UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HILL DERMACEUTICALS, INC.	)	
	)	
Plaintiff	)	
	)	**Civil Action No. 07-552 (RCL)**
v.	)	
	)	
U.S. FOOD & DRUG ADMINISTRATION, *et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

Now before the court comes plaintiff, Hill Dermaceuticals, Inc's ("HDI's") motion [4] for a stay to prevent the approval of any generic versions of HDI's Derma-Smoothe/FS® (flucinolone acetonide) Scalp Oil or Body Oil ("Derma-Smoothe") until the Food and Drug Administration ("FDA") provides a substantive response to HDI's citizen petition. Upon full consideration of the motion, defendants' opposition, the reply, the entire record herein, and applicable law, this Court finds that plaintiff's motion will be DENIED.

I. BACKGROUND

Plaintiff HDI manufactures and distributes the drug Derma-Smoothe. On September 30, 2004, HDI submitted a citizen petition[1] to the FDA requesting that it require any potential manufacturer of a generic version of Derma-Smoothe to follow specific clinical procedures in

[1] Citizen petitions may be filed with the FDA by those with rights to or scientific knowledge of a brand name drug. These petitions request that the FDA take or refrain from certain administrative action. *See* 21 C.F.R. §§ 10.25(a), 10.30(e).

proving the generic version's bioequivalence[2] to Derma-Smoothe. Particularly, HDI requested that the FDA require any generic manufacturer to, in its Abbreviated New Drug Application ("ANDA"),[3] demonstrate bioequivalence only through studies using clinical endpoints rather than through the more typically required studies that employ skin blanching equivalence tests. (*See* Mot. to Stay at 9.)

On March 24, 2005, the FDA responded to HDI's citizen petition by letter stating: "FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 C.F.R. § 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources." (Ltr. to Roth, Ex. C to Compl.) (hereinafter "Tentative Response") HDI asserts that the FDA's Tentative Response is inadequate according to the text of 21 C.F.R. § 10.30(e). Citing this inadequacy, HDI states that the FDA violated the Administrative Procedure Act ("APA") and has endangered public safety. (*See* Mot. to Stay at 1–2.) HDI thus requests that this Court issue a stay preventing FDA approval of any generic

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[2] Bioequivalence means that the "rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of the absorption of the listed [innovator] drug . . . ." 21 U.S.C. § 355(j)(8)(B).

[3] Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers of a generic drug may seek FDA approval through an abbreviated process, the ANDA, rather than by filing a new drug application—an "NDA"—that must contain more extensive scientific data demonstrating the safety and effectiveness of "innovator" drugs. *See* 21 U.S.C. § 355(j). ANDA applicants can rely on the FDA's previous findings of safety and effectiveness of the corresponding innovator drug's NDA and must only provide the more limited information set out by the relevant FDCA provisions and accompanying regulations. *See* 21 U.S.C. § 355(j)(2)(A), (j)(4); 21 C.F.R. §§ 314.127(a), 314.94(a). Most relevant to the current case is the requirement that an ANDA include information demonstrating that the generic drug is the "bioequivalent" of the referenced innovator drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. §§ 314.127(a)(6)(i); 314.94(a)(7). ANDAs that fail to satisfy these requirements do not receive FDA approval.

version of Derma-Smoothe until it receives a "substantive" response to its citizen petition. (*See Id.* at 1.) Defendants claim that they have complied with all applicable statutes and regulations and that a stay is consequently improper. (*See* Def.'s Opp. at 10–11.)

II. ANALYSIS

A. APPLICABLE LAW

1. Legal Standard for Stay

The four-factor standard used by courts for a motion to stay agency action is the same legal standard as that used in a motion for preliminary injunction. *Compare Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (applying four-factor standard in a preliminary injunction case), *with Cuomo v. U.S. Nuclear Regulatory Comm'n*, 772 F.2d 972, 974 (D.C. Cir. 1985) (per curiam) (applying same standard in a motion to stay).

> The factors to be considered in determining whether a stay is warranted are: (1) the likelihood that the party seeking the stay will prevail on the merits of the appeal; (2) the likelihood that the moving party will be irreparably harmed absent a stay; (3) the prospect that others will be harmed if the court grants the stay; and (4) the public interest in granting the stay.

Cuomo, 772 F.2d at 974 (citing *WMATC v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977); *see Va. Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958) (explaining the four factors). No one factor is determinative and the Court should balance a movant's showings regarding the four factors on a sliding scale. *See Shalala*, 140 F.3d at 1066; *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995) ("If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak."). Granting a motion to stay—like granting injunctive

relief—is an "extraordinary remedy" and it is the movant's obligation to justify the court's use of such a measure. *Cuomo*, 772 F.2d at 978; *see Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (stating that a "preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion").

2. Legal Standard for Review of FDA Actions

"The APA entitles 'a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action . . . to judicial review thereof.'" *Biovail Corp. v. U.S. Food and Drug Admin.*, 448 F. Supp. 2d 154, 160 (D.D.C. 2006) (quoting 5 U.S.C. § 702). Specifically, the APA requires that agencies decide matters "within a reasonable time." 5 U.S.C. § 555(b). And, courts are required to "compel agency action that is unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1); *see Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 63 (2004) (noting that under the APA, courts can only compel agencies to take actions that they are "legally *required* to take"); *Pub. Citizen Health Research Group v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 32 (D.C. Cir. 1984) (stating that "[a]t some point administrative delay amounts to refusal to act, with sufficient finality and ripeness to permit judicial review").

3. Regulatory Framework – FDA Action on Citizen Petitions

FDA regulations govern the procedure for submitting citizen petitions by interested persons such as HDI. *See* 21 C.F.R. § 10.30. Once citizen petitions are submitted, the FDA Commissioner is required to respond in one of three manners "within 180 days of receipt of the petition." 21 C.F.R. § 10.30(e)(2). The statute specifies that:

> The response will either:
>
> (i) Approve the petition, in which case the Commissioner

> shall concurrently take appropriate action . . .
>
> (ii) Deny the petition; or
>
> (iii) Provide a tentative response, indicating why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information. The tentative response may also indicate the likely ultimate agency response, and may specify when a final response may be furnished.

Id. at § 10.30(e)(2)(i)–(iii). In ruling upon citizen petitions, the FDA takes into account: "(i) available agency resources for the category subject mater, (ii) the priority assigned to the petition considering both the category of subject matter involved and the overall work of the agency, and (iii) time requirements established by statute." 21 C.F.R. § 10.30(e)(1).

B. APPLICATION OF LEGAL STANDARD

As discussed below, upon application of the four-factor standard applicable to motions to stay, the Court finds that HDI has failed to demonstrate facts that justify the extraordinary relief requested in its motion to stay.

1. Likelihood of Success on the Merits

The Court finds that HDI has not demonstrated a likelihood of success on the merits. HDI's motion argues at length that it is manifestly unreasonable for the FDA to have delayed rendering a decision for the greater than three years that have elapsed from the filing of HDI's citizen petition in September 2004 to today. (*See* Mot. to Stay at 7.) In assessing that claim, this Court will first address the sufficiency of the FDA's Tentative Response for the purposes of § 10.30(e)(2)(iii) and will then analyze the alleged unreasonableness of the FDA's failure to offer a substantive response to HDI's petition.

i. Sufficiency of Tentative Response

The current case differs from the scenario where the FDA simply neglects to provide any response to a citizen petition. *Compare Sandoz, Inc. v. Leavitt*, 427 F. Supp. 2d 29, 34–38 (D.D.C. 2006) (holding that a delay was unreasonable where the FDA failed to make *any* response to a new drug application after almost 1,000 days had elapsed and where the FDA essentially argued that the applicable 180-day regulatory deadline was merely "aspirational") *with Biovail Corp. v. U.S. Food and Drug Admin.*, 448 F. Supp. 2d 154, 160 (D.D.C. 2006) (determining the sufficiency of a tentative response to a citizen petition where the response in question was issued within the applicable 180-day window). Here, the FDA issued a Tentative Response stating that "FDA has been unable to reach a decision on your petition because of the need to address other Agency priorities." HDI argues that the response is insufficient because it offers "effectively no response" at a time when the FDA was obligated to offer a response "sufficient to conclude that the agency's action was the product of reasoned decision making." (Reply at 3.) *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983) (holding that a reasoned analysis for recision of an agency's rule was required). The reasoned decision-making requirement was developed by the Supreme Court in a case where the National Highway Traffic Safety Administration rescinded a rule that had required passive safety restraints in vehicles without offering a sufficient explanation for doing so. *See id.* (finding that the agency was required to offer "a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance"). That case also involved a situation where Congress had required a record of rulemaking proceedings to be submitted to a reviewing court and intended that agency findings would be supported by "substantial evidence on the record." *See id.* at 43–44. A tentative response submitted in reply to a citizen petition is not an

analogous situation because: (1) the FDA has not enacted or rescinded any rule, but has rather simply written a letter indicating that it has not reached a decision and offering an explanation, however brief, of why that is so; and, (2) this Court is aware of no Congressional instruction that the FDA's rationale for issuing a tentative response to a citizen petition must be supported by a specific level of evidence. Consequently, the Court looks to the plain text of the regulation for guidance regarding how to assess the sufficiency of the FDA's Tentative Response. *See Biovail*, 448 F. Supp. 2d at 161 (citing *In re England*, 375 F.3d 1169, 1177 (D.C. Cir. 2004)) (stating that where the text of regulations are clear, courts should enforce them according to their terms). Here, the applicable regulation states that a tentative response "indicat[es] why the agency has been unable to reach a decision on the petition, e.g., because of the existence of other agency priorities, or a need for additional information." 21 C.F.R. § 10.30(e)(2)(iii). The regulation offers no other requirements of what must be included in a tentative response.

In the current case, the FDA offered the precise explanation that appears as an example in the regulation—the existence of other agency priorities. Thus, based on a clear reading of the regulation's text, the FDA's Tentative Response complies. The regulation "does not indicate that the FDA's reasoning must be of a certain degree of detail" and this Court declines to impose such a requirement when none is present on the face of § 10.30(e)(2)(iii). *Biovail*, 448 F. Supp. 2d at 162. Additionally, this Court defers to the FDA's interpretation of its own "regulation unless it is 'plainly erroneous or inconsistent with the regulation.'" *Id.* (quoting *Mistick PBT v. Chao*, 440 F.3d 503, 513 (D.C. Cir. 2006)).

For the above reasons, the substance of the FDA's Tentative Response is sufficient for the purposes of § 10.30(e)(2)(iii) and meets the 180-day deadline. Consequently, HDI is unlikely to succeed on the merits of a claim based on the FDA's failure to provide a response

within the mandatory 180-day window.

ii. Providing Substantive Response Within a Reasonable Time

Although the FDA complied with the § 10.30(e)(2)(iii) 180-day requirement by issuing its Tentative Response, the agency has offered no further response to HDI in the over two-and-a-half years that have followed. This Court is concerned by such a delay and believes that upon completion of plaintiff's discovery, evidence could show that granting relief in favor of HDI is justified. *See* 5 U.S.C. § 555(b) (requiring that agencies act in a reasonable time); *Pub. Citizen Health Group v. Comm'r, Food & Drug Admin.*, 740 F.2d 21, 32 (D.C. Cir. 1984) (stating that administrative delay can amount to refusal to act, thus permitting judicial review). Such discovery may provide insight into how the FDA prioritizes its responses to citizen petitions. For example, HDI could offer evidence demonstrating which citizen petitions receive first preference and how the FDA makes decisions regarding how to allocate its limited resources. At this time, the Court cannot say that HDI is likely to succeed on the merits of a claim based on the reasonableness of the FDA's failure to provide a substantive response. However, at the time of the case's ultimate disposition, the Court may find that the delay here is sufficient to compel FDA action.

2. Irreparable Harm

Irreparable harm is a high standard wherein the alleged injury must be "certain and great" and "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam). Additionally, because HDI failed to show a substantial likelihood of success on the merits, it must make a "very strong" showing of irreparable harm to justify this Court's relief. *See Biovail*, 448 F. Supp. 2d at 164. As set forth below, the Court finds that HDI

will not be subject to irreparable harm in the absence of a stay.

HDI claims that because of the FDA's unreasonable delays, HDI would risk irreparable damage to its business reputation and goodwill if the FDA were to approve an ANDA without requiring the standards requested in HDI's Citizen Petition. (*See* Mot. to Stay at 10.) However, this argument refers to a harm that may in fact be remote. That harm is as tenuous as that which was claimed in *Biovail* where plaintiff's alleged harm to its reputation would only occur "*if* the generic version is harmful and *if* the FDA applies improper procedures and approves it, and *if* the generic drug *causes*" harm to the public. *Biovail*, 448 F. Supp. 2d at 165. This type of alleged harm is "insufficient to justify . . . extraordinary relief." *Id.* Here, HDI's alleged harm only occurs only if: (1) the FDA rejects HDI's citizen petition; (2) the FDA approves a generic drug that is not bioequivalent to Derma-Smoothe;[4] (3) the approved generic drug is in fact harmful; and, (4) the injury caused by the generic drug harms HDI's reputation and goodwill. Such an unlikely chain of events does not meet the irreparable harm standard, especially when HDI would have an opportunity to seek emergency relief from this Court once the FDA denied its citizen petition and improperly approved an ANDA. *See id.* (stating that the innovator drug manufacturer "will still have an opportunity to appeal any denial of its citizen petition, albeit after the ANDA is approved"). HDI has not shown that any economic harm it would suffer in the intervening period between improper FDA approval and receiving this Court's emergency relief reaches the level of irreparable harm. *See id.* (finding that movant did not show that

[4] The FDCA requires that generic drug applicants meet many requirements including demonstrating bioequivalence. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(F); 21 C.F.R. §§ 314.127(a)(6)(i); 314.94(a)(7). This Court will not presume that the FDA—having thus far not provided a decision regarding HDI's citizen petition—will approve a generic drug that does not meet all requisite safety standards. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 415 (1971) (presumption of regularity supports official agency acts).

judicial review of the FDA's decision would be rendered meaningless due to the level of economic harm that the innovator drug manufacturer would endure before emergency relief could be granted).

3. Harm to Others and Public Interest

HDI asserts that although generic ANDA applicants may suffer minor delays if the Court grants a stay, the potential injury to the health and safety of the general public will be great. (Mot. to Stay at 10.) Furthermore, HDI claims that the public interest in promoting judicial economy weighs in favor of granting a stay. (*See id.* at 11). This Court finds that neither harm to others nor the public interest—the final two factors of the applicable four-prong standard—weigh in favor of a stay. First, as the Court discussed above, HDI has not established a great potential injury to the health and safety of the general public. Additionally, the FDA has stated that "*if* the Agency were to approve an ANDA referencing Derma-Smoothe, [it] would deny or grant HDI's petition prior to taking such action, or at the latest, at the same time as issuing such approval." (Axelrad Dep. ¶ 12.) At that time, HDI would have the opportunity to challenge the denial of its citizen petition, and consequently seek relief preventing the sale of the allegedly unsafe and non-bioequivalent generic drug. *See* 21 C.F.R. § 10.45 (providing for an opportunity to appeal denial of citizen petitions).

This Court does not deny that the public interest weighs strongly in favor of preventing unsafe drugs from entering the market. However, HDI has not established that extraordinary relief from this Court is required at this time to prevent the release of unsafe generic versions of Derma-Smoothe. In fact, the public interest in "receiving generic competition to brand-name drugs as soon as is possible," which often leads to reduced consumer prices, weighs in favor of denying a stay at this time. *See Biovail*, 448 F. Supp. 2d at 166. Furthermore, the Court does not

find that a stay would promote judicial economy or efficiency. If a stay were granted today, judicial resources would be exhausted to protect HDI and the public from a theoretical harm not at all certain to occur. Instead, this Court sees a public interest in conserving current judicial resources until such a time that HDI's feared theoretical harm becomes a reality that justifies relief from this Court. The Court is also concerned that granting a stay would send a signal to other drug manufacturers that they can seek and receive extraordinary judicial relief at a time when such relief is premature. This scenario would burden the court system and hinder judicial efficiency.

III. CONCLUSION

For the above reasons, this Court concludes that plaintiff HDI's motion for a stay preventing FDA approval of ANDAs referencing Derma-Smoothe until the FDA provides a substantive response to HDI's citizen petition shall be DENIED. The FDA has complied with regulations requiring it to offer a tentative response to citizen petitions within 180 days, and upon analysis of the applicable four-factor standard, the Court finds that a stay is not justified.

A separate order shall issue this date.

Signed by United States District Judge Royce C. Lamberth on November 29, 2007.