UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

HILL DERMACEUTICALS, INC., **Plaintiff,**	)	
v.	)	**Civil Action No. 11-1950 (RCL)**
U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, **Defendants,**	)	
and	)	
AMNEAL PHARMACEUTICALS, LLC, **Intervenor-Defendant.**	)	

MEMORANDUM OPINION

Plaintiff Hill Dermaceuticals, Inc. ("Hill") has brought this action against the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Health and Human Services ("HHS"), Kathleen Sebelius, in her official capacity as Secretary of HHS, and Margaret Hamburg, M.D., in her official capacity of Commissioner of FDA. Amneal Pharmaceuticals, LLC ("Amneal") has intervened as a defendant. Hill manufactures fluocinolone acetonide topical oil products under the brand names Derma-Smoothe/FS (Body Oil and Scalp Oil) and Derm-Otic Oil Ear Drops. On October 17, 2011, the FDA approved requests by Identi Pharms, Inc. ("Identi") to market purported generic versions of these fluocinolone acetonide products. Hill seeks to enjoin the FDA to withdraw or suspend its approval of the three abbreviated new drug applications ("ANDAs") submitted by Identi on the basis that the approval contravenes the sameness requirements, the misbranding restrictions, and the bioequivalence requirements of the Food, Drug, and Cosmetic Act and its implementing regulations. 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(2)(A)(iv), 352(a); 21 C.F.R. §§ 314.94(a)(8)(iv), 320.1, 320.22(b). Hill also claims that

FDA's approval of Identi's three ANDAs constitutes arbitrary and capricious agency action in violation of the Administrative Procedure Act. 5 U.S.C. § 706.

Before the Court is plaintiff's Motion [3] for a preliminary injunction. Upon consideration of plaintiff's Motion, Federal defendants' opposition [25], intervenor defendant's opposition [40], plaintiff's reply [27], Federal defendants' surreply [42], the arguments made in open court on November 29, 2011, the entire record in this case, and the applicable law, the Court will DENY plaintiff's Motion [3] for a preliminary injunction. The Court will explain its reasoning in the analysis that follows.

I. BACKGROUND

A. Statutory and Regulatory Framework

1. New Drug Applications and Abbreviated New Drug Applications

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, pharmaceutical companies seeking to market "pioneer" or "innovator" drugs must first obtain FDA approval by filing a new drug application ("NDA"). 21 U.S.C. § 335(a), (b). The NDA must contain extensive scientific data and other information, including investigative reports demonstrating the drug's safety and effectiveness, a statement of the drug's components, and specimens of proposed labeling for the packaging of the drug. 21 U.S.C. § 335(b)(1).

The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282, permits the submission of abbreviated new drug applications ("ANDAs") for approval of generic versions of drug products with approved NDAs. 21 U.S.C. § 355(j). The Hatch-Waxman Amendments were intended to balance encouraging innovation in drug development with accelerating the availability of lower cost generic alternatives to innovator drugs. *See* H.R. Rep. No. 98-857 (Part

I), 98th Cong., 2d Sess. at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2547–48; *see also Tri-Bio Labs., Inc. v. United States*, 836 F.2d 135, 139 (3d Cir. 1987).

2. ANDA Approval Requirements

To obtain approval, ANDA applicants are not required to submit clinical evidence to establish the safety and effectiveness of the generic drug product. Rather, an ANDA references an approved drug—the reference listed drug ("RLD")—and relies on FDA's previous finding that the RLD is safe and effective. Additionally, an ANDA applicant must provide sufficient information to show that the generic drug product has the same active ingredient or ingredients, dosage form, route of administration, and strength as the RLD. 21 U.S.C. § 355(j)(2)(A)(ii), (iii). An ANDA application must also demonstrate that its product is bioequivalent to the RLD and has the same labeling as the RLD. 21 U.S.C. §§ 355(j)(2)(A)(iv), (v). The agency must approve an ANDA unless it finds, among other things, that the ANDA has not provided sufficient evidence of the foregoing. 21 U.S.C. § 355(j)(4).

The FDCA requires that an ANDA contain "information to show that the labeling proposed for the new [generic] drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under [21 U.S.C. § 355(j)(2)(C)] or because the new drug and the listed drug are produced or distributed by different manufacturers." 21 U.S.C. § 355(j)(2)(A)(v). Permissible labeling differences include "differences in expiration date, formulation, bioavailability, . . . [or] labeling revisions made to comply with current FDA labeling guidelines or other guidance." 21 C.F.R. § 314.94(a)(8)(iv).

The FDCA also requires an ANDA to include information showing that the generic drug product is bioequivalent to the pioneer drug product. 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). A drug is considered to be bioequivalent if "the rate

and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." 21 U.S.C. § 355(j)(8)(B)(i). FDA regulations further define bioequivalence as "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e). The FDA will grant a bioequivalence waiver—that is, the FDA will not require the submission of evidence obtained in vivo measuring bioequivalence of the two products—if the generic drug product: (1) "is a solution for application to the skin, an oral solution, elixir, syrup, tincture, a solution for aerosolization or nebulization, a nasal solution, or similar other solubilized form"; (2) "contains an active drug ingredient in the same concentration and dosage form as a drug product that is the subject of an approved full new drug application or abbreviated new drug application"; and (3) "contains no inactive ingredient or other change in formulation from the drug product . . . that may significantly affect absorption of the active drug ingredient." 21 C.F.R. § 320.22(b)(3)(i)–(iii).

Furthermore, each ANDA must include "the specifications necessary to ensure the identity, strength, quality, and purity of the drug substance . . . including, for example, tests [and] analytical procedures." 21 C.F.R. § 314.50(d)(1); 21 C.F.R. § 314.94(a)(9)(i). An applicant must submit copies of analytical procedures and related descriptive information "that are necessary for FDA's laboratories to perform all necessary tests on the samples and to validate the applicant's analytical procedures," including "a detailed description of the methods of analysis [and] supporting data for accuracy, specificity, precision and ruggedness." 21 C.F.R. § 314.50(e)(2)(i). FDA's regulations include provisions to ensure the accuracy, reliability,

suitability, and reproducibility of an applicant's test methods. *See* 21 C.F.R. §§ 211.165(e), 211.194(a)(2).

B. Factual Background

1. Hill's Fluocinolone Acetonoide Products

FDA first approved Hill's NDA for Derma-Smoothe (fluocinolone acetonide 0.01% topical oil) on February 3, 1988. Hill's NDA includes Body Oil, Scalp Oil, and Oil Ear Drops, even though they are separate products. Derma-Smoothe Body Oil is indicated to topically treat atopic dermatitis for adult patients and some pediatric patients with moderate to severe atopic dermatitis. Derma-Smoothe Scalp Oil is indicated to treat scalp psoriasis on adult patients. DermOtic Oil Ear Drops are indicated to treat chronic eczematous external otitis in adults and pediatric patients two years of age and older. These products are intended for local, topical use and are not intended to be systemically absorbed. FDA has designated Derma-Smoothe as the RLDs for generic fluocinolone acetonide topical oil products.

Hill's Derma-Smoothe products include peanut oil that has been refined in accordance with the United States Pharmacopeia-National Formulary ("USP-NF") standard. When Hill submitted a supplement to its NDA in 1998, FDA requested that Hill improve its testing of the Derma-Smoothe product because the then-current USP-NF monograph for peanut oil did not include enough information to ensure that the peanut oil would be sufficiently free of peanut protein. Hill therefore changed its testing to a non-proprietary, commercially available "sandwich" enzyme-linked immunosorbent assay (S-ELISA) method to detect residual peanut proteins. FDA subsequently approved Hill's NDA supplement, including product labeling stating that the peanut oil used in the Derma-Smoothe product was routinely tested for peanut

proteins using the S-ELISA test and representing that this test could detect peanut proteins to as low as 2.5 parts per million (ppm).

In 2007, Hill submitted another supplement to its NDA in which it proposed to use an amino acid analysis instead of the S-ELISA test, claiming that the amino acid analysis was even more sensitive than the S-ELISA test. This change was not mandated by the FDA, but the FDA approved Hill's supplement. As a result, the current product labeling on Derma-Smoothe includes the following statement: "The peanut oil used in Derma-Smoothe/FS is tested for peanut proteins through amino acid analysis which can detect the quantity of amino acids to below 0.5 parts per million."

In March 2008, FDA decided to review Hill's amino acid analysis and asked Hill to provide method validation packages for Hill's S-ELISA and amino acid tests, plus support for Hill's assertion that the amino acid test "provides for increased safety for the peanut oil component and the drug product." Upon review of the materials submitted by Hill, FDA determined that neither the S-ELISA test nor the amino acid test had been appropriately validated to reliably quantify residual proteins in peanut oil.

2. Hill's Citizen Petition

In September 2004, Hill submitted a citizen petition to FDA requesting that FDA withhold approval of any ANDA for generic versions of Derma-Smoothe products unless it required an ANDA applicant to conduct clinical tests. Hill also requested that FDA require ANDA applicants to meet a 0.5 ppm upper limit for peanut protein in the refined peanut oil vehicle, to be demonstrated by using a test that is validated and capable of quantifying very low levels of peanut protein. *See* Compl. Ex. G ("Citizen Petition Response"), at 1–2.

In its response to Hill's citizen petition, issued in March 2009, the FDA denied Hill's request that FDA automatically reject any ANDA unless the labeling is identical to the RLD concerning the amount of peanut protein in the excipient and the test to identify that amount. *See* Citizen Petition Response, at 12. FDA based its decision on portions of the FDCA and FDA regulations providing that a labeling difference between the generic drug product and the RLD may permissibly reflect a difference in manufacturers. *See id.* (citing 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(2)(G); 21 C.F.R. § 314.94(a)(8)(iv)).

FDA also rejected Hill's request that FDA: (1) require ANDA applicants to demonstrate that their formulations do not cause an allergic reaction in peanut-sensitive patients and conduct studies on peanut-sensitive patients to establish the safety of their products, (2) set an upper limit for the amount of residual peanut protein, and (3) require ANDA applicants to demonstrate that their peanut oil meets this specification using a test that is "validated and capable of quantifying very low levels of peanut protein." *See id.* at 24. FDA stated that it would be sufficient for an applicant to establish that its topical product is made from peanut oil that has been fully refined in accordance with the updated USP-NF standard, because that standard adequately ensures the safety of the peanut oil for the indications in question. *See id.* at 24–25. FDA cited a number of recently published studies supporting its conclusion that the USP-NF refining process—which had been updated since the agency had approved Hill's NDA supplement regarding peanut protein in 1999—would reduce peanut protein to an acceptable level for the indications at issue. *See id.* at 27–28. FDA thus concluded that a manufacturer of fluocinolone acetonide topical oil must merely ensure that the peanut oil used is fully refined and meets the USP-NF standard, declining to require an additional test to quantify protein in refined peanut oil because it would not improve the safety of products formulated with this excipient. *See id.* at 30.

FDA also denied Hill's request that the agency require ANDA applicants to conduct clinical safety studies on peanut-sensitive patients to establish the safety of the peanut oil used in their products, concluding that the process controls included in the USP-NF specification were a more reliable means to ensure the safety of each batch. *See id.* at 31.

3. Derma-Smoothe Labeling

At the time FDA responded to Hill's citizen petition, Hill had two supplemental NDAs pending before the agency related to the labeling format, the statement regarding the amino acid test for peanut protein, and Hill's effort to validate the amino acid test. Based on its conclusions in the Citizen Petition Response, in March 2009 FDA declined to approve one supplement because Hill's amino acid test remained unvalidated. *See* Fed. Defs.' Opp. Ex. 6. FDA subsequently requested that Hill revise its labeling to remove references to the testing method and the amount of peanut protein in the product. In September 2009, FDA determined that the second supplement was not approvable because Hill declined to make FDA's requested changes to Hill's product labeling. *See* Fed. Defs.' Opp. Ex. 7.

Instead of making the labeling changes that FDA requested in 2009, Hill has requested—and FDA has granted—multiple extensions in order to respond to FDA's September 2009 response letter, claiming that it needs more time to validate its amino acid test method. *See* Fed. Defs.' Opp. Ex. 8. Hill's deadline to respond to the FDA is now September 30, 2012.

4. Identi's ANDA Applications and Generic Products

On October 17, 2011, FDA approved three ANDAs submitted by Identi, each corresponding to one of Hill's Derma-Smoothe products. Derma-Smoothe is the RLD for each of the Identi ANDAs. Identi has given intervenor-defendant Amneal the exclusive license to manufacture and market the generic products, which were launched in mid-November 2011.

Although the generic product labels include precautions for use by peanut-sensitive individuals, they do not include the following statement that appears on the labeling for Hill's products: "The peanut oil used in [product] is tested for peanut proteins through amino acid analysis which can detect the quantity of amino acids to below 0.5 parts per million."

II. LEGAL STANDARD

A preliminary injunction is an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief. *Winter v. NRDC*, 555 U.S. 7 (2008). To obtain a preliminary injunction, a party must establish that: (1) it is likely to succeed on the merits; (2) it is likely to suffer an irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *See, e.g., Mills v. District of Columbia*, 571 F.3d 1304, 1308 (D.C. Cir. 2009); *Cobell v. Norton*, 391 F.3d 251, 258 (D.C. Cir. 2004); *Nat'l Treasury Emp. Union v. United States*, 927 F.2d 1253, 1254 (D.C. Cir. 1991). The D.C. Circuit has read the Supreme Court's decision in *Winter* to "suggest if not to hold 'that a likelihood of success is an independent, free-standing requirement for a preliminary injunction,'" regardless of whether a "sliding-scale analysis" is used to weigh the four factors. *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011) (quoting *Davis v. Pension Benefit Guaranty Corp.*, 571 F.3d 1288, 1296 (D.C. Cir. 2009)).

III. ANALYSIS

A. Likelihood of Success on the Merits

Hill's assertion that it is likely to succeed on the merits of its claims rests on three bases: (1) FDA's approval of generic forms of Hill's Derma-Smoothe products violates the FDCA's "same labeling" requirement; (2) FDA's decision not to require generic manufacturers to undertake the same safety testing that it required Hill to perform is arbitrary and capricious; and

(3) FDA's approval of generic versions of Hill's products violates the FDCA's bioequivalence requirements.

1. Labeling

Hill first argues that FDA's approval of the generic versions of the Derma-Smoothe products violates the FDCA's "same labeling" requirement because the generic versions do not contain the statement that appears on the Derma-Smoothe product stating that the peanut oil used in the product "is tested for peanut proteins through amino acid analysis which can detect the quantity of amino acids to below 0.5 parts per million."

Although the Hatch-Waxman Amendments require that the labeling for a generic drug be "the same" as the labeling approved for the RLD, 21 U.S.C. § 355(j)(2)(A)(v), FDA's regulations authorize differences in labeling if "the [generic] drug product and the reference listed drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv). FDA says that its decision to approve the ANDAs without the same labeling as Hill's products falls into this exception, because such "differences between the applicant's proposed labeling and labeling approved for the reference listed drug may include . . . labeling revisions made to comply with current FDA labeling guidelines or other guidance." *Id.* The preamble to the proposed rule 21 C.F.R. § 314.94(a)(8)(iv) demonstrates that the regulation was intended to allow differences in RLD and generic labeling in circumstances where "the reference listed drug labeling does not reflect current agency labeling standards; for example, the agency may require a change in the labeling of a drug to make available important new information about the safe use of a drug product, but the reference listed drug's labeling has not yet been updated to reflect this change." 54 Fed. Reg. 28872, 28884 (proposed July 10, 1989).

In its response to Hill's citizen petition, FDA determined that adherence to the current USP-NF industry standard is sufficient to ensure that residual peanut protein remains at safe levels, eliminating the need for ANDA sponsors to conduct batch testing such as Hill had conducted. As a result, the FDA declined to require ANDA labeling to reference such a test. *See* Citizen Petition Response, at 27–30. The Court finds that FDA's response to Hill's citizen petition is "other guidance" establishing new safety standards that should be reflected on the product labeling, which properly supports the FDA's decision to approve ANDAs with different labeling than the RLD Derma-Smoothe under the exception spelled out in 21 C.F.R. § 314.94(a)(8)(iv). The exception provided for by the statutory language plainly supports FDA's approval of the ANDAs at issue, and Hill has failed to demonstrate through other arguments how it is likely to succeed on the merits under its theory that FDA's approval of the generic versions of the Derma-Smoothe products somehow violates the FDCA's "same labeling" requirement because it is not subject to this exception.

2. Testing

Hill also claims that FDA's decision not to require generic manufacturers to undertake the same safety testing that it required Hill to perform is arbitrary and capricious. According to Hill, FDA has violated the principle of reasoned decision making that an administrative agency must treat like cases alike and may not impose arbitrary and unequal regulatory burdens on similarly situated parties. *See Westar Energy, Inc. v. FERC*, 473 F.3d 1239, 1241 (D.C. Cir. 2007). Specifically, Hill argues that FDA compelled Hill to invest millions of dollars to develop and perform its amino acid test, yet has not required generic manufacturers to satisfy the same testing requirements. As a result, says Hill, the FDA has improperly approved a generic product that has a different risk/benefit profile than the approved drug on which the ANDA is based,

because Hill's product has a known and tested quantity of residual peanut protein of less than 0.5 parts per million, while the generic has an unknown quantity of residual peanut protein. Hill argues that the generic poses a greater risk to healthcare providers and peanut-sensitive individuals because it has not undergone the same testing as the RLD.

However, in its response to Hill's citizen petition, FDA determined that "at this time, there does not appear to be *any test* that has been validated for the purpose of reliably quantifying residual protein in peanut oil," including Hill's amino acid analysis that is referenced on the Derma-Smoothe labeling. Citizen Petition Response, at 26. Accordingly, the generic product and Derma-Smoothe do in fact have the same risk/benefit profile, because neither product is tested in a manner that reliably proves the quantity of residual peanut protein contained in the product. It would be nonsensical for FDA to require the generic products to undergo Hill's amino acid analysis—a test that FDA has not validated—merely so that the generic products would be tested in the same manner as the RLD. FDA therefore did not act in an arbitrary and capricious manner when it approved the fluocinolone acetonide ANDAs.

Notably, when FDA responded to Hill's citizen petition and stated that Hill's amino acid analysis was not validated, Hill had two supplemental NDAs pending before the agency related to the labeling format, the statement regarding the amino acid test for peanut protein, and Hill's effort to validate the amino acid test. Based on its conclusions in its Citizen Petition Response, in March 2009 FDA declined to approve one supplement because Hill's amino acid test remained unvalidated. *See* Fed. Defs.' Opp. Ex. 6. FDA subsequently requested that Hill revise its labeling to remove references to the testing method and the amount of peanut protein in the product. In September 2009, FDA determined that the second supplement was not approvable because Hill declined to make FDA's requested changes to Hill's product labeling. *See* Fed.

Defs.' Opp. Ex. 7. But instead of making the labeling changes that FDA requested in 2009, Hill has requested—and FDA has granted—multiple extensions in order to respond to FDA's September 2009 response letter, claiming that it needs more time to validate its amino acid test method. *See* Fed. Defs.' Opp. Ex. 8. Hill's deadline to respond to the FDA is now September 30, 2012, and the reference to the amino acid analysis remains on the Derma-Smoothe product labeling.

While FDA's decision to approve the fluocinolone acetonide ANDAs was not arbitrary and capricious, its subsequent actions allowing references to an unvalidated test to remain on the Derma-Smoothe product labeling may very well have been. This does not weigh in Hill's favor; rather, it demonstrates that Hill continues to misrepresent the efficacy of a testing method on its labeling that the FDA has declined to validate. Nonetheless, the fact that FDA may have acted improperly by extending its approval of Hill's current labeling is immaterial here because the FDA did not act in an arbitrary and capricious manner by not requiring generic manufacturers to undertake unvalidated amino acid testing, and Hill has failed to demonstrate a likelihood of success on the merits of its argument otherwise.

3. Bioequivalence

Under its third theory, Hill asserts that the FDA's approval of the generic products violates the statutory bioequivalence requirements. The FDA will grant a bioequivalence waiver ("biowaiver") for an ANDA—that is, the FDA will not require the submission of evidence obtained in vivo measuring bioequivalence of the two products—if the generic drug product: (1) "is a solution for application to the skin, an oral solution, elixir, syrup, tincture, a solution for aerosolization or nebulization, a nasal solution, or similar other solubilized form"; (2) "contains an active drug ingredient in the same concentration and dosage form as a drug product that is the

subject of an approved full new drug application or abbreviated new drug application"; and (3) "contains no inactive ingredient or other change in formulation from the drug product . . . that may significantly affect absorption of the active drug ingredient." 21 C.F.R. § 320.22(b)(3)(i)–(iii).

All parties agree that the second and third requirements for a biowaiver are satisfied. Thus, the question of whether FDA properly granted a biowaiver turns on whether the Derma-Smoothe products are solutions. The parties have made conflicting submissions regarding the definition and makeup of a "solution." Hill argues that its products are not solutions, and thus the requirements for a grant of a biowaiver are not met. FDA counters that the Court should defer to the agency's expertise and uphold its decision to grant a biowaiver to the generic products. The Court declines to blindly uphold the FDA's purported scientific decisions before reviewing the complete administrative record and examining the bases for FDA's decision to grant the biowaiver. Yet FDA's failure to provide the Court with the full administrative record at this point also means that the Court does not have enough information at this time to determine whether Hill is likely to succeed on the merits of its claim that its products are not solutions, rendering FDA's grant of a biowaiver improper. Without the complete administrative record before the Court, the plaintiff has not made a showing that it is likely to succeed on the merits of its claim under the theory that Derma-Smoothe is not a solution and thus FDA's grant of a biowaiver was improper.

B. Likelihood of Irreparable Harm

Although Hill has failed to demonstrate a substantial likelihood of success on the merits, it makes a strong showing that it is likely to suffer irreparable harm in the absence of a preliminary injunction. Irreparable harm exists "where the movant has made a strong showing

that the economic loss would significantly damage its business above and beyond a simple diminution in profits." *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 43 (D.D.C. 2000). "To shoehorn potential economic loss into a showing of irreparable harm, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence." *Hi-Tech Pharmacal Co. v. FDA*, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) (citing *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025 (D.D.C. 1981)).

Hill argues that, absent injunctive relief, it will suffer significant damage to its business. Hill is a small, family-owned company with 150 full-time employees that depends upon its Derma-Smoothe products for the company's livelihood, as the products make up 90% of Hill's revenues and sales. *See* Compl. Ex. D, ¶¶ 6, 17–21. Historical evidence demonstrates that generic drugs have achieved up to 90% market saturation within several months of entering the market. *See id.* ¶ 20. As the Supreme Court recently observed, "[n]inety percent of drugs for which a generic version is available are now filled with generics" and "[i]n many cases, once generic versions of a drug enter the market, the brand-name manufacturer stops selling the brand-name drug altogether." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2584 (2011). Because pharmacists will substitute the generic product for the brand-name drug—and are often required to substitute generic products under state law—a generic drug company will automatically capture a sizeable portion of the sales of the drug, even if the generic is only marginally less costly and not as safe as the branded drug. *See* Pl.'s Reply Ex. 3, ¶ 9.

This evidence demonstrates that new competition from a generic in the marketplace will almost certainly cause Hill severe market loss and economic injury, which, given the primary role that the Derma-Smoothe products play in Hill's business, could be completely devastating to

the company's vitality. Hill thus makes a strong showing that it is likely suffer irreparable harm in the absence of a preliminary injunction.

C. Balance of Equities and the Public Interest

Amneal has demonstrated that it would suffer substantial harm were the Court to enter a preliminary injunction. Amneal has already incurred considerable expenses to launch its generic products, including the costs of research and development, regulatory matters, manufacturing, labeling, and marketing. Mot. to Intervene Ex. 1, ¶ 5. Additionally, Amneal has secured at least ten contracts with customers for the sale of the generic products. *Id.* A preliminary injunction would require Amneal to discontinue the marketing and distribution of its products, which would result in lost profits on current sales, wasted investment in product and labels already manufactured, and uncertainty about future attempts to market and sell the products. *Id.* ¶ 6.

Furthermore, if—as the Court has found—Hill is not likely to establish that the fluocinolone acetonide ANDAs were wrongly approved, then public interest considerations weigh against a preliminary injunction. *See, e.g.*, *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998). The purpose of the Hatch-Waxman Amendments is to provide the public with the benefits of generic competition to branded drugs. *See id.* at 1326–27. Congress expected that competition "to make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. Even in this case, where the generic product is only marginally cheaper than Derma-Smoothe and the savings to consumers will not be significant, Congress's purpose in passing the Hatch-Waxman Amendments is directly implicated. FDA is mandated by the FDCA to make lower-cost generic drugs available to the public where, as here, those drugs are found to meet the requirements for

approval. It is therefore not in the public interest for the Court to grant a preliminary injunction preventing these generic drugs from being sold on the market.

Despite Hill's strong argument that it is likely to suffer harm to its business in the absence of a preliminary injunction, the risk that Hill will lose its market share is outweighed by the strong public interest in the availability of lower-cost generic drugs in the market. Furthermore, Hill has failed to demonstrate that it has suffered any loss at all since Amneal's product launch in mid-November—rather, Hill's claimed harm will manifest itself at some uncertain point in the future. Conversely, were the Court to enter a preliminary injunction, Amneal would undoubtedly suffer immediate harm because it would be forced to remove its generic products from the market and thus would be unable to perform on its contracts related to the generic products. Moreover, entering a preliminary injunction would not preserve the status quo, as Amneal's generic products have already launched. The balance of equities therefore weighs in favor of Amneal and the public interest and against Hill.

IV. CONCLUSION

Although Hill has made a strong showing that it will likely suffer irreparable harm in the absence of a preliminary injunction, this showing is outweighed by Hill's inability to demonstrate any likelihood of success on the merits of its claims against FDA. Indeed, "[w]ithout any probability of prevailing on the merits, [a plaintiff's] purported injuries, no matter how compelling, do not justify preliminary injunctive relief." *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 38 F. Supp. 2d 114, 140 (D.D.C. 1999). Additionally, the balance of equities weighs in favor of Amneal and the public interest and away from granting a preliminary injunction to Hill. For the foregoing reasons, Hill's Motion for a preliminary injunction is hereby DENIED.

Signed by Royce C. Lamberth, Chief Judge, on December 2, 2011.