United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 12, 2026 Decided August 18, 2026

No. 25-5041

VANDA PHARMACEUTICALS, INC.,
APPELLANT

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:23-cv-00280)

Paul W. Hughes III argued the cause for appellant. With him on the briefs were *Sarah P. Hogarth*, *Connor J. Suozzo*, and *Emmett Witkovsky-Eldred*.

David L. Peters, Attorney, U.S. Department of Justice, argued the cause for defendants-appellees. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Daniel Tenny*, Attorney.

Brian T. Burgess argued the cause for intervenor-appellee Teva Pharmaceuticals, USA, Inc. With him on the brief was *Isabel M. Marin*.

Before: MILLETT and PAN, *Circuit Judges*, and ROGERS, *Senior Circuit Judge*.

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

MILLETT, *Circuit Judge*: Before a generic version of a name-brand drug can appear on pharmacy shelves, the Food and Drug Administration ("FDA") must approve both the drug and its labeling. That labeling includes not just the basic information and graphics on the container, but also all of the accompanying instructions, warnings, and in-depth information about the drug.

As part of that approval process, the generic manufacturer must show that its labeling is "the same as" the name-brand drug's. 21 U.S.C. § 355(j)(2)(A)(v). This case centers on an exception to that sameness requirement for "changes required * * * because the [generic] drug and the [name-brand] drug are produced or distributed by different manufacturers[.]" *Id.*

Vanda Pharmaceuticals, Inc., markets a drug with the established (generic) name tasimelteon under the brand name Hetlioz. Tasimelteon treats Non-24-Hour-Sleep-Wake Disorder. That condition predominantly affects vision-impaired individuals. The FDA approved labeling for Hetlioz that includes the brand name "Hetlioz" and the dosage "20 mg" embossed in braille on the bottle, as well as accompanying instructions in roman script to pharmacists: "Do not cover Braille" and "Dispense in original container." J.A. 242.

A competitor, Teva Pharmaceuticals, USA, Inc., applied to market generic tasimelteon with labeling that omits both the braille lettering and the associated pharmacy instructions. The FDA approved Teva's generic and its labeling.

Shortly thereafter, Vanda filed both a citizen petition with the FDA and this lawsuit arguing that the FDA's approval of Teva's labeling was contrary to law and arbitrary and capricious.

The district court granted the FDA's and intervenor Teva's motions for summary judgment on the ground that removal of the braille and its accompanying instructions fell into the exception for changes "required" because of a change in manufacturers. The court also rejected Vanda's arbitrary and capricious claims.

We affirm in part and vacate in part. We vacate the grant of summary judgment only as to the FDA's approval, in reliance on the different-manufacturer exception, of a label without "20 mg" in braille and without the accompanying pharmacy instructions. We remand to the district court with instructions to remand to the agency without vacatur to decide whether the label nonetheless satisfies the baseline statutory requirement that Teva's label be "the same as" the Hetlioz label, which would make the inclusion of any braille script and the accompanying pharmacy instructions unnecessary. We otherwise affirm the grant of summary judgment in favor of the FDA and Teva.

I

A

1

Under the Food, Drug, and Cosmetic Act ("FDCA"), the Secretary of Health and Human Services must approve all drugs sold in the United States. 21 U.S.C. § 355(a). To bring a novel drug to market, a manufacturer must submit to the FDA

a new drug application ("NDA") that contains, among other things, a full statement of the drug's composition, studies supporting the safety and efficacy of the drug, and "specimens of the labeling proposed to be used for such drug[.]" *Id.* § 355(b). The FDCA's definition of labeling sweeps broadly, encompassing "all labels and other written, printed, or graphic matter * * * upon any article or any of its containers or wrappers, or * * * accompanying such article." *Id.* § 321(m).

The FDCA sets minimum requirements for the content and format of labeling, backed up by criminal penalties. *See* 21 U.S.C. §§ 331(a)–(c), 333, 352. A drug is deemed "misbranded" if:

> any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness * * * and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Id. § 352(c). Under FDA regulations, a "word, statement, or other information" can lack the required "conspicuousness" due to "[s]mallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter." 21 C.F.R. § 201.15(a)(6).

One of the words that must appear on every drug's labeling is the drug's "established name[,]" 21 U.S.C. § 352(e)(1)(A), "which is a nonproprietary name assigned to the drug by the FDA[,]" *Novartis Pharms. Corp. v. Leavitt*, 435 F.3d 344, 346

(D.C. Cir. 2006).[1] Tasimelteon is the established name the FDA assigned to the drug at issue in this case. The established name must be printed "prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug[.]" 21 U.S.C. § 352(e)(1)(B). Congress imposed this requirement to "bring to the attention of doctors and patients the fact that many of the drugs sold under familiar trade names are actually identical to drugs sold under their 'established' or less familiar trade names at significantly lower prices." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 138 (1967).

FDA regulations fill in additional details. The established name must "accompany [the] proprietary name or designation each time it is featured on the label or in the labeling for the drug[.]" 21 C.F.R. § 201.10(g)(1). Also, the established name must have "a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features." *Id*. § 201.10(g)(2).

A drug that does not satisfy these requirements, either at the NDA stage or post-approval, may not be sold in interstate commerce. 21 U.S.C. § 331(a)–(c).

2

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21

[1] Because the established name in this case is the same as the generic name, this opinion uses the phrases "established name" and "generic name" interchangeably. The established name in this case is also the same as the active ingredient.

U.S.C. § 355), commonly known as the "Hatch–Waxman Act," amended the FDCA to provide a shorter route to market for generic drugs that are sufficiently similar to the name-brand drug to ride its regulatory coattails, *id.* § 101, 98 Stat. at 1585–1592. After a period of brand exclusivity in the marketplace, generic manufacturers can file an abbreviated new drug application ("ANDA") that specifies the name-brand drug, which the statute calls the "listed drug," and provides evidence of similarity to the listed drug across all relevant dimensions. *See* 21 U.S.C. § 355(j)(2)(A). Among other things, the generic drug's route of administration, dosage form, and strength must be "the same as those of the listed drug[,]" *id.* § 355(j)(2)(A)(iii), and the two drugs must contain the same active ingredients, *id.* § 355(j)(2)(A)(ii). The generic drug must also be "bioequivalent" to the listed drug, *id.* § 355(j)(2)(A)(iv), meaning that "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug[,]" *id.* § 355(j)(8)(B)(i).

As relevant here, the Act's similarity requirements extend to the labeling that accompanies the drug. The FDA cannot approve an ANDA unless it contains:

> information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug * * * except for changes required * * * because the new drug and the listed drug are produced or distributed by different manufacturers.

21 U.S.C. § 355(j)(2)(A)(v).[2] This opinion refers to that provision as a whole as the "same-labeling provision," and to the exception for "changes required * * * because the new drug and the listed drug are produced or distributed by different manufacturers" as the "different-manufacturer exception."

Separately, the ANDA must contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for" the listed drug. 21 U.S.C. § 355(j)(2)(A)(i).

B

1

Vanda Pharmaceuticals, Inc., manufactures the drug tasimelteon, which it markets under the brand name Hetlioz. Thirteen years ago, Vanda submitted an NDA for Hetlioz, for use in treating Non-24-Hour-Sleep-Wake Disorder. Individuals suffering from that disorder cannot align their circadian rhythm with a 24-hour day, often leading to insomnia and excessive daytime sleepiness. The disorder "is most prevalent in patients who are totally blind." FDA Resp. to Citizen Pet. at 3, Dkt. Nos. FDA-2023-P-0313, FDA-2023-P-0344 (July 24, 2023).

Vanda's proposed labeling for its tasimelteon bottle included, in roman script, the brand name ("Hetlioz"), the established name ("tasimelteon"), the unit dosage ("20 mg"),

[2] We have omitted the first exception, which is for generic drugs granted permission by the Secretary to contain additional modifications under 21 U.S.C. § 355(j)(2)(C). That provision has no relevance to this appeal.

and instructions for use and storage. Two of those elements—the brand name and the dosage—would also be embossed in braille lettering on the bottle.

The FDA did not—and does not—require manufacturers to place braille on labeling. So the agency evaluated only whether Vanda's proposal would compromise the label's accuracy and comprehensibility to patients. The FDA recommended that Vanda conduct a label comprehension study to evaluate whether "the intended patient population can understand the information in braille presented on the label." FDA DNP Letter at 2, Vanda Citizen Pet., Dkt. No. FDA-2023-P-0313 ("Citizen Pet.") Ex. 9 (July 29, 2013). Because the braille "may be helpful" to patients, the FDA also recommended adding to the label two instructions to the pharmacist: "Dispense in original container" and "Do not cover the Braille." FDA Label Review at 2, Citizen Pet. Ex. 11 (Sept. 26, 2013).

Vanda added those instructions to the label and completed a study of 22 braille readers to determine whether the label with braille would be comprehensible to patients. *See* FDA Resp. to Citizen Pet. at 10. The study did not address any other aspect of patient safety. *See id*. Of that group, seventeen correctly interpreted the second line as "20 mg" and all 22 identified at least five out of the seven letters in "Hetlioz[.]" FDA Comprehension Study Review at 2, Citizen Pet. Ex. 15 (Dec. 31, 2013); Vanda Opening Br. 12 (reciting the results of the study). While not requiring the use of braille, the FDA deemed the results of the study "acceptable" and approved the addition of braille to the label. FDA Comprehension Study Review at 3.

Hetlioz entered the market in 2014. Its approved label bears the brand name and the dosage in braille, the established

name and dosage in roman script, and instructions to pharmacists in roman script: "Dispense in original container" and "Do not cover Braille." J.A. 242 (Hetlioz label).

2

In 2018, three generic manufacturers submitted ANDAs seeking approval to sell tasimelteon: Teva Pharmaceuticals, USA, Inc., MSN Pharmaceuticals Inc., and Apotex Corp. MSN's proposed labeling featured the generic name, "tasimelteon," and the dosage, "20 mg," embossed in braille. Teva and Apotex submitted labeling proposals without any braille lettering.

The FDA determined that "[b]raille is not required for the generics of Hetlioz." J.A. 255 (formatting modified). The agency explained that the inclusion of braille was "proposed by [Vanda] as 'nice to have' information," but was not a "condition of approval for" Hetlioz. J.A. 255.

The FDA approved the Apotex and Teva generics in December 2022. *See* FDA Resp. to Citizen Pet. at 3 n. 29. In keeping with their initial proposals, Teva and Apotex omitted both the braille itself and the accompanying pharmacy instructions from their labels. *See id.* at 4. MSN's generic, which the FDA approved in January 2023, included the braille and the related instructions. *See* J.A. 208; FDA Resp. to Citizen Pet. at 3 n. 29.

3

Shortly after the approvals, Vanda filed a citizen petition with the FDA demanding that the agency "revoke the approval" of Teva's ANDA and "order a recall of Teva's product." Citizen Pet. at 1. Vanda argued that the FDA's

approval of labels without braille and the associated dispensing instructions violated the FDCA's "same labeling" and "conditions of use" requirements and created "severe and immediate risks to public safety." Citizen Pet. at 2 (formatting modified).

Days later, Vanda sued the FDA, the Department of Health and Human Services and its Secretary, and the FDA Commissioner (collectively, "FDA") in the United States District Court for the District of Columbia. The complaint alleges that the FDA's approval of Teva's ANDA violated the Administrative Procedure Act, 5 U.S.C. § 706(2), as both contrary to law and arbitrary and capricious. Teva intervened as a defendant.[3]

While the case was pending in district court, the FDA denied Vanda's citizen petition. The FDA determined that the removal of braille was a "permissible difference due to [a] difference in manufacturer." FDA Resp. to Citizen Pet. at 17. As a baseline, because the Hetlioz label did not contain the generic name—tasimelteon—in braille, "[a] difference in labeling related to braille was * * * *inevitable* for any generic tasimelteon product[.]" *Id.* at 9 (emphasis added). On top of that, the FDA found that "the inclusion of the strength (or a product name) in braille and the associated statements [to the

[3] Vanda unsuccessfully sued Teva and Apotex in a different circuit, claiming that their tasimelteon products infringed the Hetlioz patents. *See Vanda Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-cv-651, 2022 WL 17593282, at *28 (D. Del. Dec. 13, 2022), *aff'd*, No. 2023-1247, 2023 WL 3335538 (Fed. Cir. May 10, 2023) (Federal Circuit affirming on the ground that Vanda's patent claims were invalid for obviousness). Vanda also has challenged the FDA's approval of MSN's tasimelteon product. *See Vanda Pharms., Inc. v. FDA*, No. 23-cv-2812, 2024 WL 4133623, at *1 (D.D.C. Sept. 10, 2024).

pharmacy were not] necessary for the safe and effective use of the drug product." *Id.* The FDA explained that Vanda had "voluntarily proposed" the braille labeling, without providing any evidence that safety or efficacy concerns required its inclusion. *Id.* And the FDA's own post-approval monitoring revealed no "adverse event reports or medication error reports related to the exclusion of braille or the braille-related statements" on the two generic labels. *Id.* at 11.

Following that decision, Vanda added to its complaint claims that the FDA's denial of the citizen petition was arbitrary and capricious and contrary to law. The parties then cross-moved for summary judgment.

The district court denied Vanda's motion and granted the FDA's and Teva's cross-motions for summary judgment. *Vanda Pharms., Inc. v. FDA*, 766 F. Supp. 3d 85, 90 (D.D.C. 2025).

To start, the district court held that the FDA's approval of Teva's ANDA did not violate the same-labeling provision, reasoning that the omission of braille and its accompanying instructions fell within the different-manufacturer exception. *Vanda Pharms.*, 766 F. Supp. 3d at 95 (citing 21 U.S.C. § 355(j)(2)(A)(v)). Drawing on the FDCA's "text, structure, history, and purpose, along with relevant agency and judicial precedent[,]" 766 F. Supp. 3d at 102, the court read the different-manufacturer exception "to allow the FDA to consider generic proposals for *safe* changes to *voluntary* label features[,]" *id.* at 97 (emphases added); *see also id.* at 98 (finding persuasive "[t]he FDA's repeated approvals of comparable changes in generic label ANDAs") (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). On that basis, the district court held that Teva's removal of braille comported with the same-labeling provision since the use of

braille was "voluntary[and] not required by the FDA for safety or efficacy reasons." *Vanda Pharms.*, 766 F. Supp. 3d at 97.

Next, the district court rejected Vanda's argument that the statement "Dispense in original container" was a condition of use that Teva could not remove under 21 U.S.C. § 355(j)(2)(A)(i). *Vanda Pharms.*, 766 F. Supp. 3d at 103. The plain text of the statute, the district court reasoned, indicates that "'conditions of use' encompasses the 'method or duration of administration or application' of a drug[,]" not "instructions to pharmacies for delivering the drug." *Id.* at 102 (citation omitted). Because "instructions for dispensing a drug are not the same as directions for actually using it," the FDA's approval of a label without the text "Dispense in original container" did not violate the statute. *Id.* at 103.

Finally, the district court found no merit to Vanda's arbitrary and capricious challenges. *See Vanda Pharms.*, 766 F. Supp. 3d at 103–105. The court held that the FDA had not unlawfully changed its position, *see id.* at 104, and had "reasonably considered the relevant [safety] issues[,]" *id.* at 105 (quotation marks omitted).

II

The district court had jurisdiction under 28 U.S.C. § 1331, and this court has jurisdiction under 28 U.S.C. § 1291. We review the district court's grant of summary judgment *de novo*. *New Mexico Cattle Growers Ass'n v. Fish & Wildlife Serv.*, 148 F.4th 755, 764 (D.C. Cir. 2025).

Vanda principally challenges the FDA's approval of Teva's braille-free labeling as contrary to the FDCA's same-labeling provision.

The parties' disagreement centers on whether the omission of braille falls within the statute's exception for "changes required * * * because the new drug and the listed drug are produced or distributed by different manufacturers[.]" 21 U.S.C. § 355(j)(2)(A)(v). Vanda insists that this exception permits only changes that are *necessary*—due, for instance, to a permissible modification to the underlying drug. The FDA and Teva argue that the exception embraces *any* change to the label involving aspects voluntarily added by the name-brand manufacturer that do not jeopardize safety or efficacy.

We hold that the statute forecloses the FDA and Teva's expansive reading of the different-manufacturer exception. Perhaps the statute's baseline "sameness" requirement permits some safety-neutral variation across labels like the inclusion or omission of braille script. But as a matter of statutory text, a labeling modification can fall into the different-manufacturer exception only when that change is "required" by the change in manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

Within that framework, we affirm in part and vacate in part the district court's judgment. Because generic manufacturers cannot feature a trademarked brand name on their labeling, Teva was "required" to omit "Hetlioz" in both roman font and braille from its label. Having removed the brand name, Teva was not required to add the established name tasimelteon in braille because it is not in braille on Hetlioz's label. But because neither the FDA nor Teva points to any factor that might have necessitated the removal of either tasimelteon's strength—"20 mg"—in braille or the accompanying dispensing instructions "Do not cover Braille" and "Dispense in original container" from the label due to a change in manufacturer, the FDA's approval of those portions of Teva's label based just on the different-manufacturer exception was contrary to law.

A

This appeal turns on a narrow question of statutory interpretation: whether the removal of braille and the associated instructions to the pharmacist were "required * * * because the new drug and the listed drug are produced or distributed by different manufacturers[.]" 21 U.S.C. § 355(j)(2)(A)(v).

1

In interpreting the scope of the different-manufacturer exception, "[w]e begin with the text." *Smith v. Berryhill*, 139 S. Ct. 1765, 1774 (2019). Recall that the same-labeling provision imposes a baseline rule: "[T]he labeling proposed for the [generic] drug [must be] the same as the labeling approved for the listed drug[.]" 21 U.S.C. § 355(j)(2)(A)(v).

The provision then establishes two exceptions to that rule, only one of which is relevant here—the different-manufacturer exception. That exception applies to "changes required * * * because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v).

"[T]he plain meaning of the word 'required' is the opposite of that of the word 'optional.'" *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1362 (Fed. Cir. 2003); *see also In re Boyd*, 213 F. 774, 775–776 (2d Cir. 1914) ("The words 'require' and 'permit' express different ideas; in the ordinary use of the English language the one does not include the other."). "Require" means "to demand as necessary or essential" or "make indispensable." *Require*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1929 (1986); *Require*,

WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1929 (1981) (same); *see also Require*, BLACK'S LAW DICTIONARY (5th ed. 1979) ("To direct, order, demand, instruct, command, claim, compel, request, need, exact."); *Required*, AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1105 (1981) ("Needed; essential.").

Simply put, "'[r]equire' conveys a sense of necessity[.]" *Hall v. Trivest Partners, L.P.*, 178 F.4th 986, 991 (6th Cir. 2026); *see also Carey v. Donohue*, 240 U.S. 430, 435–438 (1916) (reading statute that applied when a "recording * * * is required" to mean "those cases in which recording was *necessary*") (emphasis added); *Mississippi River Fuel Corp. v. Slayton,* 359 F.2d 106, 119 (8th Cir. 1966) ("'Required' implies something mandatory, not something permitted by agreement."), *rev'd on other grounds*, *Levin v. Mississippi River Fuel Corp*., 386 U.S. 162 (1967); *cf. Public Citizen v. Nuclear Regul. Comm'n*, 901 F.2d 147, 155 (D.C. Cir. 1990) ("[I]n common parlance 'requirement' means something compelled, not merely suggested.").

Reading "required" as "mandatory" ensures that the different-manufacturer exception continues to operate "as just that—an exception[.]" *EPA v. Calumet Shreveport Refin., L.L.C.*, 145 S. Ct. 1735, 1751 (2025); *see id.* (reading statutory exception to "incorporate[] the more demanding, 'core[,]' understanding of 'based on[]'" because "the function of the * * * exception [is] just that—an exception"). When a clause supplies an exception to a baseline rule, we must read that clause "narrowly in order to preserve the primary operation of the provision." *Garland v. Aleman Gonzalez*, 142 S. Ct. 2057, 2068 n.6 (2022) (quoting *Maracich v. Spears*, 570 U.S. 48, 60 (2013)).

Hewing to the natural meaning of "required" allows those common changes to a generic's labeling that the misbranding law, intellectual property rules, or other legal provisions necessitate. For example, when a generic manufacturer changes how it formulates the drug—by, say, including a different inactive ingredient, 21 U.S.C. § 355(j)(4)(H)—the FDCA's misbranding provisions will often *require* corresponding changes to the labeling, *see id.* § 352(a)(1) (deeming a drug "misbranded * * * [i]f its labeling is false or misleading in any particular"); *Zeneca, Inc. v. Shalala*, 213 F.3d 161, 169 (4th Cir. 2000) ("Because a difference in preservative is a permitted variation in formulation, it is reasonable for the FDA to interpret its own regulation to allow corresponding differences in labeling to identify the preservative and provide any appropriate warnings."). A generic also may need to omit certain indications to avoid infringing the name-brand manufacturer's patents. *See Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626, 630 (D.C. Cir. 2025) ("[A]ll parties agree[d] that the changes" to the label "were required to avoid infringement of Novartis's patents."). And other intellectual property requirements, like trademark law, may potentially force a generic to change certain words or formatting on its label. *Cf. Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 853–855 (1982) (recognizing that drug manufacturers may be liable in some circumstances for infringing registered trademarks affixed to generic-drug containers).

2

Applying the plain meaning of the different-manufacturer exception to the facts of this case, we hold that omission of the braille "Hetlioz" was required by the change in manufacturers. We also reject Vanda's argument that Teva was required to include the established name and active ingredient

"tasimelteon" in braille, because it is not in braille on the Hetlioz label. The different-manufacturer exception did not, however, permit Teva to omit "20 mg" in braille or the instructions "Do not cover Braille" and "Dispense in original container" from its label.

a

As all agree, Teva was required to omit the brand name "Hetlioz" from its label in both its roman-script and braille forms. *See* Vanda Reply Br. 19 ("[C]hanging Hetlioz to tasimelteon *is* required for intellectual property reasons[.]"); *see also* FDA Resp. to Citizen Pet. at 8 ("The petitioner has not explained how, under its proposed interpretation, the generic drugs would be expected to comply with the same labeling requirement when the [proprietary name, Hetlioz] in braille (and Roman script) * * * is a name that does not appear on the generic's container labeling at all[.]").

Vanda insists only that, having removed the braille "Hetlioz," Teva was then required to substitute the established (generic) name, tasimelteon, in braille. Vanda Reply Br. 19. Vanda presses that argument even though the established name tasimelteon appears only in roman script, and not in braille, on its own label. Requiring that Teva's label include the established name in braille when it is not on the Hetlioz label would dictate difference, not sameness.

Yet Vanda does not develop any argument or supply any authority as to why the sameness requirement dictates such divergence. Nor does Vanda explain why discrepant treatment of the established name is "required * * * because" Teva is a different manufacturer. 21 U.S.C. § 355(j)(2)(A)(v). Vanda cites no statutory provision, regulation, or case that requires a generic manufacturer to display the established name in a

different manner than it appears on the name-brand label—at least when, as here, neither patient safety nor label-comprehensibility requires the change.

If anything, Vanda may have uncovered a potential defect in *its own label*. The FDCA requires that the drug's "established name" be printed "prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug[.]" 21 U.S.C. § 352(e)(1)(B). Under FDA regulations, the established name must accompany the proprietary label "each time it is featured on the label * * * for the drug[,]" with "a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, *including typography, layout, contrast, and other printing features*." 21 C.F.R. § 201.10(g)(1)–(2) (emphasis added).

Yet Vanda placed only its own brand name Hetlioz—*not* the established name tasimelteon—in braille on its label. And Vanda's briefing leaves us empty-handed as to any legal basis for mandating that Teva display the established name in a different form or typography than the name-brand label does. To be sure, Vanda touts the safety benefits of its use of braille. *See, e.g.*, Vanda Opening Br. 13. But the FDA never required braille on safety grounds. *See* FDA Resp. to Citizen Pet. at 10. And even if it had, it might well be unlawful for Teva "to attach a safer label to [its] generic" by adding braille wording that Vanda omitted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011).

In sum, all agree that, as a generic manufacturer, Teva was required to omit the name brand "Hetlioz" from its label in both roman and braille script. But Vanda has failed to present any sound argument as to how the statute or caselaw mandates that Teva put the established name and active ingredient

tasimelteon in braille when it does not so appear on the Hetlioz label.

b

i

Based on the arguments before us, the different-manufacturer exception does not permit the removal of the braille "20 mg" from Teva's label.

Neither Teva nor the FDA has argued that removing these features was *necessary* due, for instance, to intellectual property requirements or to avoid misbranding. Instead, they attempt to rewrite the statute by replacing "required" with "optional and safe." *See* FDA Br. 38 (arguing that the different-manufacturer exception permits "[c]hanges to voluntarily adopted forms of presenting information that will not diminish or otherwise materially affect the drug's safety or efficacy") (quotation marks omitted); Teva Br. 30 ("[A] generic manufacturer's voluntary choices about labeling presentation (rather than content) also fit within the different-manufacturer exception."). That argument defies the statutory text.

To support their reading, the FDA and Teva point to a definition of "require" as "suitable or appropriate in a particular case[.]" FDA Br. 24 (quoting *Require*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1929 (1986)); Teva Br. 28 (same). But the FDA and Teva do not meet their own mark. That definition reads, in full: "to call for as suitable or appropriate in a particular case: *need* for some end or purpose[.]" *Require*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1929 (1986) (emphasis added). So even under the FDA and Teva's preferred definition, a change must be *needed*,

not just desired. And the FDA and Teva have not identified any need to remove the "20 mg" in braille.

For the first time at oral argument, Teva pointed the court to *National Railroad Passenger Corp. v. Boston & Maine Corp.*, 503 U.S. 407 (1992). *See* Oral Arg. Tr. 173:20–174:23. That case is of no help to Teva. In *National Railroad*, the Supreme Court considered a very different statutory scheme that granted Amtrak condemnation authority over "property * * * owned by the railroad and required for intercity rail passenger service." 503 U.S. at 410–411 (quoting 45 U.S.C. § 562(d)(1) (repealed 1994)). At step two of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), the Court deferred to the Interstate Commerce Commission's reading of "required" as "useful or appropriate[,]" *National R.R.*, 503 U.S. at 418–419.

So all *National Railroad* decided was that the agency's reading of the statutory text was not unreasonable. Our task is different—we must discern what Congress meant using traditional tools of statutory construction. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262, 2266 (2024).

In addition, all statutory language must be read in context, and the relevant phrase here is "changes required * * * because" there is a new manufacturer. 21 U.S.C. § 355(j)(2)(A)(v). Unlike in *National Railroad*, "required" appears in a linguistically cabined exception to a general health and safety rule. In other words, whatever breathing room "require" might leave in other statutes and contexts, Congress's identification of the change in manufacturer as a specific exception that warrants changing a drug's labeling counsels against the FDA's and Teva's "whatever we choose, consistent with safety" reading. Rather than setting sameness as the default, with an exception for necessary changes, the FDA and

Teva's interpretation would set difference as the default, with exceptions only (1) for formatting that the FDA mandated the name brand to adopt, and (2) to avoid safety or efficacy problems. "Congress * * * is unlikely to intend for an exception to swallow the rule." *Calumet Shreveport Refin.*, 145 S. Ct. at 1751.[4]

ii

The FDA's and Teva's remaining arguments do not persuade.

First, the FDA and Teva insist that this court's decision in *Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493 (D.C. Cir. 1996) supports their atextual reading. Not at all.

In *Bristol-Myers Squibb*, this court held that the different-manufacturer exception "accommodate[s] the situation in which the generic drug manufacturer has sought * * * approval for fewer than all of the indications of the pioneer manufacturer's drug[,]" and accordingly was allowed to omit some indications from the label. 91 F.3d at 1500 (quotation marks omitted). That holding, however, did not require this court to interpret the scope of the different-manufacturer exception. Instead, the decision rested on other statutory

[4] The FDA notes that this court has declined to read "require" as "connot[ing] the idea of compulsion." FDA Br. 46 (alteration in original) (quoting *Railway Lab. Execs.' Ass'n v. Railroad Ret. Board*, 749 F.2d 856, 861 (D.C. Cir. 1984)). Hardly. In that case, we decided only that the phrase "required under the laws" was ambiguous as to whether "the law" meant only "*express* provisions" of law or also included laws "creat[ing] such a strong preference so as to *in effect* compel" certain conduct. *Id.* A definition of "required" as "merely *permitted* or *requested*" was not on the table. *Id.* at 861 n.8.

provisions that separately allow generic labels to list a subset of the name-brand drug's indications. *See id.* (Section 355(j)(2)(A)(i) "would be redundant if the same-label requirement * * * applied to indications for use."); *id.* (Section 355(j)(3) "lists the circumstances in which the Secretary may disapprove an ANDA[,]" and the label's failure to "list every indication approved for the pioneer is not among these.").

Even more to the point, the labeling change in that case was required by the change in manufacturer. Because the FDA had recently approved a supplemental indication for the name-brand drug, the statute precluded any generic from carrying that new indication on its labeling, 21 U.S.C. § 355(j)(4)(D)(iv). *See Bristol-Myers Squibb*, 91 F.3d at 1496. As a result, the generic manufacturer was legally *required* to remove that indication from its label. The only question before this court was whether the generic could enter the market at all with the modified label.

Second, the FDA points to its own regulations and past practice. No doubt an agency's expert view and experience can be "especially informative" when "it rests on factual premises within [the agency's] expertise." *Loper Bright*, 144 S. Ct. at 2267 (quoting *Bureau of Alcohol, Tobacco & Firearms v. Federal Lab. Rels. Auth.*, 464 U.S. 89, 98 n.8 (1983)). But that is not this case. The FDA has not shown that it brought any source of expertise to bear in concluding that "required" means "optional unless unsafe."

FDA regulations, in fact, mirror the ordinary meaning of required as something mandatory. For example, the different-manufacturer regulation provides that labeling differences:

> may include differences in expiration date, formulation, bioavailability, or pharmacokinetics,

> labeling revisions made to comply with current FDA labeling guidelines or other guidance, or omission of an indication or other aspect of labeling protected by patent or accorded exclusivity under [the FDCA].

21 C.F.R. § 314.94(a)(8)(iv). Every item on that list is required to be changed by the generic to accurately reflect a characteristic of the underlying drug or otherwise to comply with federal law.

The FDA's past practice does not move the needle either. The agency notes that it "routinely approves generic labeling that differs from the name-brand drug's routine color, font, and formatting choices[,]" FDA Br. 38, and that it has approved a "generic product that did not include halal and kosher certifications in their labeling, where the [name-brand drug] did." FDA Br. 12. Some of those changes may have been necessary—keeping a halal certification on a drug that does not satisfy halal manufacturing standards might well constitute prohibited mislabeling. *See* 21 U.S.C. § 352(a)(1). As for the others, nothing in the FDA's explanation casts expert light on why a change in manufacturer mandates such changes.

Third, the FDA's argument, at most, amounts to a policy concern that "[a] narrow reading of the same-labeling requirement would force generic manufacturers to copy every minute aspect of a brand-name drug's labeling, such as the graphics included in the drug's packaging, the font used for the drug's package insert, and the color of the drug's container." FDA Br. 39. Or, as Teva puts it, "[i]t would be aberrant to read the FDCA as permitting safe variation in a generic drug's substance, but not in its label." Teva Br. 30 (quoting *Vanda Pharms.*, 766 F. Supp. 3d at 98).

Those concerns are unfounded. The FDCA does not categorically prohibit "safe variation" in a generic drug's label. To the contrary, the exceptions in the same-labeling provision permit labeling modifications that are necessary to ensure accuracy concerning variations like changes to the inactive ingredients or slight differences in absorption. *See* 21 U.S.C. § 355(j)(4)(H) (permitting safe variation in inactive ingredients); *id.* § 355(j)(4)(F) (requiring generics to be only bioequivalent).

In addition, Vanda, the FDA, and Teva agree that the same-labeling provision allows *de minimis* variations in labels, such as fonts, type size, and colors. They simply ground those permissible changes in different statutory provisions. The FDA and Teva insist that the different-manufacturer exception embraces those *de minimis* changes. *See* FDA Resp. to Citizen Pet. at 7; Teva Br. 37. Vanda is of the view that the word "same" does the work: *De minimis* changes preserve the baseline "sameness" of the label. *See* Oral Arg. Tr. 18:11–14 ("[A] de minimis change * * * qualifies as the same, and you don't get into the exception for the different manufacturer. We would just say that's the same—for effective purposes, the same label.").

As we have just held, the FDA and Teva's reading of the different-manufacturer exception conflicts with its plain text because, unless legally mandated, font, color, and stylistic changes are not *required* because of the change in manufacturers. Vanda's reading, on the other hand, hinges on a question that the parties have not squarely put before us: what it means for a generic's label to be "the same as" the name-brand's. 21 U.S.C. § 355(j)(2)(A)(v). That "same[ness]" requirement may well leave some room for minor, safety-neutral marketing changes in labeling as long as the required statutory and regulatory components of the labels are properly

reproduced. But none of the parties has developed an argument as to whether a label that omits Vanda's optional addition of braille preserves "sameness" within the meaning of the FDCA generally or in line with a *de minimis* exception for fonts, scripts, typography, and colors. That is a question the FDA can address on remand in light of Vanda's view on appeal that "the same as" does not require the labels to be identical and allows for variation in fonts and safety-neutral styles of presenting information. All we decide today is the narrow question that the omission of "20 mg" in braille is not required because of the change in manufacturers from Vanda to Teva, for purposes of the different-manufacturer exception.

* * * * *

Because the statutory text forecloses FDA and Teva's reading of "required" as "optional and safe," we reverse the district court's grant of summary judgment to Teva and the FDA as to whether the removal of the braille "20 mg" and the braille-specific instructions "Do not cover Braille" and "Dispense in original container" under the different-manufacturer exception was contrary to law.

Vanda asks us to go one step further and vacate the FDA's approval of Teva's generic instead of remanding without vacatur. In weighing whether to remand without vacatur, this court considers "(1) the seriousness of the deficiencies of the action, that is, how likely it is the agency will be able to justify its decision on remand; and (2) the disruptive consequences of vacatur." *Center for Biological Diversity v. EPA*, 141 F.4th 153, 183 (D.C. Cir. 2025) (*per curiam*) (quoting *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019)). Here, both factors militate against vacatur.

First, the FDA's error may be curable on remand. Although the FDA could not approve Teva's label without "20 mg" in braille under the different-manufacturer exception, it may determine on remand that the Hetlioz label and the braille-free Teva label are nonetheless "the same." After all, "same" does not necessarily mean "identical." *See Same*, BLACK'S LAW DICTIONARY (5th ed. 1979) ("The word 'same' * * * does not always mean 'identical.' It frequently means of the kind or species, not the specific thing."); *Same*, WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2007 (1986) ("[R]esembling in every way: not different *in relevant essentials* at one time[.]") (emphasis added); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme.") (quotation marks omitted); *cf. Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (holding "that the statute does not unambiguously require the term 'same as'" in 21 U.S.C. § 355(j)(1)'s active-ingredient provision "to be defined as complete chemical identity"). That reading could perhaps provide a more natural textual home for the FDA's longstanding font, style, typography, and color exception to the same-labeling requirement.

Second, vacating the FDA's approval of Teva's tasimelteon would require Teva to withdraw its drug from the market based solely on a failure to satisfy a statutory labeling requirement even though no safety or efficacy concerns have been associated with the absence of 20 mg in braille. FDA Resp. to Citizen Pet. at 10; *see* Section III.B, *infra*. Such a recall could prove extremely disruptive to patients and medical providers.

Because vacatur is inappropriate, we instruct the district court to remand to the agency to address in the first instance

whether the Teva label satisfies the baseline requirement of being "the same as" the Hetlioz label under Section 355(j)(2)(A)(v), thereby rendering the applicability of the different-manufacturer exception irrelevant to the omission of 20 mg in braille.

B

Vanda also argues that Teva's omission of the instructions "Do not cover Braille" and "Dispense in original container" violates the "conditions of use" provision, 21 U.S.C. § 355(j)(2)(A)(i). That provision requires an ANDA to contain "information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for" the listed drug. *Id.*

This argument adds nothing to the mix. The FDA suggested adding these instructions only to the extent the label contains braille. *See* FDA Label Review at 1–2. If "20 mg" must appear in braille on the bottle, these instructions will have to be included. Should the FDA decide on remand that braille need not be embossed for the labels to be "the same," then the instructions can be omitted as superfluous and potentially misleading.[5]

[5] Vanda suggests in a footnote that "the instruction to 'dispense in original packing' has independent significance" because "dispensing tasimelteon in its original container ensures that the patient always receives the drug in a package of the same size, shape, and texture[.]" Vanda Opening Br. 49 n.5. But Vanda points to no authority that requires a drug's package to remain the "same size, shape, and texture" across manufacturers or over time. This court will not overturn agency actions based on "cursory arguments made only in a footnote." *Doe v. SEC*, 114 F.4th 687, 693 (D.C. Cir. 2024)

III

Vanda separately contends that the FDA's approval of Teva's generic was arbitrary and capricious for three reasons. None succeeds.

A

Contrary to Vanda's argument, *see* Vanda Opening Br. 52–54, the FDA's decision was fully consistent with the government's position in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). There, the Solicitor General filed an amicus brief arguing, in relevant part, that generic drug manufacturers could not unilaterally add safety warnings to their labels. Vanda points specifically to the following portion of the Solicitor General's brief:

> FDA has consistently taken the position that an ANDA holder may not unilaterally change its approved labeling. For example, in promulgating its final rule implementing labeling requirements for ANDAs, FDA rejected the suggestion that the regulations should permit generic manufacturers to deviate from the brand-name labeling "to add contraindications, warnings, precautions, adverse reactions, and other safety-related information." FDA explained that "[e]xcept for labeling differences due to [issues not relevant here], the ANDA product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval." FDA stated instead that an

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(quoting *Hutchins v. District of Columbia*, 188 F.3d 531, 539 n.3 (D.C. Cir. 1999) (*en banc*)).

> ANDA holder wishing to add a warning should furnish adequate supporting information to FDA, which would then determine whether the labeling for all drugs should be modified.

Brief for the United States as Amicus Curiae Supporting Respondents at 16–17, *PLIVA*, 564 U.S. 604 (Nos. 09-993, 09-1039, 09-1501), 2011 WL 741927, at *16–17 (citations omitted).

Vanda claims that this portion of the brief advances a "narrow interpretation of the same-labeling requirement fundamentally opposed to the construction [the FDA] has advanced" in this case. Vanda Opening Br. 52. Not at all.

Under the Administrative Procedure Act, "'agencies are free to change their existing policies as long as they provide a reasoned explanation for the change,' 'display awareness that they are changing position,' and consider 'serious reliance interests.'" *FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025) (formatting modified) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–222 (2016)).

Vanda has failed to identify any departure from the position articulated in the *PLIVA* brief. The Solicitor General simply explained that the same-labeling requirement precludes generics from unilaterally adding warnings that do not appear on the name-brand label. Nothing in the FDA's position here quibbles with that interpretation. Nor could it: The Supreme Court ultimately read the statute the same way as the above-quoted portion of the Solicitor General's brief. *See PLIVA*, 564 U.S. at 618.

This case deals with the removal of braille lettering that the FDA allowed, but did not require, on the Hetlioz label. That

is quite different from the generic adding or subtracting safety warnings. In addition, the FDA's arguments here are grounded in the meaning of the different-manufacturer exception, which was not at issue in *PLIVA*. Brief for the United States as Amicus Curiae Supporting Respondents, 2011 WL 741927, at *16 (characterizing the different-manufacturer exception as "not relevant here").

Anyhow, the whole argument is a tempest in a teapot. "No explanation could justify or make lawful the agency's new interpretation of the statute" because "[t]he agency must act pursuant to the court's best reading of the statute." *Centro de Trabajadores Unidos v. Bessent*, 167 F.4th 1218, 1238 (D.C. Cir. 2026).

B

Vanda next argues that the FDA acted arbitrarily and capriciously by "concluding that Teva's omission of Braille had no negative safety implication" when "substantial evidence" indicated that "including Braille on a drug label makes the product safer[.]" Vanda Opening Br. 54–55.

An agency acts arbitrarily and capriciously when it "entirely fail[s] to consider an important aspect of the problem" or "offer[s] an explanation for its decision that runs counter to the evidence before" it. *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). An agency must also support its findings with "substantial evidence[,]" meaning "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Robinson v. National Transp. Safety Board*, 28 F.3d 210, 215 (D.C. Cir. 1994).

The FDA's actions easily pass muster. To start, Vanda's complaint is about the failure to put the medication's established name tasimelteon in braille. Yet, as already explained, Vanda's own label does not include tasimelteon in braille either. That is because the FDA concluded that the "inclusion of braille * * * is unnecessary for the safe use" of the drug. FDA Resp. to Citizen Pet. at 17. Nothing unreasonable about that.

In addition, the FDA thoroughly explained why, in its view, removing braille did not pose a safety concern. The agency explained that Vanda itself had never provided evidence that including braille on the label would enhance safety or efficacy. The Label Comprehension Study only "assess[ed] whether the intended users could understand the braille" on the label. FDA Resp. to Citizen Pet. at 10. The study, which involved only 22 participants, was never designed to "establish that braille is necessary for the safe and effective use of the drug product." *Id.*

Nor did the academic paper that Vanda cited in its citizen petition raise any safety flags. That paper, the FDA explained, merely "explore[d] medication usage patterns and investigate[d] the demand for braille labeling in Saudi Arabia[,]" a country with higher braille literacy than the United States. FDA Resp. to Citizen Pet. at 11 & n.75. The study also relied entirely on a survey conducted over Google Docs, without any analysis of whether the sample was representative or the study was scientifically reliable. *Id*. at 11 n.75.

The FDA next explained that it "continuously monitors the safety of approved drug products[,]" and had identified "[n]o adverse event reports or medication error reports related to the exclusion of braille or the braille-related statements" from Teva's label. FDA Resp. to Citizen Pet. at 11. While FDA

would evaluate any future adverse "evidence and take regulatory action deemed appropriate at that time," the FDA found Vanda's "concerns about the potential product mix-ups to be speculative and unsupported by current evidence." *Id.* at 11 n.77, 12.[6]

Finally, the FDA noted that the braille labels would impact at most a small percentage of visually impaired patients. The FDA cited Vanda's own statistic that "only 10% of the blind population actually read[s] Braille." FDA Resp. to Citizen Pet. at 10 n.69. The agency added that "there are also other methods to convey labeling information to the larger visually-impaired community[,]" including "large print labels, auditory technologies such as 'talking bottles,' and radio frequency identification tags." *Id.* at 10 & n.70.

Vanda's attempts to chip away at this explanation fail.

First, Vanda insists that the FDA "did not address * * * safety discussions" that took place during the review of Teva's ANDA. Vanda Opening Br. 55. It points to two internal FDA statements, one of which thought it "might be less safe" to omit braille, and another that concluded braille was not required for safety. J.A. 255–256.

While the tentative views of individual staff members may have differed internally, the FDA explained that it "consider[ed] the totality of the views from the various subject

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[6] Vanda waves around a single complaint that it received "about Braille disappearing from a patient's prescription." Vanda Reply Br. 28. But that patient did not voice any safety or efficacy concerns. *See* J.A. 335 (product complaint record stating "[t]he patient reported to Vanda Case Manager that the 30 day supply bottle of HETLIOZ did not have Braille labeling. No further information was provided.").

matter experts" across the agency in reaching its ultimate decision that braille is not a needed safety feature for tasimelteon. J.A. 918 n.31. Nothing in the record overcomes the weight of the FDA's expert judgment.[7]

Second, Vanda argues that the FDA gave short shrift to "safety information contained in Vanda's original application." Vanda Opening Br. 55–56. But the supposed "safety information" it cites is nothing of the sort.

Vanda first plucks a sentence out of context from the recommendations of the U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, an agency working group that Congress charged with developing non-binding "best practices *for pharmacies* to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels." Pub. L. No. 112–114, Title IX, § 904(a)(3)(A), 126 Stat. 993, 1090 (2012) (emphasis added). While the Working Group recognized that "[p]ersons with visual impairments * * * all too often report inadvertently taking the wrong medication," it then recommended a "*variety* of delivery methods"—including audio, large print, braille, and radio frequency identification devices—that *pharmacists* could employ to address that problem. U.S. Access Board Working Group on Accessible Prescription Drug Container Labels, Working Group Recommendations (July 10, 2013) (emphasis added), https://perma.cc/PD8M-FXRH.

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[7] Because Vanda's arbitrary and capricious challenges target "the FDA determination as a whole, both the ANDA decision and the citizen[] petition," Oral Arg. Tr. 12:14–17, we consider the FDA's reasoning underlying both decisions. *See* Oral Arg. Tr. 12:4–9 (counsel for Vanda stating "I think we're willing to agree that for our arbitrary and capricious arguments, we will take into account all of FDA's reasoning").

Vanda next cites guidance from the European Union that requires braille labeling on medication containers. *See* Vanda Opening Br. 56. But the FDA reasonably explained why it reached a contrary policy judgment: "[T]he European Union Council Directive is a policy concerning the use of braille on drug labeling in foreign countries and under a different regulatory framework[;] it carries no legal weight in the United States." FDA Resp. to Citizen Pet. at 11.[8]

C

To round out its arbitrary-and-capricious challenges, Vanda argues that FDA's "approval of Teva's ANDA, which lacks Braille lettering, contradicts its approval of MSN['s] ANDA, which *does* include Braille lettering." Vanda Opening Br. 61.

Not at all. The FDA's consistent position has been that including braille "is not a requirement for the generic products[,]" because Vanda voluntarily placed it on the Hetlioz label. Based on that reasoning, the FDA allowed generics to choose whether to remove the braille—as Teva and Apotex did—or incorporate it as MSN did. There is nothing inconsistent about leaving the choice to the generic manufacturer.

[8] Vanda insists that there are "*numerous* readily available academic studies demonstrating" "the enhanced safety of Braille lettering." Vanda Opening Br. 59–60. Vanda never cited those studies to the FDA, so they are not part of the record on review.

IV

For the foregoing reasons, we affirm in part and vacate in part the district court's grant of summary judgment. We vacate the grant of summary judgment only as to the FDA's approval, in reliance on the different-manufacturer exception, of a label without "20 mg" in braille and without the accompanying pharmacy instructions. We remand to the district court with instructions to remand to the agency without vacatur to decide whether the label nonetheless satisfies the baseline statutory requirement that Teva's label be "the same as" the Hetlioz label, which would make the inclusion of any braille script and the accompanying pharmacy instructions unnecessary. We otherwise affirm the grant of summary judgment in favor of the FDA and Teva.

So ordered.