UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MEDINATURA, INC.,

Plaintiff,

v.

FOOD AND DRUG ADMINISTRATION *et al.*,

Defendants.

Civil Action No. 20-2066 (RDM)

MEMORANDUM OPINION AND ORDER

Plaintiff MediNatura, Inc., has filed a motion seeking "injunctive relief pending appeal" pursuant to Federal Rule of Civil Procedure 62(d). Dkt. 43 at 1. This is MediNatura's second motion for an injunction pending appeal and its third motion overall seeking a preliminary or temporary injunction. Like its two predecessors, this third motion for injunctive relief will be **DENIED**.

I. BACKGROUND

As the Court has previously explained, in 2019, the Food and Drug Administration ("FDA") withdrew a policy document that had provided the regulatory framework for marketing homeopathic drugs in the United States for more than thirty years. *See MediNatura, Inc. v. Food & Drug Admin.*, No. 20-cv-2066, 2020 WL 6262121, at *2–7 (D.D.C. Oct. 23, 2020). The document, known as CPG 400.400, "established conditions under which homeopathic drugs could 'ordinarily' be marketed without the FDA's premarket approval [under the Federal Food, Drug, and Cosmetic Act ("FFDCA")], so long as the drugs complied with statutory and regulatory requirements for labeling, manufacturing, and registration." *Id.* at *1. Even before

the withdrawal of CPG 400.400, however, the FDA "retained authority to address unusual risks or concerns." *Id.* at *29. That is, "the Policy's use of the word 'ordinarily' contemplated that its waiver of the FFDCA's premarket approval requirements would not apply if an exceptional circumstance required enforcement." *Id.* at *16.

MediNatura imports and distributes six injectable homeopathic drugs. *Id.* at *7. Following the withdrawal of CPG 400.400, the FDA did not "launch an all-out offensive directed at homeopathic drugs," but rather "continue[d] to focus on the drugs that it believes pose the greatest risk to the public." *Id.* at 29. On June 11, 2020, the FDA sent MediNatura a warning letter asserting that MediNatura's "'injectable products are unapproved new drugs under" the FFDCA and that, as a result, "[i]ntroducing or delivering these products for introduction into interstate commerce violates' the FFDCA." *Id.* at *8 (quoting Dkt. 1 at 210 (Ex. I)). In the letter, the FDA explained that it had singled out these products, in part, because "'injectable drug products can pose risks of serious harm to users' because they 'are delivered directly into the body, sometimes directly into the bloodstream, and therefore, bypass some of the body's key defenses against toxins and microorganisms that can lead to serious and life-threatening conditions.'" *Id.* "The letter warned that failure to correct the identified violations 'may result in legal action without further notice,' including 'refusal of admission into the United States, and such products may be subject to detention without physical examination.'" *Id.* (quoting Dkt. 1 at 213 (Ex. I)). Less than a week after sending the warning letter, the FDA "added [MediNatura's injectable] products to an Import Alert, which offered guidance to FDA field offices on which drugs to consider for detention at the border." Dkt. 42 at 2; *MediNatura*, 2020 WL 6262121, at *9.

MediNatura brought this lawsuit to challenge both the withdrawal of CPG 400.400 and the addition of its injectable products to the Import Alert. Dkt. 1. MediNatura filed a motion for preliminary injunction, Dkt. 5, and the FDA responded with a motion to dismiss, Dkt. 11. On October 23, 2020, the Court resolved those motions is a lengthy opinion. The Court first dismissed MediNatura's claims related to the Import Alert on the ground that the Alert did not constitute final agency action. *See MediNatura*, 2020 WL 6262121, at *23–24. The remaining claim, which challenges the rescission of CPG 400.400, survived the FDA's motion to dismiss. *Id.* at *11–23. But the Court nevertheless denied MediNatura's motion for preliminary injunction as to that claim, holding that none of the four preliminary injunction factors favored granting the requested relief. *Id.* at *25–31.

The Court concluded that MediNatura was unlikely to succeed on the merits of its challenge to the withdrawal of CPG 400.400 because the FDA had reasonably considered the industry's reliance interests and had reasonably rejected the industry's alternative policy proposals. *Id.* at 25–29. Next, the Court held that MediNatura had not shown that it was likely to suffer irreparable harm in the absence of an injunction, for two reasons. First, at that stage, the company had "reported only that one shipment of one of its products, Engystol, was detained, while another shipment of that same product was permitted to proceed into the country." *Id.* at 30. Having a single shipment held at the border was not "the sort of systematic detention and denial of admission" that would pose an existential threat to MediNatura's business. *Id.* Second, the Court concluded that MediNatura's theory of harm had a causation problem. *Id.* at 31. "[E]ven assuming that MediNatura would suffer irreparable harm from the detention of its products, the Court [was] unconvinced that MediNatura ha[d] demonstrated that such harm would be directly traceable to the withdrawal of CPG 400.400," as opposed to the agency's

"arguably independent decisions" to prioritize injectable products for enforcement action. *Id.* Finally, the Court held that the balance of equities and public interest favored the FDA, because "[t]he public has a strong interest in the FDA's enforcement of the FFDCA, which protects public health and safety." *Id.* The Court thus denied MediNatura's motion for preliminary injunction.

MediNatura appealed. Dkt. 29. While that appeal has been pending, MediNatura has filed several additional motions, and both sides have attempted to supplement the record with information about various developments since the Court's initial decision. MediNatura first moved for entry of partial final judgment under Rule 54(b) on its Import Alert claims, which would have permitted the company to appeal the dismissal of those claims along with the denial of the preliminary injunction motion. Dkt. 31. The Court denied that motion. Dkt. 35.

On February 12, 2021, MediNatura filed its first motion for an injunction pending appeal, in that instance invoking Federal Rule of Civil Procedure 65, which governs preliminary injunctions. Dkt. 39 at 1. In its motion, MediNatura argued that a temporary injunction pending the resolution of its appeal was necessary based on additional enforcement actions that the FDA had taken against the company's imports. As noted above, at the time of the Court's October 23, 2020 opinion, MediNatura had attempted to import only two shipments of its products since the issuance of the Import Alert, one of which was allowed to proceed while the other was detained. *MediNatura*, 2020 WL 6262121, at *9. After the Court's decision, MediNatura attempted to import an additional eight shipments, and all eight were detained. Dkt. 39-1 at 8. MediNatura argued that these "recent developments" were significant to every aspect of the four-factor injunction analysis. *Id.* at 10–17. First, MediNatura maintained that the inability to import its products had caused the company irreparable injury, because it had run out of inventory and was

about to furlough 22 staff members from its prescription injectables business. *Id.* at 4, 14–15. Second, MediNatura argued that the "consistent pattern of denials of MediNatura's shipments" demonstrated that the Import Alert was legally binding and therefore constituted final agency action, increasing MediNatura's likelihood of success on the merits. *Id.* at 11. Finally, the company asserted that the public interest favored an injunction because "[m]edical providers who have been unable to obtain MediNatura's homeopathic injectable drugs for their patients have been forced to choose between leaving their patients without pain relief options or prescribing riskier treatments like corticosteroids or opioids." *Id.* at 15. In its opposition, the FDA revealed additional factual developments—most notably, that on February 21 or 22, 2021,[1] FDA field offices issued final orders refusing admission to all nine of MediNatura's detained shipments. Dkt. 40 at 6.

The Court denied MediNatura's motion for an injunction pending appeal under Rule 65. Dkt. 42. The Court explained that MediNatura's motion for an injunction pending appeal was subject to the same four-factor test as its prior motion for preliminary injunction. That is, to obtain an injunction, MediNatura "must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 20 (2008).

To begin, the Court recognized that "MediNatura's new arguments with respect to irreparable harm [were] substantial." Dkt. 42 at 3. In light of the FDA's final refusal of admission with regard to nine of MediNatura's shipments, the company had run out of supplies

[1] The parties continue to dispute which day the orders issued, and both dates appear on the face of the orders.

and was on the verge of laying off the employees of its prescription-drug division. *Id.* at 4. In its motion, MediNatura had asserted that, "[a]bsent immediate intervention, MediNatura's prescription homeopathic drug business *will not survive* long enough for the D.C. Circuit to hear argument in its pending appeal." Dkt. 39-1 at 4 (emphasis added). As such, the Court concluded that the company had made "a much stronger case for irreparable harm than in its prior motion." Dkt. 42 at 4.

The other three injunction factors, however, still favored the FDA. The Court observed that "MediNatura's argument regarding its likelihood of success on the merits of its challenge to the Import Alert . . . [was]—simply put—bewildering." *Id.* Relying at least in part on intervening developments, MediNatura argued that it was likely to succeed on the merits of its Import Alert claims, but it had not moved for reconsideration under Rule 54(b) of the Court's dismissal of those claims. Indeed, MediNatura disclaimed any desire for the Court to revisit its earlier dismissal decision. Dkt. 41 at 11. The Court concluded: "MediNatura cannot establish a likelihood of success on the merits of these counts, at least not before this Court, unless it first asks the Court to reconsider its dismissal of those claims." Dkt. 42 at 5. Likewise, MediNatura could not show a likelihood of success on the merits of its appeal based on recent developments, because the D.C. Circuit's consideration of the case would be based on the record as it existed at the time of the Court's earlier decision. *Id.* at 6. The Court observed that, "[o]n appeal, [MediNatura] will not be able to argue that the Court's decision was incorrect because of events that occurred after that decision, so these late-breaking developments are irrelevant to MediNatura's chances of success on appeal." *Id.* Finally, the Court explained that, in any event, the FDA's issuance of final orders refusing admission to MediNatura's products undermined the company's argument that the interlocutory Import Alert had been final agency action. *Id.* at 7–8.

As for the two remaining preliminary injunction factors, "[t]he company ha[d] also failed to offer any good reason to revisit the Court's prior conclusion that neither the public interest nor the balance of equities supports enjoining the FDA from enforcing the requirements of the [FFDCA] against drugs that it has not determined are safe and effective for their intended uses." *Id.* at 9 (citing *MediNatura*, 2020 WL 6262121, at *31). The Court therefore denied the motion for injunctive relief pending appeal. *Id.*

MediNatura has now moved for another "temporary injunction pending appeal," this time invoking Rule 62(d). Dkt. 43. The FDA opposes the motion. Dkt. 44. The Court held argument on the motion on March 12, 2021, Minute Entry (Mar. 12, 2021), and MediNatura filed a notice of supplemental authority on March 14, 2021, Dkt. 45. The motion is now ripe for decision.

II. ANALYSIS

As an initial matter, MediNatura appears to have resolved some of the procedural shortcomings in its prior motion by invoking the correct Federal Rule of Civil Procedure. Rule 62 governs injunctions pending appeal, whereas Rule 65 deals with preliminary injunctions. Regardless which rule applies, however, MediNatura acknowledges that the Court still must apply the same four-factor test applicable to all injunction motions—although there is some debate about whether the standard for demonstrating a likelihood of success on the merits is lower for an injunction pending appeal, as discussed below. Dkt 43 at 1. This means that MediNatura "must establish [1] that [it] is likely to succeed on the merits, [2] that [it] is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in [its] favor, and [4] that an injunction is in the public interest." *Winter*, 555 U.S. at 20.

Taking the factors out of order, MediNatura has still made a substantial showing of irreparable injury, albeit a somewhat weaker showing than in its second motion. The company's counsel indicated at oral argument that MediNatura has either laid off or furloughed all 22 sales staff from its prescription-drug division. Mar. 12, 2021 Hrg. Tr. (Rough at 2). Now that those cuts have been made, however, it is less clear what additional irreparable harm is likely in the future. Counsel for MediNatura explained at oral argument that, even with its prescription division already shuttered, the company remains responsible for certain overhead costs, including those associated with importing and distributing its injectable products. *Id.* (Rough at 6–8). But counsel struggled to quantify these costs: he could not say with certainty whether the costs were fixed or variable or whether they were associated with warehouse space or some other aspect of the supply and distribution chain. *Id.* In addition, counsel backtracked from MediNatura's statement in its earlier motion that its prescription drug division would "not survive long enough for the D.C. Circuit to hear argument in its pending appeal." Dkt. 39-1 at 4. Instead, counsel said that his "best estimate" was that the possible lifespan of the company's prescription division in the absence of an injunction could be "measur[ed] in terms of weeks, perhaps in single digits of months," although the business's future was uncertain. Mar. 12, 2021 Hrg. Tr. (Rough at 4). MediNatura, of course, bears the "considerable burden of proving that [its] losses are certain, great[,] and actual." *MediNatura*, 2020 WL 6262121, at *30 (quoting *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 52 (D.D.C. 2011)). But despite at least some uncertainty about the company's ongoing costs, the Court agrees that the combination of lost revenue, continued obligations for overhead costs (whatever those costs may be), and lost goodwill (based on the company's inability to supply its customers) constitute irreparable injury. It is far less clear, however, that MediNatura will suffer additional irreparable harm in the eight

days between now and March 24, 2021, when the D.C. Circuit will hear oral argument and will be best situated to assess MediNatura's likelihood of success on appeal.

The Court again concludes that the balance of equities and public interest weigh in favor of the FDA. MediNatura argues that "as supplies of MediNatura's homeopathic injectable products have run out, doctors and patients have increasingly been forced to turn to less desirable and risk[i]er alternatives like steroids or opioids, or forego treatment for chronic pain." Dkt. 43 at 5. In support, the company refers to "21 letters from doctors and other medical providers illustrating that MediNatura's pain-relief injections are typically used for patients for whom conventional FDA-approved drugs are dangerous." *Id.* But if the Court is asked to balance the opinion of 21 medical providers against the congressional command that the FDA prevent the importation into the United States of drugs that the agency has not deemed safe and effective, the choice is clear. As the Court has already explained, "[t]he public has a strong interest in the FDA's enforcement of the FFDCA, which protects public health and safety." *MediNatura*, 2020 WL 6262121, at *31. The FDA, as an agency tasked with preserving public health, is owed substantial deference in its decisions about which unapproved drugs to target for enforcement, even where those enforcement actions represent a break with past practice.

That leaves the first factor: likelihood of success on the merits. Whereas MediNatura premised its prior motion for injunctive relief pending appeal primarily on its Import Alert claims, the company changes course in its current motion and instead argues that it is likely to succeed on the merits of its challenge to the withdrawal of CPG 400.400. Dkt. 43 at 3–4. The Court has already concluded, however, that MediNatura is not likely to succeed on the merits of this claim. *See MediNatura*, 2020 WL 6262121, at *25–29. And, unlike the recent developments that at least arguably bear on the Import Alert claims, nothing has changed about

the withdrawal of CPG 400.400 since the time of the Court's original decision. MediNatura is thus no more likely to succeed on the merits of that claim now than it was when the Court decided it was unlikely to succeed several months ago.[2]

MediNatura does not dispute that the merits of its challenge to the withdrawal of CPG 400.400 are the same today as they were at the time of the Court's earlier opinion. Rather, the company contends that a lower standard applies to a court's consideration of the likelihood of success on the merits for an injunction pending appeal under Rule 62(d). According to MediNatura, "[w]hile courts in this circuit analyze a motion for injunction pending appeal under the same four-factor test as a preliminary injunction motion, they 'often recast the likelihood of success factor as requiring only that the movant demonstrate a serious legal question on appeal where the balance of harms strongly favors a stay.'" Dkt. 43 at 3 (quoting *Dunlap v. Presidential Advisory Comm'n on Election Integrity*, 319 F. Supp. 3d 70, 83 n.5 (D.D.C. 2018)); *see also Al-Anazi v. Bush*, 370 F. Supp. 2d 188, 193 & n.5 (D.D.C. 2005).

MediNatura is partially correct. When pressed at oral argument, counsel for the company could not identify any cases in which a court that initially denied a motion for preliminary injunction nevertheless later granted an injunction pending appeal using a lower standard. Mar. 12, 2021 Hrg. Tr. (Rough at 34–35). After oral argument, however, MediNatura filed a notice of supplemental authority drawing the Court's attention to two such cases. Dkt. 45. In the first case, environmental groups challenged the Forest Service's plan for logging in the

[2] As for the Import Alert claims, the Court remains convinced that MediNatura cannot show a likelihood of success on those claims without—at the very least—first seeking reconsideration of the Court's decision to dismiss them. *See* Dkt. 42 at 5–6. Even on reconsideration, moreover, MediNatura would need not only to demonstrate that the Import Alert constituted final agency action but also to show a likelihood on the merits that the Import Alert was substantively or procedurally invalid. It is far from clear that MediNatura could make any of these showings.

Beaverhead-Deerlodge National Forest to reduce fire risk. *Native Ecosystems Council v. Kimbell*, No. 05-cv-110-M, 2005 WL 8167434, at *1 (D. Mont. Nov. 21, 2005). Although the court had denied the plaintiffs' motion for preliminary injunction, it granted an injunction pending appeal. The court reasoned that "if [it did] not grant an injunction pending the resolution of [p]laintiffs' appeal, and logging continue[d], there [was] a chance that a substantial portion of the Project [would] already have been completed by the time the Ninth Circuit consider[ed] the merits of [p]laintiffs' claims." *Id.* Although the district court had found that the plaintiffs were unlikely to succeed on the merits, "there [was] a possibility that the Ninth Circuit [would] disagree," and "[i]f logging ha[d] been completed or substantially completed by that time," the courts "[would] no longer [have been] able to grant appropriate relief." *Id.* An injunction pending appeal was thus "a prudent measure to preserve [p]laintiffs' right to challenge the Project's effects on the environment." *Id.* at 2.

In the other case, trade groups challenged on First Amendment grounds a San Francisco ordinance requiring warning labels on sugar-sweetened beverages. *Am. Beverage Ass'n v. City & Cty. of San Francisco*, No. 15-cv-3415, 2016 WL 9184999, at *1 (N.D. Cal. June 7, 2016). The court initially denied the plaintiffs' motion for a preliminary injunction, but granted an injunction pending appeal based on the "particular circumstances" of the case. *Id.* at *2. The court granted the injunction pending appeal because plaintiffs had raised "a plausible argument that there are serious questions on the merits and irreparable injury" and because there was "a good chance that the injunction pending interlocutory appeal will be relatively brief because the appeal will likely be resolved on an expedited basis." *Id.*

The Court agrees with these decisions that the standard for granting an injunction pending appeal is, at least at times, more flexible than a rigid application of the traditional four-

part standard applicable to granting a preliminary injunction, under the plain language of Rule 62(d). The rule provides, in relevant part, that "[w]hile an appeal is pending from an interlocutory order . . . that . . . refuses . . . an injunction, the court may . . . grant an injunction." Fed. R. Civ. P. 62(d). As such, "the express language of Rule 62([d]) . . . contemplates the possibility that the district court may grant an injunction pending appeal from an interlocutory order denying preliminary injunction." *Am. Beverage Ass'n*, 2016 WL 9184999, at *2. In at least some circumstances, then, "an injunction pending appeal may be appropriate, even if the Court believed its analysis in denying preliminary injunctive relief is correct." *Id.*

Nothing in the logic of these two cases or the text of the rule, however, dictates that the Court must adopt the "serious legal question" test that MediNatura proposes—much less that the Court should do so categorically for all Rule 62(d) motions. Notably, the cases in this district from which MediNatura draws that test all dealt with motions seeking a stay of a district court's order pending appeal, not motions seeking affirmative injunctions against defendants. *See Dunlap*, 319 F. Supp. 3d at 106–10. An affirmative injunction against a defendant, even on a temporary basis pending appeal, is an extraordinary remedy, which disrupts the legal status quo in a way that a stay pending appeal does not. In considering a motion for an affirmative injunction pending appeal under Rule 62, therefore, courts generally require "a strong showing that [the movant] is likely to succeed on the merits." Wright *et al.*, 11 Fed. Prac. & Proc. Civ. § 2904 (3d ed.). In cases where the risk of irreparable harm is especially great, an injunction pending appeal may be "warranted even though it does not appear that there is a strong likelihood that the party will succeed on the merits," but, "because the burden of meeting the standard is a heavy one, more commonly" a request for an injunction pending appeal in such circumstances "will be denied." *Id.* Indeed, setting the bar for obtaining an injunction pending

appeal too low would undermine the demanding standard for a preliminary injunction, permitting movants to skirt that standard simply by appealing any denial.

Instead, the cases that MediNatura cites are better understood to stand for the proposition that, in rare cases, the threat of irreparable harm may be so grave and the balance of equities may favor a plaintiff so decisively that an injunction pending appeal of a difficult or novel legal question may be proper. Decisions in this district, accordingly, have relied on the "serious legal question" standard for likelihood of success on the merits "only when the other three factors tip sharply in the movant's favor." *In re Special Proceedings*, 840 F. Supp. 2d 370, 372 (D.D.C. 2012). An injunction pending appeal may be especially appropriate where, in the absence of such an injunction, the subject matter of the dispute will be destroyed or otherwise altered in a way that moots the pending appeal. Once a tree has been felled and sent to the sawmill, another tree may be planted in its place, but the original 100-year-old pine is gone forever. On the other side of the ledger, a short delay in clearing the trees does little prejudice to the government. Likewise, in a compelled speech case, the disputed words, once uttered, cannot be put back in the speaker's mouth. Because speech is irreversible, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 299 (D.C. Cir. 2006) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976) (plurality)). Where these sorts of harms are at issue, and where the balance of the equities and the public interest strongly favor granting relief, an injunction pending appeal may be necessary to preserve the ability of the court of appeals to consider the case before it becomes moot, even where the plaintiff's chances on the merits are uncertain.

As the FDA points out, this analysis is conceptually akin to the sliding scale that the D.C. Circuit traditionally applied in considering preliminary injunction motions. As the FDA also

points out, that sliding scale approach may not have survived the Supreme Court's decision in *Winter*. Dkt. 44 at 4. The sliding scale permitted "a strong showing on one factor [to] make up for a weaker showing on another." *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011). Since *Winter*, the D.C. Circuit has hinted on several occasions that "a likelihood of success is an independent, free-standing requirement for a preliminary injunction." *Id.* at 393 (quoting *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009) (Kavanaugh, J., concurring)); *see also Archdiocese of Wash. v. Wash. Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018) (observing that *Winter* may be "properly read to suggest a 'sliding scale' approach to weighing the four factors be abandoned"). But, to date, the court of appeals has declined to decide the issue. *See, e.g.*, *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 7 (D.C. Cir. 2016); *Sherley*, 644 F.3d at 393.

Given the language of Rule 62(d) and the interest in preserving the jurisdiction of the courts of appeals to consider at least certain cases on the verge of mootness, the Court is persuaded that, notwithstanding *Winter*, there may be rare cases in which a court should issue an affirmative injunction pending appeal, even if the movant's likelihood of success on the merits is uncertain. But this is not such a case.

First, although MediNatura has satisfied the irreparable injury prong of the analysis, the risk of irreparable injury is not so extraordinary as to outweigh the other three factors. Even if the company's refused shipments were destroyed, more products can be ordered in the future. The economic harm to MediNatura, though dire, is not on the same level as the harms at issue in the cases on which it relies, where action by the defendant threatened immediately to moot the case. At this point, the question is how long MediNatura can carry its prescription drug business without any product to sell—and counsel has acknowledged that the company will likely be able

to do so for weeks or "single digits of months." Mar. 12, 2021 Hrg. Tr. (Rough at 4). Significantly, this will give the D.C. Circuit the opportunity to hear oral argument and to consider the parties' respective positions. To be sure, the court of appeals may not be able to issue its opinion within this time. But MediNatura can seek an injunction pending appeal from the D.C. Circuit, *see* Fed. R. App. P. 8(a)(2), and, after hearing oral argument, the D.C. Circuit will be far better equipped than this Court to decide whether MediNatura is likely to prevail on the merits of its appeal. The principal reason for a district court to grant an injunction pending appeal based on a showing of less than a likelihood of success is to avoid the risk that the case will become moot before the court of appeals has a chance to disagree. When, as here, the D.C. Circuit will have the opportunity to reach its own conclusion about the likelihood of success on the merits based on a fully developed appellate record, there is little reason for the district court to apply a less demanding standard.

Second, as explained above, the balance of equities and public interest favor the FDA, such that MediNatura cannot show that "three factors tip sharply in the movant's favor," as required before a court can even arguably relax the likelihood of success on the merits standard. *In re Special Proceedings*, 840 F. Supp. 2d at 372. As the Supreme Court emphasized in *Winter*, "[i]n exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24 (internal quotation marks and citation omitted). Although MediNatura frames the relief it seeks as "narrow" and "temporary," Dkt. 43 at 6, its request is in fact rather remarkable. The company asks the Court to order the FDA to release into the United States drugs about which the agency has safety concerns and that have not received premarket approval, as required by the FFDCA. Once those shipments come in, the drugs would then be distributed to doctors and

injected into patients across the country over the course of weeks or months. According to the FDA, it "has repeatedly explained its safety concerns about MediNatura's injectable products," including one product "promoted to improve the severity and duration of symptoms in viral infections . . . in the midst of a viral pandemic." Dkt. 44 at 7 (internal quotation marks and citation omitted). The public interest strongly disfavors second-guessing the FDA's expert judgments about how to enforce the FFDCA against admittedly unapproved drugs and how best to protect the public health, especially where that second-guessing would come on an incomplete record in the context of an emergency motion.

Third and finally, the claim that MediNatura presses on the merits is disconnected from its theory of harm in a way that undermines its claim for injunctive relief. MediNatura argues it has raised a serious question on appeal "regarding the sufficiency of the Government's consideration of stakeholders' reliance interests when withdrawing CPG 400.400." Dkt. 43 at 3. But the company does not seek to enjoin the withdrawal of CPG 400.400 pending appeal. Instead, it asks the Court for an order that "enjoins [the] FDA from enforcing Import Alert 66-41 to detain MediNatura's homeopathic injectable products at domestic ports of entry." Dkt. 43-1 at 1.

At oral argument, MediNatura's counsel attempted to draw the necessary causal connection by arguing that "the relief that [MediNatura is] seeking flows directly from the withdrawal of CPG 400.400 . . . [b]ecause the import alert could not exist in its current form and be enforced the way it has been by the FDA since August 2020 if CPG 400.400 still were in effect." Mar. 12, 2021 Hrg. Tr. (Rough at 26). But that is not quite right. Even "[b]efore the FDA withdrew the policy, homeopathic drug manufacturers could '*ordinarily*' market their drugs without premarket approval—but the agency retained authority to address unusual risks or

concerns." *MediNatura*, 2020 WL 6262121, at *29 (emphasis added). "In the FDA's warning letter to MediNatura, the FDA explained that it had singled out the company's 'especially concerning' products for enforcement, stressing that 'injectable drug products can pose risks of serious harm to users' because they 'are delivered directly into the body, sometimes directly into the bloodstream, and therefore, bypass some of the body's key defenses against toxins and microorganisms that can lead to serious and life-threatening conditions.'" *Id.* at *31 (quoting Dkt. 1 at 210 (Ex. I)). For this reason, in denying MediNatura's original motion for preliminary injunction, the Court could not "conclude that MediNatura ha[d] shown a likelihood that the company will suffer an irreparable injury in the near-term due to the FDA's withdrawal of CPG 400.400—as opposed to the agency's arguably independent decisions to issue the warning letter and Import Alert." *Id.* That reasoning holds true today, and, thus, even if the Court were to conclude that MediNatura is likely to succeed on its challenge to the withdrawal of CPG 400.400 (which the Court is not inclined to do), that would still not provide a basis for enjoining the Import Alert or preventing the FDA from refusing admission to MediNatura's shipments pursuant to the recent final orders.

In sum, although it may be appropriate in rare circumstances to relax the requirement of showing a likelihood of success on the merits in assessing a motion for injunction pending appeal, the Court concludes that, in this case, MediNatura has not carried its burden of demonstrating an entitlement to injunctive relief pending appeal. The company is, of course, free to ask the D.C. Circuit for an injunction pending appeal pursuant to Fed. R. App. P. 8(a)(2).

CONCLUSION

For the foregoing reasons, it is hereby **ORDERED** that MediNatura's second motion for an injunction pending appeal, Dkt. 43, is **DENIED**.

SO ORDERED.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: March 16, 2021