# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

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Argued March 24, 2021 Decided May 28, 2021

No. 20-5341

MEDINATURA, INC.,
APPELLANT

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

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Appeal from the United States District Court
for the District of Columbia
(No. 1:20-cv-02066)

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*David B. Salmons* argued the cause for appellant. With him on the briefs were *Jason R. Scherr* and *Douglas A. Hastings*.

*Courtney L. Dixon*, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Brian M. Boynton*, Acting Assistant Attorney General, *Scott R. McIntosh*, Attorney, and *Annamarie Kempic*, Deputy Chief Counsel for Litigation, U.S. Food and Drug Administration.

Before: HENDERSON, ROGERS and WILKINS, *Circuit Judges*.

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

KAREN LECRAFT HENDERSON, *Circuit Judge*: The Federal Food, Drug, and Cosmetic Act (FDCA) regulates homeopathic drugs. A 1988 Food and Drug Administration (FDA) guidance document outlined the circumstances in which the FDA intended to exercise its discretion not to enforce the full force of the FDCA against homeopathic drugs. In October 2019, the FDA withdrew the guidance document. Shortly thereafter, the FDA added six of appellant MediNatura, Inc.'s prescription injectable homeopathic products to an import alert, notifying FDA field staff that the products appeared to violate the FDCA. MediNatura challenged both actions and sought preliminary injunctive relief to stop the withdrawal of the guidance as well as the enforcement of the import alert. The district court dismissed MediNatura's import alert-based claims, concluding the import alert was non-final agency action. It also declined to enjoin the withdrawal of the guidance because MediNatura failed to establish its entitlement to a preliminary injunction. As detailed *infra*, we affirm.

## I. BACKGROUND

### A. Statutory and Regulatory Background

The FDCA defines "drug" as, *inter alia*, (1) articles recognized in the "official Homoeopathic Pharmacopoeia of the United States"; (2) "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals"; and (3) "articles (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1). Under the FDCA, it is unlawful to distribute any "new drug" without FDA approval. *Id.* §§ 331(d), 355(a). A drug is a "new drug" if it is "not generally recognized . . . as safe and effective for use under the conditions prescribed, recommended, or suggested in

the labeling thereof." *Id.* § 321(p)(1). Even if a drug is so recognized it remains a "new drug" unless it has been "used to a material extent or for a material time under such conditions." *Id.* § 321(p)(2). Therefore, if a drug is widely used or used for a substantial time and is generally recognized as safe and effective ("GRAS/E") it is not a "new drug" needing approval. To obtain approval for a new drug, a sponsor must submit a New Drug Application (NDA) to the FDA. *Id.* § 355(b). The FDA "implement[s] a structured risk-benefit assessment" in evaluating an NDA. *Id.* § 355(d).

Imported drugs are subject to the FDCA. *Id.* § 381(a). If an imported drug "appears" to violate the FDCA, it may be refused admission after FDA detention. *Id.*; Joint Appendix (J.A.) 1227 (FDA Regulatory Procedures Manual (RPM)). Should a drug be detained, the FDA provides the importer notice and an opportunity to be heard. 21 C.F.R. § 1.94(a); J.A. 1266 (RPM). The importer may introduce testimony to demonstrate the admissibility of the drug. 21 C.F.R. § 1.94(a); J.A. 1266 (RPM). The FDA considers the testimony and then decides whether to release the drug or formally deny admission. 21 U.S.C. §§ 381(a), (b); J.A. 1266–67 (RPM). An importer may seek reconsideration from the FDA and ultimately judicial review. 21 C.F.R. §§ 10.33, 10.45.

### B. FDA Regulation of Homeopathic Drugs

Homeopathy is an alternative medical practice "based on two unconventional theories": (1) "'[l]ike cures like'—the notion that a disease can be cured by a substance that produces similar symptoms in healthy people"; and (2) the "'[l]aw of minimum dose'—the notion that the *lower* the dose of the medication, the *greater* its effectiveness." *Homeopathy*, Nat'l Insts. of Health, https://www.nccih.nih.gov/health/homeopathy (last updated Apr. 2021) (emphasis in original).

Homeopathic drugs are subject to the FDCA requirement that any "new drug" must be approved. 21 U.S.C. §§ 321(g), 321(p), 331(d), 355(a). The FDA has never approved an NDA for a homeopathic drug nor found a homeopathic drug to be GRAS/E and thus not a "new drug" requiring an NDA. Instead, the FDA has exercised its enforcement discretion regarding the sale of homeopathic drugs through its 1988 Compliance Policy Guide 7132.15 § 400.400 "Conditions Under Which Homeopathic Drugs May be Marketed" (CPG 400.400). J.A. 218 (CPG 400.400). CPG 400.400 "delineate[d] those conditions under which homeopathic drugs may *ordinarily* be marketed in the U.S." *Id.* (emphasis added). The FDA announced its intention to "consider[] for regulatory follow-up" homeopathic drugs not in compliance with certain FDCA requirements—including labeling, packaging and manufacturing requirements. *Id.* at 223. CPG 400.400 did not exempt homeopathic drugs from approval requirements and, while CPG 400.400 was in place, the FDA took enforcement steps against certain unapproved homeopathic drugs.[1]

In March 2015, the FDA announced that it was reevaluating its enforcement policies for homeopathic drugs, explaining that, since CPG 400.400's issuance, the homeopathic drug industry had expanded significantly and it had received numerous reports of "[n]egative health effects from drug products labeled as homeopathic." Homeopathic Product Regulation: Evaluating the Food and Drug Administration's Regulatory Framework After a Quarter-Century, 80 Fed. Reg. 16,327, 16,328 (Mar. 27, 2015). It then

[1] *See, e.g.*, J.A. 1335–36 (warning a company that its homeopathic remedy linked to adverse health effects was a new drug marketed without approval and noting that "there may be circumstances where a product that otherwise may meet the conditions set forth in [CPG 400.400] may nevertheless be subject to enforcement action").

sought public input on its "current enforcement policies," including whether "the current enforcement policies under the CPG [are] appropriate to protect and promote public health." *Id.*

In December 2017, following its evaluation of CPG 400.400, the FDA announced that "in the best interest of public health," it intended to replace CPG 400.400 with a "risk-based" enforcement approach "consistent with FDA's risk-based regulatory approaches generally." Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry, 82 Fed. Reg. 60,403, 60,405 (Dec. 20, 2017). The proposed guidance (2017 Draft Guidance) identified categories of homeopathic products that posed higher risks and therefore a higher enforcement priority—including products that had reported safety concerns, that contained potentially harmful ingredients or that "pose[d] a greater risk of harm to users due to their routes of administration." J.A. 232 (2017 Draft Guidance). Notwithstanding the categories, the FDA noted that the guidance will "provide notice that any product labeled as homeopathic that is being marketed illegally is subject to FDA enforcement action at any time," *id.*, and that "[t]he continued marketing of products that have neither been approved by FDA nor found to be GRAS/E is a public health concern," *id.* at 230–31. The FDA stated that CPG 400.400 would be withdrawn once the new guidance issued. Drug Products Labeled as Homeopathic; Draft Guidance, 82 Fed. Reg. at 60,404.

In July 2018, the FDA received a citizen petition from Americans for Homeopathy Choice (Citizen Petition). The petition requested various actions from the FDA and, as relevant here, asserted that the homeopathic industry and its consumers had relied on CPG 400.400 for decades and that replacing it would upset that reliance interest. The FDA

responded to the petition on October 24, 2019, stating that the reliance interest was overcome by the FDA's need to withdraw CPG 400.400 and noting reasons why. The next day, the FDA published notice—effective immediately—that it was withdrawing CPG 400.400. Compliance Policy Guide Sec. 400.400 Conditions Under Which Homeopathic Drugs May Be Marketed; Withdrawal of Guidance, 84 Fed. Reg. 57,439, 57,440 (Oct. 25, 2019). Since issuing CPG 400.400, it explained, the homeopathic industry had grown significantly and it had recently encountered "situations in which homeopathic products either caused or could have caused significant harm." *Id.* Because CPG 400.400 was "inconsistent with [the FDA's] risk-based approach to enforcement," it announced the withdrawal of CPG 400.400 at that time (notwithstanding the previous notice that the withdrawal would not occur until the 2017 Draft Guidance was finalized) as well as its intent to apply a general risk-based approach to enforcement until new guidance was finalized. *Id.* Also on October 25, 2019, the FDA published a new version of its draft guidance (2019 Draft Guidance) closely mirroring the 2017 Draft Guidance. *See* Drug Products Labeled as Homeopathic; Draft Guidance for Food and Drug Administration Staff and Industry, 84 Fed. Reg. 57,441 (Oct. 25, 2019).

### C. Procedural History

MediNatura manufactures, imports and distributes homeopathic products, including six prescription injectable products manufactured in Germany (Products), all of which complied with CPG 400.400's requirements. In June 2020, the FDA issued a warning letter to MediNatura, noting the Products were "especially concerning from a public health perspective" because "[i]njectable products are delivered directly into the body . . . bypass[ing] some of the body's key defenses" and the Products contained "potentially toxic or

otherwise harmful ingredients." J.A. 399 (Warning Letter). The FDA explained that it considered the Products "unapproved new drugs" and that they could not be distributed without approval. *Id.* Six days later, the FDA added MediNatura's Products to Import Alert 66-41 (Import Alert), which lists products that "appear[] to be" unapproved new drugs in violation of the FDCA.[2] J.A. 405 (Import Alert).

On July 29, 2020, MediNatura filed suit against the FDA, alleging that the FDA (1) arbitrarily and capriciously withdrew CPG 400.400 and added the Products to the Import Alert by failing to consider reliance interests or alternative actions (Claim I); (2) improperly added the Products to the Import Alert without undergoing notice-and-comment pursuant to the Administrative Procedure Act (APA) (Claim II); and (3) arbitrarily and capriciously added the Products to the Import Alert with no reasoned explanation (Claim III). *MediNatura, Inc. v. FDA*, 496 F. Supp. 3d 416, 433 (D.D.C. 2020).[3] MediNatura sought a preliminary injunction to enjoin the FDA from enforcing the Import Alert against its Products and to enjoin the FDA from withdrawing CPG 400.400. *Id.* The FDA moved to dismiss the suit and separately opposed the preliminary injunction, arguing that neither action was final agency action and that the withdrawal of CPG 400.400 was

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[2] Import alerts inform FDA staff of products that "appear to be in violation of FDA's laws and regulations" and thus may be detained. *Import Alerts*, U.S. Food & Drug Admin., https://www.fda.gov/industry/actions-enforcement/import-alerts (last updated May 14, 2019).

[3] The district court concluded that MediNatura's purported fourth claim—the FDA did not consider alternative actions—was not a separate claim but "a separate *reason* that the withdrawal of CPG 400.400 (and issuance of the Import Alert) was arbitrary and capricious" and analyzed it under Claim I. *Id.* at 454 (emphasis in original).

unreviewable because it was committed to the FDA's discretion. *Id.*

While the lawsuit was pending, MediNatura ordered two shipments of Engystol, one of its Products listed on the Import Alert, from Germany. *Id.* One shipment entered the United States through Los Angeles and the other shipment was detained in Houston. *Id.* at 434. The FDA notified MediNatura that the Houston shipment was detained because it appeared to be an unapproved new drug and informed MediNatura of its right to a hearing.

On October 23, 2020, the district court held that the Import Alert was not final agency action under the APA and dismissed the Import Alert-based portions of Claims I–III. *Id.* at 453. It also held the withdrawal of CPG 400.400 was final agency action, *id.* at 444, but was not committed to agency discretion by law, and thus denied the FDA's motion to dismiss that portion of Claim I, *id.* at 451. The district court then denied preliminary injunctive relief on MediNatura's Claim I challenge to the withdrawal of CPG 400.400, concluding that MediNatura failed to meet the preliminary injunction requirements. *Id.* at 454–62.

During the litigation, MediNatura attempted eight more shipments of its Products, all of which were detained. MediNatura participated in the FDA's hearing process, providing "written testimony" to the FDA "to support release of each of the shipments subject to detention." J.A. 206 (Declaration of MediNatura CEO). On February 22, 2021, the FDA notified MediNatura that it denied admission to the detained shipments. In a separate letter,[4] the FDA stated that

[4] On February 19, 2021, the FDA replied to MediNatura's challenge to the June 2020 warning letter. The FDA treated its reply as a response to the evidence MediNatura presented in its challenges

MediNatura's Products are "not 'generally recognized . . . as safe and effective' . . . . [and] [a]s a result, the products are unapproved new drugs." Supp. A. 53 (quoting 21 U.S.C. § 321(p)). In that letter, the FDA set out its reasoning for its conclusion that the Products do not meet the GRAS/E standard.

## II. ANALYSIS

### A. Finality of the Import Alert

Our review of the district court's dismissal of the Import Alert claims is *de novo*. *Reliable Automatic Sprinkler Co. v. Consumer Prod. Safety Comm'n*, 324 F.3d 726, 731 (D.C. Cir. 2003).

Under the APA, we review only agency action that is "final." 5 U.S.C. § 704. To qualify as "final," agency action must (1) "mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature" and (2) constitute action "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997) (internal citations and quotations omitted). Both *Bennett* prongs must be met to make agency action final. *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018). The law surrounding the APA's finality requirement is "hardly crisp" and our precedent "lacks many 'self-implementing, bright-line rule[s],' given the 'pragmatic' and 'flexible' nature of the inquiry as a whole." *Rhea Lana, Inc. v. Dep't of Lab.*, 824 F.3d 1023, 1027 (D.C. Cir. 2016) (alteration in original) (quoting *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1279 (D.C. Cir. 2005)). Under this pragmatic inquiry, we find the FDA's addition of MediNatura's Products to the Import Alert fails *Bennett*'s first

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both to the warning letter and to the FDA's administrative proceedings. *See* Supplemental Appendix (Supp. A.) 53, 54 n.1.

prong. The action does not mark the consummation of the agency's decisionmaking process because it is interlocutory and, accordingly, not reviewable under the APA. *See Soundboard*, 888 F.3d at 1267.[5]

As earlier discussed, *see* Part I.A., *supra*, when a product is detained pursuant to an import alert, the importer is given notice and is afforded an opportunity to be heard. The importer may submit evidence to establish the drug's admissibility. After reviewing the evidence, the FDA determines whether to refuse admission. Should that determination be adverse to the importer, the importer may seek judicial review. MediNatura took advantage of that process. MediNatura received notice of the reasons its Products were detained and of its right to a hearing. MediNatura "fully participated in the hearing process." J.A. 206 (Declaration of MediNatura CEO). And on February 22, 2021, the FDA refused admission to each of MediNatura's detained shipments, concluding MediNatura had not established that the Products were not "new drugs."[6]

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[5] The harms MediNatura claims from the listing of its Products on the Import Alert are evaluated under *Bennett*'s second prong. *See Soundboard*, 888 F.3d at 1272 (considering "impact on industry" under *Bennett*'s first prong would "bootstrap[] *Bennett*'s second prong into its first"); *id.* ("The point where an agency's decisionmaking process is complete cannot be pulled to and fro by the gravity of any particular decision.").

[6] A lawsuit may become moot if the challenged agency action is "super[s]eded in full" by subsequent agency action. *See Fund For Animals, Inc. v. Hogan*, 428 F.3d 1059, 1064 (D.C. Cir. 2005). The parties agreed in supplemental briefing that the February 22 refusals of admission did not moot MediNatura's challenge to the addition of its Products to the Import Alert. We agree. The addition of a product to an import alert represents the FDA's determination that the product appears to violate the FDCA and a subsequent refusal of admission after administrative proceedings affirms that

The procedures following a product's addition to the Import Alert manifest the interlocutory nature of that decision, especially considering the finality requirement's "several functions." *DRG Funding Corp. v. Sec'y of Hous. & Urb. Dev.*, 76 F.3d 1212, 1214 (D.C. Cir. 1996); *cf. Southwest Airlines Co. v. DOT*, 832 F.3d 270, 275 (D.C. Cir. 2016) ("the way in which the agency subsequently treats the challenged action" relevant to whether action is final). First, treating a product's addition to the Import Alert as final agency action would not allow the FDA "an opportunity to apply its expertise and correct its mistakes" as the FDA's procedures prescribe. *DRG Funding*, 76 F.3d at 1214. Should the FDA ultimately determine that its decision to include a product on the Import Alert is incorrect, it can then apply its expertise and correct the mistake if challenged by the importer. Judicial review at this stage would "disrupt[] the agency's processes." *Id.*

Indeed, the "completion of [the FDA's] processes may obviate the need for judicial review." *Id.* at 1215. After the addition of a product to the Import Alert, an importer "still enjoys an opportunity to convince the agency to change its mind." *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir.

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determination. Yet the addition of a product to an import alert also has a practical function—it assists FDA field staff by notifying them of products that appear to violate the FDCA and thus are subject to detention. Absent listing on an import alert, products that can or should be detained are more likely to proceed into the United States. Accordingly, the FDA's February 22 decisions refusing entry to the Products do not supersede *in full* its earlier decision to add the Products to the Import Alert because relief could still be granted to MediNatura by enjoining the FDA from listing MediNatura's Products on the Import Alert. Notwithstanding the February 22 refusals of admission do not fully supersede the inclusion of MediNatura's Products on the Import Alert, the listing remains non-final agency action, as discussed *infra*.

1986). Should it succeed in convincing the FDA that its products are GRAS/E and thus not "new drugs" requiring an NDA, nothing would remain for the importer to appeal because products listed on the Import Alert are only those that "appear" to be new drugs without an NDA; the agency would then correct its mistake by removing the products from the Import Alert. Judicial review of the decision to add a product to the Import Alert is premature because it may be "rendered unnecessary" if the importer succeeds. *CSX Transp., Inc. v. Surface Transp. Bd.*, 774 F.3d 25, 31 (D.C. Cir. 2014); *see also Automatic Sprinkler*, 324 F.3d at 733 ("It conserves both judicial and administrative resources to allow the required agency deliberative process to take place before judicial review is undertaken.").

In MediNatura's view, the FDA's addition of its Products to the Import Alert is the consummation of decisionmaking because the FDA "unambiguously stated" that the Products are unapproved new drugs. Appellant's Br. 30 (quoting *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1138 (D.C. Cir. 2010)). To support its position that the FDA had reached a "final" view of MediNatura's Products' admissibility, MediNatura directs us to FDA press releases, the warning letter and the FDA's withdrawal of CPG 400.400. Granted, a "series of agency pronouncements" can establish final agency action. *Ciba-Geigy*, 801 F.2d at 435 n.7. But the FDA's contemporaneous actions are "insufficient to transform" the Import Alert into final agency action. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 945 (D.C. Cir. 2012). As in *Holistic Candlers*, the FDA "made clear" that it would consider further evidence—pursuant to its own procedures—"before taking any final . . . action." *Id.* at 946; *cf. Automatic Sprinkler*, 324 F.3d at 734 (series of agency actions non-final as "the agency has not yet done that which the statutory scheme requires for its

conduct to constitute final agency action"—namely, reach a final decision after an administrative proceeding).

The fact that the FDA's final decision regarding the admissibility of MediNatura's Products is the same as its interlocutory decision does not retroactively transform the interlocutory decision into a final decision. Its ultimate decision demonstrates only that the FDA was unpersuaded by MediNatura's evidence. The FDA does not dispute that its February 22 decisions finding MediNatura's Products "new drugs" requiring an NDA and subsequent admission refusal *are* final agency actions. Should MediNatura wish to challenge those decisions, MediNatura may seek to raise them in district court on remand.

### B. Withdrawal of CPG 400.400

MediNatura also sought preliminary injunctive relief from the FDA's withdrawal of CPG 400.400 (Withdrawal), claiming that it failed to consider reliance interests or alternatives. The district court denied MediNatura's motion because it failed to meet the preliminary injunction requirements. We agree. To obtain a preliminary injunction a plaintiff "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Abdullah v. Obama*, 753 F.3d 193, 197 (D.C. Cir. 2014) (alteration in original) (internal quotations omitted). We "review the district court's balancing of the preliminary injunction factors for abuse of discretion"

and review any underlying question of law *de novo*. *Id.* at 197–98.

### *1. Likelihood of Success on the Merits*

#### i. Reliance Interests

When an agency changes policy, it must "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Accordingly, an agency must "assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020). If an agency changes its policy despite reliance interests, it must provide a "reasoned explanation" therefor. *Id.* at 1916.

The FDA did not explicitly address reliance interests in its Federal Register notice withdrawing CPG 400.400. *See* Withdrawal of Guidance, 84 Fed. Reg. at 57,439–41. It did, however, address reliance interests in its response to the Citizen Petition, which response issued one day before the Withdrawal. *See* J.A. 1395–96 (Petition Response). Accordingly, to establish that the FDA failed to consider reliance interests, MediNatura must show that (1) the FDA cannot rely on its Petition Response for its discussion of reliance interests or (2) even if the FDA can so rely, the FDA's discussion of reliance interests in the Petition Response is inadequate. The district court was not persuaded that MediNatura could establish either requirement and neither are we.

MediNatura argues that the FDA's reliance on the Petition Response constitutes a forbidden *post hoc* rationalization. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87, 94 (1943) (*Chenery I*);

*see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) (court "may not accept appellate counsel's *post hoc* rationalizations for agency action," agency action must be upheld "on the basis articulated by the agency itself"). Granted, precedent suggests that our review is confined to the specific order that sets out the agency action. *See, e.g.*, *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168–69 (1962) ("*Chenery* requires that an agency's discretionary order be upheld, if at all, on the same basis articulated in the order by the agency itself"); *Williams Gas Processing–Gulf Coast Co. v. FERC*, 373 F.3d 1335, 1345 (D.C. Cir. 2004) ("It is axiomatic that we may uphold agency orders based only on reasoning that is fairly stated by the agency in the order under review."). But other precedent suggests our review is broader. *See, e.g.*, *Michigan v. EPA*, 576 U.S. 743, 758 (2015) ("foundational principle of administrative law that a court may uphold agency action only on the grounds that the agency invoked when it took the action"); *Regents*, 140 S. Ct. at 1909 ("An agency must defend its actions based on the reasons it gave when it acted."); *Council for Urological Interests v. Burwell*, 790 F.3d 212, 222 (D.C. Cir. 2015) ("we look to what the agency said at the time of the rulemaking—not to its lawyers' post-hoc rationalizations").

*Chenery I*'s doctrine "rests on several bases." *Population Inst. v. McPherson*, 797 F.2d 1062, 1072 (D.C. Cir. 1986). Principally, "[w]here Congress or the Executive vouchsafes part of its authority to an administrative agency, it is for the agency and the agency alone to exercise that authority." *Id.* It "is incompatible with the orderly functioning of the process of judicial review" "[f]or the courts to substitute their or counsel's discretion for that of [an agency]." *Burlington Truck Lines*, 371 U.S. at 169. The rule "vindicate[s] the administrative process, for the purpose of the rule is to avoid propel[ling] the court into the domain which Congress has set aside exclusively for the

administrative agency." *Id.* (internal citations and quotations omitted). Accordingly, "review of the propriety of administrative action properly encompasses . . . an examination of the reasoning and rationale actually offered for the particular action being reviewed." *Population Inst.*, 797 F.2d at 1072.

*Chenery I*'s concern, then, is not focused so much on the specific location of the agency's rationale as it is on the agency's articulation of its rationale *at the time* it takes its action so that a court is able to review that rationale. *See Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 469 (D.C. Cir. 1998) ("we may consider only the regulatory rationale actually offered by the agency during the development of the regulation"). Accordingly, we have looked to explanations outside the precise agency action at issue to evaluate whether to sustain that action. *See, e.g.*, *Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 645–46 (D.C. Cir. 2020) (court evaluated both EPA's one-page directive announcing new policy and its supporting memorandum); *Grand Canyon*, 154 F.3d at 469 ("[f]ortunately for the government," National Park Service offered "adequate and reasonable justification" for its action in separate report and final rule "elaborated on that explanation"); *cf. Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 612–13 (D.C. Cir. 2017) (agency did not identify support for its position in its rulemakings or other proceedings).

We do not attempt today to delineate the bounds of the "rationale actually offered by the agency during the development of the [action]." *Grand Canyon*, 154 F.3d at 469. We do conclude, however, that MediNatura has not shown that it is likely to succeed in establishing that the Petition Response is outside those bounds, wherever they lie. The Petition Response can be appropriately categorized as the rationale offered by the FDA during the development of its action. The

Citizen Petition responded specifically to the FDA's ongoing assessment of its homeopathic drug enforcement policies. The Petition Response issued only one day *before* the Withdrawal and explicitly addressed the FDA's imminent withdrawal decision. An October 22, 2019 internal FDA memorandum regarding safety issues associated with homeopathic products noted that it received the Citizen Petition as "part of [the] process" of evaluating its homeopathic drug enforcement policies, the FDA took "into consideration the [C]itizen [P]etition" and it "intend[ed] to respond to the Petition simultaneous with withdrawal of CPG 400.400." J.A. 1347 (FDA Memorandum). And, as discussed *infra*, the FDA's reasons in its Petition Response for concluding that reliance interests were outweighed are elaborated on in its next-day Withdrawal.

In its response to the Citizen Petition, the FDA identified four considerations that "overc[a]m[e]" the alleged reliance interests. J.A. 1395–96 (Petition Response). Granted, CPG 400.400's longevity imposes on the FDA a substantial explanatory burden. *See Encino Motorcars*, 136 S. Ct. at 2126 ("because of decades of industry reliance on the [agency's] prior policy—the [summary discussion of reliance interests] fell short of the agency's duty to explain"). But the FDA did not give a "summary discussion;" its explanation appears "adequate and reasonable" and the FDA also "elaborated on that explanation" in its Withdrawal. *Grand Canyon*, 154 F.3d at 469.

The FDA first noted "the fact that the [FDCA] . . . include[s] premarket review and approval requirements from which homeopathic drug products are not exempt." J.A. 1395–96 (Petition Response). In district court, the FDA had unsuccessfully argued that it was not required to consider reliance interests because CPG 400.400 never exempted

homeopathic drugs from FDCA requirements in the first place and, accordingly, any reliance interest was not reasonably recognized. *MediNatura*, 496 F. Supp. 3d at 455–56. The district court rejected that line of reasoning and the FDA does not raise it on appeal. That CPG 400.400 did not exempt homeopathic drugs from premarket approval processes, however, does dilute the strength of reliance interests based on CPG 400.400. *See Regents*, 140 S. Ct. at 1913 (disclaimer that program "conferred no substantive rights" was "surely pertinent in considering the strength of any reliance interests").

The FDA next noted, "the recent growth of safety concerns associated with homeopathic drug products." J.A. 1396 (Petition Response). It elaborated on safety concerns both in the Petition Response and in the Withdrawal, explaining that, during CPG 400.400's existence, the FDA "encountered multiple situations in which homeopathic drug products posed a significant risk to patients." Withdrawal of Guidance, 84 Fed. Reg. at 57,440; *see also* J.A. 1384 (Petition Response). In 2016, homeopathic drug products were associated with adverse health events based on "belladonna toxicity." Withdrawal of Guidance, 84 Fed. Reg. at 57,440. The adverse health events included "reports of infant deaths and seizures." *Id.* And by 2009, the FDA had "received more than 130 reports of anosmia (loss of the sense of smell)" associated with a certain homeopathic product. *Id.* According to the FDA, those were "two examples among many." *Id.*

The FDA's third rationale overriding reliance interests was "the continued expansion of the homeopathic industry since issuance of the CPG 400.400, resulting in an increasing number of consumer exposures." J.A. 1396 (Petition Response). And in its Withdrawal, the FDA observed that the use of homeopathic products increased by 15 per cent in U.S. adults between 2007 and 2012 and found "the increased population

exposure that it apparently represents, has contributed to FDA's enhanced focus on the safety of homeopathic drugs in recent years and the evaluation of the CPG." Withdrawal of Guidance, 84 Fed. Reg. at 57,440.

The fourth rationale involved "the agency's interest in its general risk-based approach to enforcement." J.A. 1396 (Petition Response). As the FDA elaborated in the Withdrawal, CPG 400.400 "does not accurately reflect the Agency's current thinking" because "[r]isk-based enforcement best reflects FDA's public health priorities." Withdrawal of Guidance, 84 Fed. Reg. at 57,440. The FDA announced its decision to apply "its general approach to prioritizing regulatory and enforcement action, which involves risk-based prioritization in light of all the facts of a given circumstance" before finalizing new guidance. *Id.*

This documentation in both the Petition Response and the Withdrawal manifests that the FDA was "cognizant" of the reliance interests dependent on CPG 400.400 and explained its "good reasons" for concluding that those interests were insufficient to hold off the Withdrawal. *Encino Motorcars*, 136 S. Ct. at 2126 (internal quotations omitted).

ii. Consideration of Alternatives

When taking action, an agency must consider alternatives "within the ambit of the existing standard." *State Farm*, 463 U.S. at 51. An agency is not required to "consider all policy alternatives," *id.*, or "every alternative device and thought conceivable by the mind of man," *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 551 (1978). An agency must consider only "'significant and viable' and 'obvious' alternatives." *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013) (quoting *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 (D.C. Cir. 1987)).

MediNatura argues that the FDA did not adequately consider alternatives to withdrawing CPG 400.400, including (1) creating a specific process for assessing whether homeopathic drugs are GRAS/E or a process for assessing homeopathic NDAs or (2) delaying the Withdrawal to provide the industry time to adapt and/or providing a grace period. We disagree.

MediNatura's first suggestion—creating an NDA or GRAS/E process specifically for homeopathic drugs—appears to be neither "within the ambit of the existing standard," *State Farm*, 463 U.S. at 51, nor an "obvious" or "viable" alternative, *Nat'l Shooting Sports*, 716 F.3d at 215 (quoting *City of Brookings*, 822 F.2d at 1169). The GRAS/E process determines whether a drug is a "new drug" requiring an NDA and the NDA process determines whether a new drug is approved. CPG 400.400 outlined the FDA's enforcement discretion regarding homeopathic drugs. Alternatives related to the FDA's enforcement discretion are of course within "the ambit of" CPG 400.400. But GRAS/E and NDA processes are not part of the FDA's exercise of its enforcement discretion. It is not clear to us that the FDA must consider changing those distinct and separate processes when it changes its enforcement discretion guidelines. Further, the FDA determined that Withdrawal was necessary *at that time* due to immediate public health concerns. Withdrawal of Guidance, 84 Fed. Reg. at 57,440. A time-intensive promulgation of NDA or GRAS/E regulations specifically for homeopathic drugs was not a viable alternative due to the immediate concerns the FDA was facing. And, as the district court noted, MediNatura's arguments are based on the idea that the FDA must leave open an opportunity for legal marketing of homeopathic drugs; nevertheless, "if it is not possible for the industry to comply with the requirements of the [FDCA], that is a problem to take up with Congress." *MediNatura*, 496 F. Supp. 3d at 459.

MediNatura's second suggestion—delaying withdrawal or providing a grace period—we find similarly unavailing. The FDA indicated its interest in reevaluating CPG 400.400 beginning in 2015 and its intention to withdraw CPG 400.400 in 2017. As the district court recognized, manufacturers that wished to protect themselves "could have petitioned for GRAS/E status or filed an NDA in the years between the FDA's initial announcement of its intentions and the eventual withdrawal." *Id.*[7] Further, even under CPG 400.400, the FDA had the authority to enforce FDCA premarket approval requirements against homeopathic drugs. From the FDA's perspective, delaying withdrawal or providing a grace period would make little sense because it could nonetheless take enforcement actions against homeopathic drug manufacturers with CPG 400.400 in place. Moreover, the FDA explicitly addressed why it withdrew CPG 400.400 "at this time" instead of waiting for a finalized guidance—in effect, delaying the Withdrawal. Withdrawal of Guidance, 84 Fed. Reg. at 57,440–41. The FDA sought to replace "outdated policy" that no longer reflected its thinking in light of recent public health concerns. *Id.* at 57,441. In doing so, the FDA reasonably concluded that it was more important to subject homeopathic drug manufacturers to a risk-based regime than to perpetuate a non-risk-based regime.

### *2. Irreparable Harm and Public Interest/Balance of Equities*

Finally, we agree with the district court that MediNatura did not meet the remaining preliminary injunction requirements. MediNatura did not demonstrate that any harm

[7] Because MediNatura submits that the NDA process is prohibitively expensive and impossible for homeopathic drug makers to meet, a grace period or delay would most likely have been of no benefit.

it is suffering is directly traceable to the withdrawal of CPG 400.400. *See Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam) ("movant must show that the alleged harm will directly result from the action which the movant seeks to enjoin"). During CPG 400.400's long existence, the FDA has maintained its discretion to enforce the FDCA against homeopathic drugs if warranted. And the FDA in fact enforced the FDCA's preapproval requirements against certain homeopathic drugs during that time. The FDA identified MediNatura's Products as particularly worrisome because they are injectable products, labeled as containing potentially toxic and harmful ingredients. Therefore, even if the FDA were required to maintain CPG 400.400, the FDA would not be required to admit MediNatura's Products or be prevented from taking similar steps against future shipments of the Products.

If the government is the party sought to be enjoined, the public interest and balance of equities factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, the merged factors weigh against equitable relief. The public has a strong interest in the enforcement of the FDCA to protect public health. Requiring the FDA to keep in place a guidance document that no longer reflects its current enforcement thinking, particularly in light of present public health concerns related to homeopathic drugs, is not in the public interest. Moving towards a risk-based approach to enforcement will enable greater compliance with the FDCA.

For the foregoing reasons, we affirm the district court's judgment. Should MediNatura choose to challenge the FDA's February 22 final action, it may seek to do so in district court subject to that court's discretion.

*So ordered.*