Nos. 23-235 and 23-236

IN THE
Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

DANCO LABORATORIES, L.L.C., ET AL.,
Petitioners,
v.
ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF *AMICUS CURIAE* MOUNTAIN STATES LEGAL FOUNDATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

Mountain States Legal Foundation is a non-profit, public-interest law firm in Lakewood, Colorado. Since its founding in 1977, Mountain States has used pro bono litigation to fight for and restore the rights enshrined in the Constitution. Mountain States protects individual liberty, the right to own and use property, the principles of limited and ethical government, and the benefits of free enterprise. Mountain States has fought for farmers, mineral-interest owners, ranchers, recreationists, and others working the land against encroachments upon their rights by the federal government and non-government groups that advocate for a bigger, unlawful role for federal executive-branch actors.

In our work, we often come across federal regulators who disagree with our clients' interpretations of the laws purported to govern our clients' actions. For example, our clients frequently find themselves in disputes with federal regulators regarding the limits of the Department of the Interior's legal authority, how to interpret the statutes that the Department and its subparts implement, and how to challenge an action by the Department that our clients allege is unlawful or otherwise unreasonable.

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[1] No counsel for any party has authored this brief in whole or in part, and no entity or person, aside from *amicus curiae* and its counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

But several agencies, including the Department of the Interior and (in this case) the Food and Drug Administration, have devised regulatory schemes that—whether or not intentionally—create a "trap for the unwary litigant." *Darby v. Cisneros*, 509 U.S. 137, 147 (1993). The traps mire those who would challenge the regulators' actions in interminable procedural swamps, denying the challengers access to the federal courts.

Here, the Food and Drug Administration used the "trap" it created by promulgating 21 C.F.R. §§ 10.25, 10.30, and 10.45 to withhold ruling on a citizen petition to revoke the FDA's approval of a drug *for nearly fourteen years* before ultimately denying it, *see* Pet.App.9a—all the while, the challengers could neither obtain relief (because the agency did not "stay" approval of the drug) nor (in the FDA's view) seek recourse to the federal courts (because the agency's decision on revocation was not "final").

Mountain States and its clients face similar hurdles when challenging regulatory actions by the Department of the Interior. The Department has issued regulations to channel "appeals" of several categories of its actions to its own Board of Land Appeals. The regulation that establishes the appeal procedure, 43 C.F.R. § 4.411, says nothing about whether the challenged action remains "in effect" or is stayed during the appeal. But a separate regulation sets up a trap for the unwary litigant: 43 C.F.R. § 4.21 says that if the challenger—which might be a rancher unrepresented by counsel at the time he or she challenges a regulatory action—does not *also* file a "petition for a stay pending appeal," then the

Department "may generally implement the decision" being challenged even though the appeal is pending.[2] Further, the Department says that the challenged action cannot be "final" for purposes of recourse to the federal courts *unless* either (1) a petition for a stay is filed and denied, or (2) the Board of Land Appeals has decided the appeal. But the Board's review can last for years, just as the FDA's "review" of a citizen petition in this case lasted nearly fourteen years. And all that time, the challenged action stays in effect *against* the challenger.

The result is unlawful and untenable. Congress mandated that the people should have recourse to federal courts to challenge federal agency actions. Instead, the FDA here, just like the Department of the Interior and its Board of Land Appeals, has created a trap to deny court access to the public.

Accordingly, Mountain States writes as *amicus* to bring the Court's attention to the FDA's delay in this case and how that delay harmed those who would challenge the FDA's actions. Mountain States further respectfully urges the Court to address this unlawful administrative-appeal procedure so that Mountain States will have even stronger precedent at hand to convince the Department of the Interior to change its own procedure.

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[2] *See* IBLA FAQs, https://www.doi.gov/oha/organization/ibla/faqs, (last visited Feb. 26, 2024).

SUMMARY OF THE ARGUMENT

Amicus takes no position on the underlying merits of this case but supports Respondents because of a shared concern over the harm imposed by the Food and Drug Administration's unlawful administrative-exhaustion regulation, which purports to prohibit a party from challenging "any" otherwise-final "administrative action" in court *unless* the party has first filed—and the FDA has denied—a "citizen petition" asking the FDA Commissioner himself to rescind or amend the challenged action that the FDA has already taken. 21 C.F.R. § 10.45(b).

There is no hard requirement for when the FDA must resolve a citizen petition. And while that petition remains pending, the underlying FDA action goes into effect unless the FDA agrees to stay its own hand, which requires the challenger to make an extraordinary showing. *Id.* §§ 10.35(d)–(e), 10.45(c).

As a result, the FDA claims the power to take otherwise-final agency action that becomes effective immediately, while also avoiding judicial review of that action until the FDA itself decides to reject the citizen petition, which could be years or even decades later. In this case, for example, Respondents filed a citizen petition in 2002 that challenged the FDA's otherwise-final action of approving mifepristone for use in 2000. Because the FDA sat on the petition and did not deny it until 2016, Respondents had to wait well over a decade to seek judicial review of that 2000 approval.

Amicus submits this brief to explain that, as applied to "agency action otherwise final," the FDA's

exhaustion regulation is unlawful under the Administrative Procedure Act. 5 U.S.C. § 704.[3] Congress anticipated that agencies might try to use procedural roadblocks to delay—perhaps for years or even decades—judicial review of otherwise-final action, and Section 704 responds with its own broad language prohibiting an agency from imposing such hurdles, regardless of the name or form they may take.

Specifically, Section 704 prohibits an agency from mandating intra-agency appeal of otherwise-final agency action *unless* the underlying action remains "inoperative" pending resolution of the appeal, and it also prohibits agency requirements of "any form of reconsideration" before a suit can be filed. Thus, in the context of otherwise-final action, the FDA can mandate the citizen petition process as a prerequisite to filing suit, or it can have its otherwise-final agency actions take effect immediately—but it cannot do both.

In Section 704, "Congress clearly was concerned with making the exhaustion requirement unambiguous so that aggrieved parties would know precisely what administrative steps were required before judicial review would be available." *Darby v. Cisneros*, 509 U.S. 137, 146 (1993). The FDA's exhaustion regulation has resulted in significant confusion about when a party may file suit challenging FDA action and has also caused parties

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[3] *Amicus* addresses only those agency actions subject to the APA, not those subject to specialty review schemes that may impose different requirements. *See, e.g.*, 15 U.S.C. §§ 717r, 3416(a).

and courts to try circumventing the regulation's harsh effects, which can otherwise prevent judicial review for years. *See* Part III, *infra*.[4]

Amicus uses this opportunity to explain why the FDA's exhaustion regulation is unlawful in the context of a lawsuit challenging otherwise-final agency action. And the importance of the Court's guidance on 5 U.S.C. § 704 in this case will have meaningful implications on cases that *amicus* often litigates involving land- and resources-disputes in the West and the Department of the Interior's regulatory requirement that challengers first seek relief at the Department's Board of Land Appeals.

There, the Department of the Interior has promulgated a regulatory requirement that challengers seek administrative appellate review, 43 C.F.R. § 4.411(a); but if the challenger does not *also* separately and simultaneously file a "petition for a stay pending appeal," then the agency decision under review remains effective even though the appeal is running, *id.* § 4.21(a), (c). This creates a trap for the unwary litigant. It puts potential challengers at great risk of the harms that 5 U.S.C. § 704 seeks to avoid: they become stuck in an appeal of a regulatory decision—mired by inaction by the Board of Land Appeals—while the challenged regulatory action is

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[4] *See also* Michael Krupka, *Exasperated But Not Exhausted: Unlocking the Trap Set by the Exhaustion Doctrine on the FDA's REMS Petitioners*, Vand. L. Rev. (forthcoming 2024), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4692395 (arguing the FDA regulation is unlawful and providing statistics on average delays for citizen petitions).

nevertheless "in effect," and they have no recourse to judicial review for years and years. Rather, the initial agency decision "while a mandatory administrative appeal is pending [is] effectively insulate[d] … from judicial scrutiny." *Farrell-Cooper Mining Co. v. U.S. Dep't of the Interior*, 864 F.3d 1105, 1107 (10th Cir. 2017).

Finally, one note regarding scope: this brief addresses only exhaustion of administrative remedies, not issue exhaustion. The FDA's exhaustion regulation purports to require an additional layer of agency review before judicial review may be obtained and therefore directly implicates exhaustion of administrative remedies (i.e., the requirement to "proceed[] through each step of the [agency's] administrative review scheme and receive[] a 'final decision' before seeking judicial review"). *Carr v. Saul*, 593 U.S. 83, 88 & n.2 (2021). Section 704 of the APA likewise "codified the doctrine of exhaustion of administrative remedies." *Darby*, 509 U.S. at 153. But exhaustion of administrative remedies "should not be confused" with "issue exhaustion" (i.e., "giv[ing] the agency an opportunity to address an issue before seeking judicial review of that question"). *Carr*, 593 U.S. at 88 & n.2; *see Alaska Survival v. Surface Transp. Bd.*, 705 F.3d 1073, 1081 n.5 (9th Cir. 2013) (distinguishing issue exhaustion from exhaustion of administrative remedies in context of Section 704).

Exhaustion of lawful administrative remedies is required under the APA, which is why it is important that agencies not impose procedural layers the APA bars. But issue exhaustion for FDA actions is typically addressed under a more flexible framework. *See, e.g.*,

Sandoz Inc. v. Becerra, 57 F.4th 272, 279 (D.C. Cir. 2023) ("The FDA's procedures are entirely distinct from those cases in which the Supreme Court has found issue exhaustion appropriate.").

ARGUMENT

I. For Otherwise-Final Action, an Agency Cannot Require an Appeal Unless the Underlying Action Is Rendered Inoperative, nor Can an Agency Require Any Form of Reconsideration.

The APA provides: "Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority." 5 U.S.C. § 704.

Congress aimed to preclude agencies from installing roadblocks to judicial review of otherwise-final agency action, whatever name or description the agency may try to use for those roadblocks. As relevant here, and as explained further below, Section 704 thus imposes two restrictions on agencies in the context of "agency action otherwise final": (1) agencies can require intra-agency appeals of such action but only if the challenged action is inoperative during the pendency of those appeals, and (2) agencies cannot require any form of reconsideration of that action.

No Mandatory Appeal Unless the Challenged Action Is Rendered Inoperative. In *McKart v. United States*, 395 U.S. 185 (1969), this Court noted that Section 704 says an "agency may require exhaustion by its own rules" but only "if the agency action is inoperative during [that] administrative review," *id.* at 207 n.2.

The Court reiterated and expanded on this point in *Darby v. Cisneros*, which held that in APA cases, courts could not require exhaustion of administrative remedies beyond those required by statute or lawful agency regulation. 509 U.S. 137 (1993). The Court addressed Section 704 and held that it "permits an agency … to require by rule that … [a] party must first appeal to the agency (*the decision meanwhile being inoperative*) before resorting to the courts." *Id.* at 147–48 (emphasis added). The Court then repeated that restriction, which is drawn directly from the text of Section 704: "In no case may appeal to 'superior agency authority' be required by rule *unless the administrative decision meanwhile is inoperative*." *Id.* at 148 (emphasis added); *see also id.* at 152 (stating again that an agency may "adopt[] a rule that an agency appeal be taken before judicial review is available" but only when "the initial decision would be 'inoperative' pending appeal," and "[o]therwise, the initial decision becomes final and the aggrieved party is entitled to judicial review").[5]

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[5] Although this conclusion is plain from the text of Section 704 itself, *Darby* noted that the *Attorney General's Manual on the Administrative Procedure Act*, "to which we have given some

Darby explained why the APA imposes this restriction on an agency's ability to require intra-agency appeals: "[O]therwise the effect of such a requirement would be to subject the party to the agency action and to repetitious administrative process without recourse" to judicial review. *Id.* at 148. "There is a fundamental inconsistency in requiring a person to continue 'exhausting' administrative processes after administrative action has become, and while it remains, effective." *Id.* at 148. Without the restriction imposed by Section 704, there would also be a strong incentive for agencies to delay ruling on appeals and thereby delay judicial oversight.

No Mandatory Request for Any Form of Reconsideration. *Darby* also acknowledged that Section 704 prohibits an agency from requiring "any form of reconsideration" of otherwise-final agency action before bringing suit, 5 U.S.C. § 704, which could likewise trap a party in a lengthy administrative labyrinth.

"[T]he word 'any' has an expansive meaning, that is, 'one or some indiscriminately of whatever kind.'" *United States v. Gonzales*, 520 U.S. 1, 5 (1997). Thus, by using the term "any form of reconsideration," the APA expansively prohibits agencies from mandating any procedure that "tak[es] up for renewed

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deference," aligned with the Court's interpretation. *Darby*, 509 U.S. at 148 n.10; *see* U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 104–05 (1947) (an agency may require an appeal "only … if the agency's decision is inoperative pending such appeal").

consideration that which has been passed or acted upon previously," *Reconsideration*, James A. Ballentine, Law Dictionary 1096 (1st ed. 1948), regardless of the terminology the agency may use to describe that process, *see Darby*, 509 U.S. at 145 (the clause prohibits mandating requests for "rehearing"); *ICC v. Bhd. of Locomotive Engineers*, 482 U.S. 270, 284 (1987) (clause also prohibits mandating requests to "reopen").

Darby did hold, however, that when a party nonetheless chooses to pursue an *optional* request for reconsideration or intra-agency appeal, it "'render[s] the orders … nonfinal'" until the agency disposes of the appeal or request for reconsideration. *Darby*, 509 U.S. at 145 (quoting *Locomotive Engineers*, 482 U.S. at 284–85).

* * *

Accordingly, as relevant here, *Darby* explained that Section 704 bars agencies from imposing barriers to judicial review of otherwise-final agency action by imposing a simple set of rules:

- An agency can require a party to undertake intra-agency appeals, or it can have the underlying action take effect immediately—but the agency cannot do both.
- An agency cannot require any form of reconsideration as a prerequisite for bringing suit.
- If a party chooses to pursue an *optional* appeal or request for reconsideration, the underlying action is deemed nonfinal as to that party until

the agency resolves the appeal or request for reconsideration.

Together, these provisions are "designed to 'remove obstacles to judicial review of agency action'" and avoid creating "a trap for unwary litigants." *Darby*, 509 U.S. at 147. In short, "[w]hen an agency takes an otherwise final action, a court cannot require a party aggrieved by that action to exhaust optional administrative appeals" or ask for reconsideration. 2 Richard J. Pierce, *Administrative Law Treatise* § 15.3, at 1242 (2018).

Despite *Darby*, the FDA has not amended its regulations to satisfy the requirements of Section 704.

II. As Applied to Otherwise-Final Agency Action, the FDA's Exhaustion Regulation Violates the APA.

The FDA's regulations provide that "[b]efore challenging FDA's decision to take or refrain from taking action," a "party must file a citizen petition" with "the Commissioner" of the FDA, pursuant to 21 C.F.R. §§ 10.25 and 10.45(b). Fed.Pet.Br.7. That requirement applies to "any form of administrative action," including otherwise-final agency action. 21 C.F.R. § 10.45(b). Section 10.45(b) further states that the challenger must then await "the decision" of the Commissioner on that petition, or else the FDA will seek dismissal of any suit for "failure to exhaust administrative remedies." 21 C.F.R. § 10.45(b).

The FDA's decision goes into effect during the pendency of the citizen petition process, unless the challenger seeks and obtains a stay from the

Commissioner. *See* 21 C.F.R. §§ 10.35(d)–(e), 10.45(e); *cf.* 43 C.F.R. § 4.21(a), (c) (same for appeals to the Department of the Interior's Board of Land Appeals). That requires the challenger to show, among other things, "irreparable injury" and "sound public policy grounds supporting the stay." 21 C.F.R. § 10.35(e); *cf.* 43 C.F.R. § 4.21(b) (same showing to achieve a stay in an appeal to the Department of the Interior's Board of Land Appeals).

As applied to otherwise-final agency action, this exhaustion regulation violates Section 704 because it clearly imposes a hurdle to judicial review of otherwise-final agency action. It makes little difference whether this is framed as a mandatory appeal that does not render the underlying decision inoperative, or instead as a form of reconsideration. Under Section 704, "[t]here is no qualitative difference between a motion for reconsideration and an appeal to a superior agency authority for purposes of finality; the initial agency decision may be modified or reversed in both types of administrative review." *Acura of Bellevue v. Reich*, 90 F.3d 1403, 1407–08 (9th Cir. 1996).

Mandatory Appeal Without Rendering Underlying Decision Inoperative. By requiring that a petition be filed with the head of the FDA asking him to "amend" or "revoke" the agency's otherwise-final action, 21 C.F.R. § 10.25(a), the FDA's exhaustion regulation could be framed as requiring an intra-agency appeal that does not automatically render inoperative the underlying action. *Appeal*, Black's Law Dictionary 124 (4th ed. 1951) ("In general terms a resort to an upper court or tribunal."). In fact,

the FDA requires an extraordinary showing to stay the effectiveness of the action. *See* 21 C.F.R. §§ 10.35(d)–(e), 10.45(c).

But Section 704 provides that an agency can mandate intra-agency appeals of otherwise-final actions, or it can make those actions effective immediately. The agency cannot do both. The FDA's regulation purports to do both, and accordingly it is unlawful. 5 U.S.C. § 704.

Mandatory Form of Reconsideration. As explained above, Section 704 also prohibits an agency from requiring "any form of reconsideration" as a prerequisite to bringing suit over otherwise-final agency action. 5 U.S.C. § 704. That broad language covers any process asking the agency to change its mind on a decision already made, regardless of the terminology the agency may use to describe that process. *See* Part I, *supra*; *Darby*, 509 U.S. at 145 (clause prohibits mandating requests for "rehearing"); *Locomotive Engineers*, 482 U.S. at 284–85.

The FDA's exhaustion regulation could be framed as mandating a form of reconsideration—and thus is unlawful for that additional reason. For example, if the challenged action was taken by or attributed to the Commissioner, then a citizen petition asking the Commissioner to "amend" or "revoke" his own prior decision, 21 C.F.R. § 10.25(a), qualifies as a classic form of reconsideration.

Similarly, in practice, citizen petitions are typically denied not by the Commissioner himself but by the same FDA office that issued the underlying decision. Here, for example, the FDA's challenged

2000 action was issued by the Center for Drug Evaluation and Research, which then denied (in 2016, after nearly fourteen years of "review") Respondents' citizen petition challenging that action.[6] The same occurred for the 2021 denial of Respondents' citizen petition challenging a 2016 FDA action.[7] Again, asking the same decisionmaker to change its mind for otherwise-final action is a classic form of reconsideration barred by Section 704.[8]

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Congress anticipated that agencies might use different language to describe the procedural roadblocks they imposed to judicial review. Section 704 responds with its own broad language barring an agency from delaying or foreclosing judicial review of

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[6] *Compare* Letter from Ctr. for Drug Evaluation & Rsch. to Sandra P. Arnold (Sep. 28, 2000), *available at* No. 2:22-cv-223 (N.D. Tex.), ECF No. 1-26, *with* Letter from Janet Woodcock, Director of Ctr. for Drug Evaluation & Rsch., to Donna Harrison *et al.* (Mar. 29, 2016), *available at* 2:22-cv-223 (N.D. Tex.), ECF No. 1-28.

[7] *Compare* Letter from Ctr. for Drug Evaluation & Rsch. to Danco Labs., LLC (Mar. 29, 2016), *available at* No. 2:22-cv-223 (N.D. Tex.), ECF No. 1-32, *with* Letter from Patrizia Cavazzoni, Director of Ctr. for Drug Evaluation & Rsch., to Donna J. Harrison & Quentin L. Van Meter (Dec. 16, 2021), *available at* 2:22-cv-223 (N.D. Tex.), ECF No. 1-44.

[8] The FDA does at least make clear that there is no need to seek reconsideration again *after* the citizen petition is denied. *See* 21 C.F.R. § 10.45(e) ("An interested person may request judicial review of a final decision of the Commissioner in the courts without first petitioning the Commissioner for reconsideration or for a stay of action.").

otherwise-final action except in narrow circumstances.

Whether viewed as imposing a mandatory appeal process to the FDA Commissioner but without automatically rendering the challenged action inoperative, or instead as a requirement to seek a form of reconsideration from the FDA before filing suit, the FDA's exhaustion regulation violates Section 704. 5 U.S.C. § 704.[9]

As *Darby* predicted, such a scheme provides the FDA with an incentive to delay adjudicating citizen petitions and thereby to delay judicial review. The FDA's exhaustion regulation has long had this effect, with studies showing that citizen petitions often languish for years and sometimes decades. *See* Krupka, *supra*, at 24–34; Memorandum, Office of the Inspector General, U.S. Department of Health & Human Services (July 17, 1998), https://oig.hhs.gov/oas/reports/phs/c9750002.pdf (noting citizen petitions pending twenty years).

The FDA's habit of taking years or even decades to rule on citizen petitions—and thereby attempt to delay or foreclose judicial review—is apparent in the case now before the Court. The FDA's 2000 decision went into effect immediately, but the FDA's regulation purported to bar Respondents from

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[9] *See, e.g.*, *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1279 (D.C. Cir. 2018) (Millett, J., dissenting) (noting that certain FTC regulations violate Section 704 because "[n]othing in the Commission's regulations provide for appeal to the Commission, let alone render the Division's 2016 Letter inoperative until review").

challenging that decision in court until after the FDA denied Respondents' citizen petition, which occurred nearly fourteen years after it was filed. This "subject[ed] the party to the agency action … without recourse" to judicial review. *Darby*, 509 U.S. at 148. That is precisely what Congress prohibited in Section 704 of the APA.

III. Some Courts Have Improperly Required Compliance with the FDA's Exhaustion Regulation, While Others Have Stretched to Avoid Its Application.

Several courts have enforced the FDA exhaustion regulation by dismissing suits filed in court before the plaintiff had filed—and the FDA had denied—a citizen petition. *See, e.g., Ctr. for Food Safety v. Hamburg*, 142 F. Supp. 3d 898, 903 (N.D. Cal. 2015); *Ass'n of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4, 21–24 (D.D.C. 2008), *aff'd*, 358 F. App'x 179, 180–81 (D.C. Cir. 2009); *Dietary Supplement Coalition, Inc. v. Sullivan*, 796 F. Supp. 441, 446 (D. Or. 1991).

Only two of those decisions, however, touched on whether the FDA's exhaustion regulation complies with Section 704. One case concluded "the 'inoperative' exception [of Section 704] applies only to *optional* administrative remedies," and "[b]ecause FDA's citizen petition requirement is mandatory, the 'inoperative' exception in section 704 is inapplicable." *Hamburg*, 142 F. Supp. 3d at 906. But that has it backwards. *Darby* held that "'[i]n no case may appeal to 'superior agency authority' be required by rule unless the administrative decision meanwhile is

inoperative.'" 509 U.S. at 148. The "inoperative" provision applies only when the appeal is mandatory, not only when it is optional. *See* Krupka, *supra*, at 48 (concluding *Hamburg* was decided wrongly because "an optional remedy cannot simultaneously be mandatory").

The *Hamburg* court appears to have confused *Darby*'s holding that pursuing an optional appeal renders the underlying action nonfinal with the separate principle that a mandatory appeal renders the action inoperative. *Hamburg* further noted that it did not have the FDA's "position" on the challengers' arguments, 142 F. Supp. 3d at 909, but that should have been addressed under issue exhaustion, not exhaustion of administrative remedies, *see* Summary, *supra* (noting the distinction).[10]

The second case to address Section 704 and the FDA's exhaustion regulation dismissed a challenge simply by quoting *Darby*'s requirement that exhaustion can be "required … by *agency rule*.'" *Ass'n of Am. Physicians*, 539 F. Supp. 2d at 22 (emphasis in original). But *Darby* refers to agency exhaustion rules *that comply with the APA*, so a court should not enforce the FDA's exhaustion requirement without determining whether that requirement is lawful

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[10] In the appeal of the *Hamburg* case, the Ninth Circuit ordered the district court to stay proceedings to allow the plaintiffs to submit a citizen petition. *Ctr. for Food Safety v. Hamburg*, 696 F. App'x 302, 303–04 (9th Cir. 2017). Although perhaps better than dismissing the suit altogether, that approach still gave full effect to the FDA's exhaustion regulation by precluding judicial proceedings until after the FDA denied the citizen petition.

under the APA as applied to the facts of that case. *See, e.g., Farrell-Cooper*, 864 F.3d at 1110 (explaining that *Darby* says parties must pursue "intra-agency appeals mandated … by agency rule" but "agencies' power to do so is expressly cabined" by the requirement that the "initial decision be 'inoperative' pending appeal").[11]

Other courts have tried to avoid the harshness of applying the FDA's exhaustion regulation as-written. The Tenth Circuit, for example, held that "because the citizen petition procedure is a regulatory rather than a statutory creation, we have discretion to waive the exhaustion requirement." *Cody Lab'ys, Inc. v. Sebelius*, 446 F. App'x 964, 969 (10th Cir. 2011) (citing *McCarthy v. Madigan*, 503 U.S. 140, 144 (1992)). That approach, however, risks conflicting with *Darby*, which held that courts cannot add administrative exhaustion requirements in APA cases beyond those imposed by statute or lawful regulation. As the D.C. Circuit has noted, "[i]f courts are forbidden from requiring exhaustion when [Section 704] of the APA does not, why should courts be free to excuse exhaustion when the next to last clause of [Section

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[11] The Tenth Circuit's decision in *Farrell-Cooper* highlights that the FDA is not the only agency whose exhaustion regulations have yielded confusion in the context of Section 704. For example, most decisions have recognized that Section 704 bars the Department of the Interior's regulations requiring an appeal to the Board of Land Appeals without *automatically* rendering the action inoperative, but a few decisions have nonetheless enforced that regulation. *See Farrell-Cooper*, 864 F.3d at 1112 (noting disagreement); *Arcamone-Makinano v. Haaland*, No. 22-8006, 2022 WL 1042573, at *2 (10th Cir. Apr. 7, 2022).

704] demands it? If an agency rule requires, without exception, that a party must take an administrative appeal before petitioning for judicial review, on what basis may a court excuse non-compliance?" *Marine Mammal Conservancy, Inc. v. Dep't of Agric.*, 134 F.3d 409, 411 (D.C. Cir. 1998). As noted above, the answer at least in this context is that *Darby* does mandate compliance with regulations on administrative exhaustion—but only when they comply with the APA itself.

Another court tried to temper the effects of the FDA's exhaustion regulation by suggesting that it may not apply at all to challenges to FDA "'regulation[s].'" *Farm-to-Consumer Legal Def. Fund v. Sebelius*, 734 F. Supp. 2d 668, 701–02 (N.D. Iowa 2010) (quoting 21 C.F.R. § 10.25(a)). That view, however, is based on a likely-incorrect reading of the relevant regulations. Section 10.25(a) allows the filing of a citizen petition asking the Commissioner "to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). The use of "other form" indicates that issuing, amending, or revoking a "regulation or order" is itself a type of "administrative action."[12] That matters because Section 10.45(b) then *mandates*, as a prerequisite for suit, filing a citizen petition asking the Commissioner

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[12] *See Cir. City Stores, Inc. v. Adams*, 532 U.S. 105, 114–15 (2001); Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 199 (2012) ("The principle of *ejusdem generis* essentially ... implies the addition of *similar* after the word other.") (emphasis in original).

to "take or refrain from taking *any form of administration action*." 21 C.F.R. § 10.45(b) (emphasis added). Because revoking regulations and orders is a form of administrative action under Section 10.25(a), it would likewise be covered by Section 10.45(b)'s use of "any form of administrative action." Section 10.45(b) therefore likely applies to challenges to orders and regulations, contrary to the suggestion in *Farm-to-Consumer*.

But as further developed below, the solution is not to try and avoid the FDA's exhaustion regulation by invoking waiver or adopting an overly strict construction of its text, but rather to acknowledge that the regulation itself is unlawful as applied to otherwise-final agency action.

IV. Courts Have Options for How Best to Resolve Exhaustion of Administrative Remedies in This Context.

A court facing invocation of the FDA's exhaustion regulation in the context of otherwise-final agency action would have several options for how best to proceed.

Require a Citizen Petition But Render the Underlying Action Inoperative. One option is to give effect to the mandatory citizen petition process but provide that the underlying FDA action itself is "inoperative" during that process. 5 U.S.C. § 704; *see, e.g.,* Krupka, *supra*, at 46–53; *Marine Mammal*, 134 F.3d at 411 (noting that the Department of Agriculture regulation at-issue "suspends the finality of ALJ decisions pending appeal"); *see also* 21 C.F.R. § 10.35(d).

This approach would presumably encourage the FDA to promptly address citizen petitions so the underlying action could go into effect. But this approach also has several practical problems. There could be a ping-pong effect where the underlying FDA action is sometimes in effect and sometimes inoperative, based on whether a citizen petition is currently pending. Further, because there is no time limit in which to file a citizen petition, FDA actions that have been in effect for decades could suddenly be rendered inoperative simply because someone filed a citizen petition.

Allow the Underlying Action to Take Effect Immediately But Provide for an Optional Citizen Petition. Alternatively, the court could hold that the citizen petition process is optional and that the challenged action is operative during that process. That is the approach that at least one court has taken in the context of a different agency. *See Idaho Watersheds Project v. Hahn*, 307 F.3d 815, 825 (9th Cir. 2002) (holding that where an agency "procedure does not render the decision inoperative," an "aggrieved party shall be allowed to proceed to federal court without being required to endure further administrative proceedings"). This would mean the court declines to enforce, in that particular case, the mandatory-petitioning clause in 21 C.F.R. § 10.45(b), and a challenger could thus sue over otherwise-final agency action without first filing a citizen petition.[13]

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[13] To be clear, the plaintiff would still need to satisfy other requirements for suit, such as Article III standing.

This second approach would free parties from having to wait years or even decades to sue over otherwise-final agency action. It may be especially appealing where a party has already filed a citizen petition to comply with Section 10.45(b), and in the meantime the underlying FDA action has been in effect for years or decades (as is the case here). The citizen petition would be treated as the pursuit of an optional appeal or request for reconsideration, which renders the agency action non-final for judicial review purposes, until the agency denies the appeal or request. *See Darby*, 509 U.S. at 145 (citing *Locomotive Engineers*, 482 U.S. at 284–85). That would also tend to work to the challengers' favor in cases where the statute of limitations to challenge the underlying agency action would otherwise have passed.

* * *

The lengthy period between the FDA's relevant action in 2000 and the lawsuit challenging that action is largely the result of the FDA's unlawful exhaustion regulation. *Amicus* uses this opportunity to explain that—for otherwise-final agency action subject to the APA—an agency cannot mandate an intra-agency appeal without rendering inoperative the challenged agency action, nor require any form of reconsideration as a prerequisite for suit. The FDA's exhaustion regulation flunks the test as applied to otherwise-final actions. The Department of the Interior's process for appeals to its Board of Land Appeals flunks the test too.

Accordingly, Mountain States respectfully asks the Court to address the unlawful administrative-

appeal procedure underlying this case so that Mountain States will have even stronger precedent at hand to convince the Department of the Interior to change its own procedure.

CONCLUSION

For the foregoing reasons, *amicus* urges the Court to hold that the FDA's exhaustion regulation violates the APA as applied to otherwise-final agency action.

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