. These

regulatory authorities permit the FDA to set forth requirements for tobacco products, providing notice and predictability for manufacturers.

First, the FDA has authority to "prescribe regulations" governing the "methods used in, and the facilities and controls used for, the manufacture, preproduction design validation …, packing, and storage of a tobacco product." *Id.* § 387f(e)(1)(A). The failure to comply with a manufacturing regulation is an independent ground for denying an application. *Id.* § 387j(c)(2)(B). Before promulgating a manufacturing regulation, the FDA must comply with numerous and detailed procedural requirements. The agency must first receive recommendations from the Tobacco Products Scientific Advisory Committee (the "Scientific Advisory Committee") and afford "opportunity for an oral hearing." *Id.* § 387f(e)(1)(B)(i)–(iii). Parties may petition for exemptions from the regulation, and such petitions may be reviewed by the Scientific Advisory Committee. *Id.* § 387f(e)(2). In establishing the effective date of a regulation, the FDA must provide a "reasonable period of time" for manufacturers to conform to the regulation at issue, and, in determining that period of time, the agency must consider a variety of factors, including historical differences in manufacturing practices, the "financial resources" of manufacturers, and the "state of … existing manufacturing facilities." *Id.* § 387f(e)(1)(B)(iv). Finally, the agency must exempt small manufacturers from such regulations for at least four years after the regulation's effective date. *Id.* § 387f(e)(1)(B)(v).

Similarly, the FDA has authority to promulgate tobacco product standards, which are uniform rules governing the composition of tobacco products or restricting their sale and distribution. *See id.* § 387g(a)(4). The failure to conform to such a standard is another independent ground for denying an

application. *Id.* § 387j(c)(2)(D). As with manufacturing regulations, tobacco product standards are subject to detailed substantive and procedural requirements. Tobacco product standards may address a range of different issues, regulating, for example, nicotine yields, the reduction of harmful components, or the testing of products. *Id.* § 387g(a)(4). With respect to procedure, the agency must employ notice-and-comment rulemaking, must review reports from the Scientific Advisory Committee, and must consider the "technical achievability of compliance" with the standard at issue, as well as the possibility that imposition of the standard will shift demand to contraband products not regulated by the FDA. *Id.* § 387g(b)–(c), (d)(1). Tobacco product standards generally may not take effect for at least a year. *Id.* § 387g(d)(2). And the Act requires the FDA to balance the concerns of manufacturers by considering information from interested parties as to whether compliance within the timeframe of the effective date is feasible; and by establishing an effective date "so as to minimize, consistent with the public health, economic loss to, and disruption or dislocation of, domestic and international trade." *Id.*

Furthermore, the FDA must consider the protection of public health when promulgating manufacturing regulations and tobacco product standards. *See id.* § 387f(e)(1)(A) (manufacturing regulations shall "assure that the public health is protected"); *id.* § 387g(a)(4) (tobacco product standards must include provisions as "appropriate for the protection of the public health"). Congress thus specified different avenues for the FDA to protect public health, and the FDA cannot impose regulatory requirements through its authority to make public health findings.

If the FDA had established regulatory standards, it could deny applications that fall short of the standards without

undertaking an individualized public health balancing for each product. Because the FDA made the choice to proceed through ad hoc adjudication, the Tobacco Control Act requires the agency to undertake a holistic analysis of whether the benefits and risks of the individual products have been shown to be appropriate for the protection of the public health.

B.

With respect to Fontem's unflavored products, the FDA failed to undertake the analysis required for a denial on public health grounds. Instead of making an overall assessment that Fontem had not shown its products were beneficial to the public, the agency identified five highly technical deficiencies. But nothing in the denial order explains how the deficiencies relate to the overall public health consequences of Fontem's unflavored products. And despite the express statutory requirement that the agency consider the "risks and benefits to the population as a whole," including the "increased or decreased likelihood that existing users of tobacco products will stop using such products," 21 U.S.C. § 387j(c)(4), nowhere in the denial order did the FDA address the potential benefits of Fontem's products for the public at large. Nor did it consider the possibility that existing users of combustible tobacco products such as cigarettes would reap health benefits by transitioning to Fontem's vaping products.

We hold that none of the five deficiencies supports the FDA's finding that Fontem's unflavored products were not appropriate for the protection of public health.

1.

In Deficiencies 1 and 2, the FDA faults Fontem for failing to provide very specific information about the physical

properties of Fontem's products, but fails to explain how the identified problems relate to the "risks and benefits to the population as a whole, including users and nonusers of the tobacco product." 21 U.S.C. § 387j(c)(4).

In Deficiency 1, the agency faulted Fontem for failing to provide the quantities of certain compounds at the "maximum allowable … temperature" of the heating coil used in Fontem's products. The agency stated that high coil temperatures could lead to the emission of harmful chemicals, and it suggested more information about "aerosol constituent testing" would be necessary for Fontem's devices to be approved. But the FDA did not explain why this deficiency was sufficiently serious to outweigh any benefits associated with Fontem's products across the population as a whole. Fontem provided evidence that even under highly conservative assumptions the concentration of harmful compounds in Fontem's vaping products was "substantially lower" than in combustible cigarettes. The FDA did not acknowledge, much less analyze, these benefits, nor did it suggest how the harms of a high coil temperature were so risky as to outweigh these benefits.

Similarly, in Deficiency 2, the FDA concluded Fontem had failed to provide sufficient information about the "puffing regimens" used to determine "toxicant yields" or about "aerosol temperature measurements." The agency expressed concern that higher puff counts could increase the heater coil temperature, thus "resulting in higher toxicant yields." But Fontem had already provided extensive information about its puffing regimens, which were chosen to reflect more risky behavior than would be likely for actual users. Nothing in the marketing denial order explains why any negative consequences associated with toxicant yields or aerosol temperature were so serious as to outweigh the asserted benefits of Fontem's products.

If the FDA wishes to prescribe uniform rules requiring "aerosol constituent testing," mandating specific tests to determine puff counts, or imposing limits on heating coil temperatures, it may do so by promulgating a tobacco product standard. Under its statutory authority, the FDA may impose requirements to eliminate or reduce "harmful components of the product"; to govern the "construction, components, ingredients, additives, constituents, … and properties" of a tobacco product; to require the "testing" of tobacco products; and to require the results of such tests to meet certain standards. *Id.* § 387g(a)(4)(A)(ii), (B)(i), (ii), (iv). The failure to meet such a standard would be a ground for denying an application, and no public health balancing would be necessary. But because the FDA has not promulgated such regulations and instead has chosen to evaluate Fontem's application on public health grounds, it must consider *all* the relevant public health considerations, including the benefits of the product.

2.

Next, Deficiencies 3 and 4 pertain to concerns about Fontem's manufacturing process or about the stability of its products. In Deficiency 3, the agency concluded Fontem had failed to provide sufficient information about its "e-liquid [quality control] testing" and its "liquidpod filling process." In particular, the agency sought the names, accreditation, and specifications of certain laboratories used by Fontem. And in Deficiency 4, the FDA determined Fontem had failed to provide "post-manufacturing microbiological stability information" for its finished products to show those products remain stable "over the defined shelf life." These may or may not be legitimate concerns, but they do not reflect the required statutory balancing for denying an application on public health grounds. The agency did not balance its concerns against the potential benefits of Fontem's products. Nor did it explain why

these deficiencies were so serious as to justify a finding that Fontem had not shown its products would be appropriate for the protection of the public health.

Deficiencies 3 and 4, like Deficiencies 1 and 2, could be sufficient grounds for the FDA to deny Fontem's products if the agency had promulgated valid manufacturing regulations or tobacco product standards. For instance, if the agency had used its regulatory authority to specify the "methods used in, and the facilities and controls used for" the manufacture of tobacco products, *see* 21 U.S.C. § 387f(e)(1)(A), Fontem would be bound to follow such methods and use such controls. And if Fontem had failed to observe such regulations, the FDA could lawfully deny approval of Fontem's products without engaging in any overall balancing analysis. Instead, however, the agency chose to proceed through ad hoc adjudication under the public health provision. The FDA has a certain amount of flexibility to deny a product after making a public health finding, but "however inclusive may be the general language of a statute, it will not be held to apply to a matter specifically dealt with in another part of the same enactment." *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 639 (D.C. Cir. 2021) (quoting *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222, 228 (1957)). Having opted not to issue manufacturing regulations or tobacco product standards, the FDA had to evaluate Fontem's application under the all-things-considered, holistic analysis required to deny a product on public health grounds. Neither Deficiency 3 nor Deficiency 4 includes the necessary analysis to support the FDA's finding.

3.

Finally, nothing in the denial order explains why Deficiency 6 justifies denying approval of Fontem's unflavored products. The FDA stated simply there were

"issues" in certain master files relied upon by Fontem, and that the agency required "additional information … to perform a complete review." But the FDA does not explain why these issues are so serious as to make impossible an informed judgment as to the overall public health consequences of Fontem's products. Nor does the agency even suggest the issues with the master files have caused uncertainty about any specific aspect of Fontem's unflavored products related to public health. Deficiency 6 makes no public health finding and therefore cannot justify the FDA's denial on public health grounds.

C.

The FDA's failure to correctly apply the public health inquiry to Fontem's unflavored products led it to make another serious error. In its initial deficiency letter, the FDA requested certain information from Fontem, thereby indicating such information would be sufficient for the agency to approve Fontem's products. *Cf.* 21 U.S.C. § 387j(c)(3) (providing an application denial "be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form"). But in several instances, the FDA changed its tune in the denial order, reproaching Fontem for failing to provide information the agency had never explicitly sought. With respect to Deficiency 2, for instance, the FDA initially requested a "scientific justification for why consecutive puffing does not cause an increased risk of user injury" and "[t]he target value, upper and lower range limits, and test data" for the studies employed by Fontem. But after Fontem provided that information, the FDA faulted Fontem for failing to provide "scientific justifications" for its puff counts or the "maximum values" of "aerosol temperature measurements." Similarly, with respect to Deficiency 3, the FDA's letter requested information about the quality control

processes at one facility. Yet the denial order faulted Fontem for failing to provide information about the processes at a different facility.

Shifting the regulatory goalposts without explanation is arbitrary and capricious. By indicating in its deficiency letter that Fontem could resolve issues with its applications by providing specific information, the FDA represented such information would be sufficient to secure approval. By later requiring different information, the agency "pull[ed] a surprise switcheroo." *Env't Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). The lack of consistency and notice to regulated entities is another unlawful consequence of the agency's departure from the holistic public health inquiry.

* * *

The FDA denied Fontem's applications solely on the ground that Fontem had not shown its flavored and unflavored products were "appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2)(A). In order to make such a finding, the agency must weigh the potential benefits of the product to the public at large against the potential risks. The agency properly engaged in that analysis as to Fontem's flavored products, and we deny the petition as to those products.

As to Fontem's unflavored products, however, the FDA failed to undertake the necessary "public health" analysis. Instead, the agency identified highly granular deficiencies but failed to evaluate the potential effects of such deficiencies on the public health or to weigh these deficiencies against the potential benefits of Fontem's products. If the FDA wishes to require fine-grained requirements of all tobacco products, it must do so by promulgating tobacco product standards or

manufacturing regulations. Otherwise, the agency must consider the overall public health consequences of the product. Congress established a comprehensive and interlocking scheme for the regulation and approval of tobacco products, defining the considerations the FDA must use to evaluate whether a product is appropriate for the protection of the public health and providing for a regulatory process that accounts for the competing interests regarding the production, marketing, and safety of tobacco products. *Cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000) (emphasizing Congress had for decades "creat[ed] a distinct regulatory scheme for tobacco products"). The FDA cannot simply ignore Congress's detailed directives when denying tobacco marketing applications.

Because the FDA failed to justify its "public health" denial of Fontem's unflavored products, we grant the petition and vacate the FDA's marketing denial order as to those products.

So ordered.