IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WINSTON LABORATORIES, INC., a Delaware corporation, Plaintiff, v. KATHLEEN SEBELIUS, as Secretary and Senior Officer of the United States Department of Health and Human Services; and MARGARET HAMBURG, M.D., as Commissioner and Senior Officer of the United States Food and Drug Administration, Defendants.	Case Number: 1:09-cv-04572 Judge: St. Eve

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

This dispute concerns whether plaintiff Winston Laboratories, Inc. is required to pay a user fee in connection with the submission of a new drug application ("NDA")[1] to the United States Food and Drug Administration. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") directs FDA to collect user fees from a variety of regulated entities, including sponsors of NDAs, upon the submission of an NDA or an NDA supplement. 21 U.S.C. § 379h(a). The Act also authorizes FDA to waive or reduce such fees under certain limited circumstances. Winston sought a fee waiver pursuant to 21 U.S.C. § 379h(d)(1)(D) (the "small business fee waiver provision"). FDA denied the request, and an FDA appeals officer affirmed that decision after an administrative appeal. Winston now seeks declaratory and injunctive relief requiring FDA to grant its fee waiver request.

The small business fee waiver provision is narrow: it applies only to those businesses that meet the Act's definition of a small business, and it applies only to the first application such

[1] A pharmaceutical company seeking to market a new drug must first obtain FDA approval by submitting an NDA under 21 U.S.C. § 355.

businesses submit. *Id.* To avoid abuse of the provision -- namely, to prevent individuals from obtaining fee waivers for successive NDAs submitted by nominally separate small businesses -- the Act directs FDA to take a broad look at any NDA sponsor seeking a small business fee waiver. For example, when determining whether a sponsor of an NDA is eligible for a fee waiver, FDA must impute to the sponsor any applications submitted by any of its affiliates. *Id.*

Winston is one of several entities established, owned, and/or controlled by a single individual, Dr. Joel Bernstein. Each of these entities has owned NDAs that preceded the NDA for which Winston now seeks a fee waiver. Because this NDA is not the first to be submitted by Winston or its affiliates, Winston is not eligible for a fee waiver. Accordingly, Winston's claims for a declaration that FDA acted improperly in denying it a fee waiver, and for an injunction requiring FDA to grant a fee waiver, are not sustainable. The Court should dismiss Winston's Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure for failure to state a claim for which relief can be granted.

I. STATUTORY FRAMEWORK

Congress added the Prescription Drug User Fee Act ("PDUFA") to the FDCA in 1992. *See* Pub. L. No. 102-571, 106 Stat. 4491, 4498, 4499 (1992).[2] The PDUFA provisions require FDA to assess and collect user fees for certain applications, establishments, and products.

The Act, as amended, directs FDA to collect fees from "[e]ach person that submits, on or after September 1, 1992, a human drug application or a supplement." 21 U.S.C. § 379h(a)(1).[3]

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[2] PDUFA was subsequently amended by the Food and Drug Administration Modernization Act of 1997, *see* Pub. L. No. 105-115, 111 Stat. 2296 (1997), and the Prescription Drug User Fee Amendments of 2002 and 2007, *see* Pub. L. No. 107-188, 116 Stat. 594 (2002); Pub. L. No. 110-85, 121 Stat. 823 (2007).

[3] The Act also directs FDA to collect fees for each establishment where "prescription drug products are manufactured in final dosage form," and for approved drugs "dispensed only under prescription." 21 U.S.C. § 379g(3) & (5); 21 U.S.C. § 379h(a)(2) & (3).

The definition of human drug application includes NDAs. 21 U.S.C. § 379g(1)(A) (defining "human drug application" to include "an application for . . . approval of a new drug submitted under [21 U.S.C. § 355(b)]").

In certain limited circumstances, FDA "shall grant to a person who is named as the applicant in a human drug application a waiver from or a reduction of one or more fees assessed to that person." 21 U.S.C. § 379h(d)(1). In determining whether a person is eligible for a fee waiver or reduction, the Act directs FDA to look not just at the named applicant but also at any affiliates: it defines a "person" seeking a fee waiver or reduction to include "an affiliate thereof," 21 U.S.C. § 379g(9) (emphasis added); and it requires FDA to consider "the circumstances and assets of the applicant involved and any affiliate of the applicant" when deciding whether the applicant is eligible for a fee waiver or reduction. 21 U.S.C. § 379h(d)(2) (emphasis added).

The Act defines "affiliate" to mean "a business entity that has a relationship with a second business entity if, directly or indirectly --

(A) one business entity controls, or has the power to control, the other business entity; or

(B) a third party controls, or has power to control, both of the business entities."

21 U.S.C. § 379g(11).

The Act enumerates four circumstances in which an applicant may qualify for a fee waiver. 21 U.S.C. § 379h(d)(1). Only the fourth is relevant here, which authorizes a waiver if "the applicant involved is a small business submitting its first human drug application to the Secretary for review." 21 U.S.C. § 379h(d)(1)(D).[4]

[4] The Act also permits a waiver in cases where "such waiver or reduction is necessary to protect the public health," 21 U.S.C. § 379h(d)(1)(A); "the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other

To qualify for a waiver under the small business fee waiver provision, the applicant and its affiliates must first meet the Act's definition of a small business. The Act defines "small business" as "an entity that has fewer than 500 employees, including employees of affiliates, and that does not have a drug product that has been approved under a human drug application and introduced or delivered for introduction into interstate commerce." 21 U.S.C. § 379h(d)(4)(A).

Further, to qualify for a fee waiver, the application for which the waiver is sought must be the first such application that the applicant and its affiliates have submitted to FDA. 21 U.S.C. § 379h(d)(1)(D). The Act emphasizes in several places that, even for otherwise qualified small businesses, a waiver is available only for the first application that the entity and its affiliates have submitted. *See* 21 U.S.C. § 379h(d)(4)(B) (FDA "shall waive . . . the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review."). *See also* 21 U.S.C. § 379h(d)(1)(D) (a waiver is available if "the applicant involved is a small business submitting its first human drug application to the Secretary for review"). The Act goes on to note that:

> After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay -- (i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and (ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.

21 U.S.C. § 379h(d)(4)(B).

In sum, an applicant cannot seek a fee waiver or reduction for any application other than the first one it submits for FDA consideration, nor can it avoid this limitation by forming and/or dissolving successive affiliate entities to submit new applications to the agency.

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circumstances," 21 U.S.C. § 379h(d)(1)(B); or where "the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person." 21 U.S.C. § 379h(d)(1)(C).

II. STATEMENT OF FACTS

A. Dr. Joel Bernstein, Winston, and Their Affiliates

This case concerns the relationships between three pharmaceutical companies and the individual who founded and/or controlled them. The companies involved are: Northbrook Testing Co., Inc., an Illinois company that was dissolved in 1984 (Compl. ¶ 31); GenDerm Corporation, also an Illinois company before its stock was sold to Medicis Pharmaceutical Corporation and it was merged into Medicis in 1997 (*id*. at ¶ 32); and Winston, a Delaware company (*id*. at ¶ 33) that remains in operation today.

Dr. Bernstein has or had significant connections to Northbrook, GenDerm, and Winston: he was the president of Northbrook and owned a majority of the company's shares until its dissolution (*id*. at ¶ 31); he was the founder and CEO of GenDerm, as well as a minority shareholder, until its merger with Medicis (*id*. at ¶ 32 & Ex. D at 17);[5] and he was the founder of Winston. Today he is CEO of Winston and, together with his immediate family, the majority owner of the company. (*Id*. at ¶ 33 & Ex. D at 17).

While Dr. Bernstein owned and controlled Northbrook, it submitted an NDA for Papulex (nicotinamide 4%). (*Id*. Ex. D at 17). GenDerm later assumed ownership of the Papulex NDA after Northbrook was dissolved, and it transferred ownership of the NDA to Winston before GenDerm's merger with Medicis. (*Id.*) GenDerm also submitted an NDA for Carbamide Peroxide Solution while Dr. Bernstein was CEO of GenDerm. (*Id.*)

B. Winston's Request for a Fee Waiver

On May 21, 2008, in advance of its submission of the NDA for Civanex cream, Winston submitted a request for a small business fee waiver, citing 21 U.S.C. § 379h(d)(1)(D). (Compl.

[5] Page citations to the Exhibits to the Complaint for Declaratory and Injunctive Relief (A-H) use the pagination contained in the Court's electronic docket (pages 1 to 44).

¶ 17 & Ex. A at 3). After reviewing the applicable record, FDA denied the request. (*Id.* at ¶ 24). In a letter dated December 1, 2008, the agency explained its determination that Dr. Bernstein, Northbrook, and GenDerm were all affiliates of Winston, that they had previously submitted NDAs to FDA, and therefore that Winston was not eligible for a fee waiver under the small business fee waiver provision. (*Id.* Ex. D at 16, 17-18).

On December 9, 2008, in a letter signed by Dr. Bernstein, Winston asked FDA to reconsider the denial. (*Id.* at ¶ 27 & Ex. E at 20-21). In support of the request, Dr. Bernstein asserted that Winston had consulted with five attorneys who opined that neither Northbrook nor GenDerm met the definition of an affiliate under the Act. (*Id.* Ex. E at 20).

FDA considered the request for reconsideration, but, after reviewing the record, it again concluded that Winston was not eligible for a fee waiver because of its affiliation with Dr. Bernstein, Northbrook, and GenDerm (*id*. at ¶ 28), and because Winston and its affiliates have previously submitted NDAs for FDA review. (*Id.* Ex. F at 25). FDA denied the request in a letter to Dr. Bernstein dated February 2, 2009. (*Id*. at 23, 24-26).

Winston responded by asking for review by FDA's Office of the Chief Counsel. (*Id.* Ex. G at 30). In that email, Winston asserted, for the first time, that it also qualified for a fee waiver under 21 U.S.C. § 379h(d)(1)(B), which authorizes FDA to waive a fee if "the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances." Winston then asserted that it could not "afford to pay a user fee of over $1 million and remain in business." (*See* Compl. Ex. G at 30). The Office of the Chief Counsel directed the matter to the User Fee Appeals Officer to review FDA's decision.

In a twelve-page decision letter, dated June 18, 2009, the User Fee Appeals Officer reviewed the record and the agency's previous decisions and determined that Winston did not

"meet the statutory criteria for a small business fee waiver" and, therefore, denied the appeal. (*Id.* at ¶ 30 & Ex. H at 33). The Appeals Officer concurred with FDA's earlier determinations that Northbrook was an affiliate of Winston, based on Dr. Bernstein's control over both entities. (*Id.* Ex. H at 39-40).[6] He further found that, because Winston and its affiliates had previously submitted an NDA for Papulex, Winston was not eligible for a fee waiver. (*Id.* at 40).

The Appeals Officer also addressed Winston's belated assertion that it was eligible for a fee waiver because "the fee would present a significant barrier to innovation." (*Id.* at 44). Because this argument was raised for the first time on appeal, the Appeals Officer declined to consider the merits; however, he invited Winston to submit to FDA an additional request for a fee waiver on these grounds. (*Id.*)

Winston declined to seek a fee waiver from FDA under 21 U.S.C. §379h(d)(1)(B), and instead filed this lawsuit on July 29, 2009.

III. Standard of Review

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a defendant may raise as a defense to a complaint the plaintiff's "failure to state a claim upon which relief can be granted." To survive a Rule 12(b)(6) motion to dismiss, the plaintiff must plead enough facts "to state a claim to relief that is plausible on its face." *Crichton v. Golden Rule Ins. Co.*, 576 F.3d 392 (7th Cir. 2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, (2007)). "The complaint 'must actually suggest that the plaintiff has a right to relief, by providing allegations that raise a right to relief above the speculative level.'" *Bridges v. Gilbert*, 557 F.3d 541, 546 (7th Cir. 2009) (quoting *Windy City Metal Fabricators & Supply, Inc. v. CIT Technical Fin. Servs., Inc.*, 536 F.3d 663, 668 (7th Cir. 2008)). Furthermore, the court need not accept as true "a legal

[6] The Appeals Officer determined there was insufficient evidence to conclude that Dr. Bernstein controlled or had power to control GenDerm, and so he declined to find that GenDerm was an affiliate of Winston. (Compl. Ex. H at 43).

conclusion couched as an actual allegation," nor inferences that are unsupported by the facts set out in the complaint. *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

Dismissal under Rule 12(b)(6) is appropriate where, as in this case, the pleadings on their face reveal "beyond doubt that the plaintiff can prove no set of facts that would entitle [it] to relief." *Bowers v. Fed'n Internationale De L'Automobile*, 489 F.3d 316, 321 (7th Cir. 2007). "[W]hen the allegations in a complaint, however true, could not raise a claim of entitlement to relief, this basic deficiency should be exposed at the point of minimum expenditure of time and money by the parties and the court.'" *Culliver v. Taylor*, 503 F.2d 397, 401 (5th Cir. 2007) (quoting *Twombly*, 550 U.S. at 558). Because Winston has not and cannot plead facts that would entitle it to relief, the Court should dismiss this case.[7]

IV. ARGUMENT

A. Winston Is Ineligible for a Fee Waiver Under the Express Terms of the Act

Where, as here, the Court is reviewing an agency's construction of statutory provisions, the two-step analysis of *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), governs. Applying the first step of *Chevron*, the Court must inquire "whether Congress has directly spoken to the precise question at issue." *Id.* at 842. If Congress's intent is clear, "that is the end of the matter" and the Court "must give effect to [such] unambiguously expressed intent." *Id.* at 842-43.

FDA's denial of Winston's fee waiver request was consistent with the plain language of the Act. FDA denied Winston's request for a small business fee waiver because Winston failed to satisfy all of the requirements for the fee waiver set forth in the Act. (Compl. Ex. H at 33, 39).

[7] The Complaint appends as Exhibits several documents that were part of the Administrative Record relating to this action. The Court may consider these attached documents in ruling on the government's motion to dismiss. *See Witzke v. Femal*, 376 F.3d 744, 749 (7th Cir. 2004). The government is prepared to file the entire Administrative Record at the appropriate time or at the Court's request.

FDA accepted that Winston and its affiliates employed fewer than 500 people (*id.* at 39), and that neither Winston nor its affiliates marketed a drug product that had been approved under a human drug application and introduced or delivered for introduction into interstate commerce. (*Id.*) FDA determined, however, that the NDA for Civanex cream was not the first NDA submitted by Winston and its affiliates (*id.*), and therefore that Winston did not meet all of the eligibility requirements for the small business fee waiver provision. (*Id.*)

FDA made this determination after finding that Winston and Northbrook are affiliates, and that Northbrook had previously submitted an NDA to FDA for review. (Comp. Ex. H at 42). Winston and Northbrook are affiliates because Dr. Bernstein was, at relevant times, the owner and CEO of both entities (*id.*), and thus controlled or had the power to control them both. (*Id.*) *See also* 21 U.S.C. 379g(11) (defining "affiliate). FDA further found that Northbrook previously submitted an NDA for Papulex, (Compl. Ex. H at 43), ownership of which passed to GenDerm and later to Winston. (*Id.* at 35).

Winston has never disputed that Dr. Bernstein controlled Northbrook and Winston (*id.* Ex. H. at 42), or that Northbrook previously submitted an NDA. (*Id.* at 43). Instead, Winston contends that, because Northbrook was dissolved before Winston was founded, Northbrook does not meet the definition of an affiliate, and so the fact that Northbrook previously submitted an NDA does not bar Winston from securing a small business fee waiver. (*Id.* at 40).

Winston's argument is not supported by the language of the Act. The Act directs FDA to examine horizontally-related entities and to treat them as one applicant for purposes of determining eligibility for the small business fee waiver. 21 U.S.C. § 379g(11)(B). It defines "affiliate" to mean "a business entity that has a relationship with a second business entity if, directly or indirectly . . . a third party controls, or has power to control, both of the business

entities," *id*., and it permits a fee waiver only if an entity and its affiliates have not previously submitted an NDA. 21 U.S.C. § 379h(d)(1)(D). Thus, if a single individual controls entities A and B, and entity A submitted an NDA in 2002, entity B cannot seek a fee waiver for an NDA it submitted in 2008. The Act does not suggest that the result should be any different if entity A continued to exist in 2008, or if it was dissolved in 2006 and entity B was formed in 2007. By virtue of the single individuals' common control over both entities, they are affiliates for purposes of the fee waiver provision of the Act, *see* 21 U.S.C. § 379g(11)(B), and, therefore, entity A's prior submission of an NDA renders entity B ineligible for a small business fee waiver. 21 U.S.C. § 379h(d)(1)(D).

Congress clearly intended that FDA take into account past actions. While the Act imposes user fees on applications submitted after September 1, 1992, *see* 21 U.S.C. § 379h(a)(1), a small business that submitted an NDA to FDA before that date would not be eligible for a fee waiver for any subsequent application. The Act unequivocally provides that only the <u>first</u> application submitted by a small business is eligible for a fee waiver, regardless of when that first application was submitted. 21 U.S.C. § 379h(d)(1)(D). Thus, a small business is ineligible for a fee waiver for an NDA it submitted in 2008 if the small business previously submitted an NDA in 1990, prior to the enactment of the user fee requirements. So, too, a small business is ineligible for a fee waiver for an NDA it submitted in 2008 if a now-dissolved affiliate submitted an NDA in 1990. There is simply no basis in the Act for reaching a different result if the earlier-submitted NDA was submitted by an affiliate. Not only would a different outcome be inconsistent, it would ignore the Act's specific requirement that FDA take into account the prior actions of affiliates. 21 U.S.C. § 379h(d)(2). This is an equitable result: since there were no user fees imposed prior to 1992, a small business or an affiliate that submitted an NDA before

1992 did not have to pay a user fee for its first NDA. When the user fee provisions were added in 1992, the Act continued to provide a means for a small business to have its first fee waived. In both cases, however, these small businesses and their affiliates must pay the user fees for any subsequent NDAs submitted after September 1, 1992.

In this case, Dr. Bernstein is the third party who, at relevant times, controlled both Northbrook and Winston. (Compl. ¶¶ 31, 33). As with the hypothetical described above, for purposes of the fee waiver provision, Dr. Bernstein's common control over both entities means that Northbrook and Winston are affiliates. Because Northbrook previously submitted an NDA, its affiliate Winston is not eligible for a small business fee waiver. In denying Winston's request for a fee waiver, FDA gave effect to the unambiguous terms of the statute, and, under *Chevron* step one, "that is the end of the matter." *Chevron*, 467 U.S. at 842.

B. FDA's Interpretation Is Consistent with the Policies Underpinning the Small Business Fee Waiver Provision

Even if Congress has not "directly" addressed "the precise question at issue," the Court cannot "impose its own construction on the statute." *Chevron*, 467 U.S. at 843. Rather, under the second step of *Chevron*, the Court must determine if the agency's interpretation is based on "a permissible construction of the statute." *Id.* In so doing, the Court should give "considerable weight . . . to an executive department's construction of a statutory scheme it is entrusted to administer" and "should not disturb" an agency's interpretive choice among conflicting policies "unless it appears from the statute or its legislative history that the [agency's interpretation] is not one that Congress would have sanctioned." *Id.* At 844, 845. Thus, under the second step of the *Chevron* analysis, "unless the regulation (and the FDA's interpretation of it) is 'arbitrary, capricious, or manifestly contrary to the statute,'" the Court must accord it deference. *United States v. Genendo Pharm., N.V.*, 485 F.3d 958, 964 (7th Cir. 2007).

Here, FDA's interpretation is based on "a permissible construction of the statute" and should not be disturbed. *Id.* At the very least, the Act does not "unambiguously forbid[] the Agency's interpretation" and therefore the Court should accord it deference. *See Barnhart v. Wilson*, 535 U.S. 212, 218 (2002). Courts have long deferred to FDA's interpretation of the Act. *See, e.g., Young v. Community Nutrition Inst.*, 476 U.S. 974, 981 (1986); *Novartis Pharmaceuticals Corp. v. Leavitt*, 435 F.3d 344, 349 (D.C. Cir. 2006) ("We have held on a number of occasions that FDA interpretations of the FDCA receive deference, as do its interpretations of its own regulations unless plainly erroneous or inconsistent with the regulations."); *Mylan v. Thompson*, 389 F.3d at 1281; *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 883 (D.C. Cir. 2004); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319, 1320 (D.C. Cir. 1998) (citing *Auer v. Robbins*, 519 U.S. 452, 461 (1997)). Courts similarly have deferred to administrative determinations that are not embodied in rulemaking or formal adjudication. *See, e.g., Apotex, Inc. v. FDA*, No. 06-5060, 2007 U.S. App. LEXIS 4270 (D.C. Cir. Feb. 23, 2007) ("the district judge's opinion, which grants *Chevron* deference to the FDA's statutory interpretation . . . embodied in FDA approval letters (i.e., informal adjudications), is supported by the Supreme Court's . . . decision in *Barnhart v. Walton*, 535 U.S. 212, 222 (2002), as well as our own decision in *Mylan Laboratories, Inc. v. Thompson*, 389 F.3d 1272, 1279-80 (D.C. Cir. 2004)").

FDA's interpretation of the Act in this case is consistent with the purposes of the fee waiver provision and agency policy. As the User Fee Appeals Officer explained in his decision:

> [P]olicy considerations support a broader interpretation of the term affiliate. Under the interpretation promoted by Winston, a company could obtain a fee waiver for its "first human drug applicant," dissolve the company, establish a new company that is essentially a duplicate of the first, and obtain a fee waiver for its next NDA (which would technically be the "first NDA of <u>that</u> incarnation of the company)." This cycle could be repeated[] indefinitely. [The Act's] emphasis

> that a waiver is only available for the first human drug application submitted by a "small business or its affiliate," and not for subsequent applications, 21 U.S.C. § 379h(d)(4)(B) (emphasis added), instead of all applications submitted by a "small business," *id.* § 379h(d)(1)(D), certainly suggests that Congress intended to prevent such abuse. To adopt an interpretation that would permit companies to easily circumvent the limitation on the small business waiver put in place by Congress is not sound public policy.

(Compl. Ex. H at 42). As discussed in Part V.A, *supra*, if the controlling individual could make entity B eligible for a fee waiver by dissolving entity A -- and, as happened here, assigning ownership for entity A's NDA to entity B -- that individual could obtain multiple fee waivers, which the Act plainly forbids. 21 U.S.C. § 379h(d)(1)(D). *See also* 21 U.S.C. § 379h(d)(4)(B) (requiring entities that previously obtained a fee waiver or reduction to pay all subsequent user fees required under the Act). So, too, Dr. Bernstein cannot claim eligibility for fee waiver for a later-submitted NDA simply by creating and dissolving successive companies that submit NDAs. Such a result would open the door to precisely the sort of abuse that Congress sought to prevent when it required FDA to consider affiliates when determining an entity's eligibility for a small business fee waiver.

In the event that Winston contends that the Act's use of the present tense in its definition of "affiliate," *see* 21 U.S.C. § 379g(11)(B) (defining an affiliate relationship where "a third party controls, or has power to control"), limits its application only to entities that exist contemporaneously, such an interpretation is contrary to Congress's clear intent that eligibility for a fee waiver extends only to the first application an applicant and its affiliates submits to FDA. It would be nonsensical to permit an individual to form and dissolve successive entities in order to secure multiple fee waivers in light of the Act's requirement that only the first NDA submitted by a sponsor and its affiliates is eligible. If Congress had intended for FDA's consideration of "affiliates" to be limited to those entities currently in existence, it could have made that requirement explicit. Congress, however, expected FDA to consider past events (for

example, the submission of an NDA), and there is no basis for distinguishing between that pivotal action and the ancillary statutory charge to consider the submissions made by affiliates.

In any case, common principles of statutory construction do not compel a narrow reading of Congress's use of tense, particularly, where, as here, doing so would be inconsistent with other related provisions in the Act. *See Coalition for Clean Air, et al. v. S. Cal. Edison Co.*, 971 F.2d 219, 225 (9th Cir. 1992) (declining to limit the interpretation of a statute written in the present tense to present events, noting that "[t]he present tense is commonly used to refer to past, present, and future all at the same time," and finding "that Congress used the present tense word . . . because it did not wish to limit [the statute's] reach to either past or future" events). *See also United States v. Miami Univ.*, 294 F.3d 797, 809 (6th Cir. 2002) (finding that the tense of a verb does not preclude application of a statute to relevant facts in the past or the future); *United States v. Julian*, 242 F.3d 1245, 1247 (10th Cir. 2001) (finding statute's use of the past tense of the word "incur" to define compensable losses did not bar its application to losses that might occur in the future, and noting that "[t]he sentence structure in the statute calls for the particular verb form, but the statute provides for 'full' recovery of 'any' counseling costs for which the victim became liable, which includes future losses"); *Steel Auth. of India, Ltd. v. United States*, 146 F. Supp. 2d 900, 905 (Ct. Int'l Trade 2001) (rejecting argument that Congress's use of the present tense of the phrase "competes with" barred an agency from taking a longer view of market activity to evaluate a purported market injury).

V. CONCLUSION

The Court should uphold FDA's application of the Act under either *Chevron* step one or two. FDA properly applied the unambiguous provisions of the Act, which do not permit a small business fee waiver where an affiliate has previously submitted an NDA, and it properly determined that, where an individual controls or has power to control two separate entities, those

two entities are affiliates under the Act. Even if there were an ambiguity, however, FDA's reasonable determination is consistent with the purpose and policy behind the fee waiver restrictions and should be accorded deference. Under Winston's interpretation, by contrast, a person could create and dissolve successive entities and secure multiple small business fee waivers for NDAs, an outcome the Act expressly forbids. An entity and its affiliates may only obtain one small business fee waiver, and then only for the first NDA that entity or its affiliates submit to FDA. 21 U.S.C. § 379(d)(1)(D).

For the foregoing reasons the Court should grant the government's motion and dismiss the Complaint.

Of Counsel:

DAVID S. CADE
Acting General Counsel
U.S. Dept. of Health & Human Services

MICHAEL M. LANDA
Acting Associate General Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

JOHN H. FUSON
Associate Chief Counsel, Litigation
Office of the General Counsel
5600 Fishers Lane, GCF-1
Rockville, MD 20857
301-827-1190
john.fuson@fda.hhs.gov

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Respectfully submitted,

PATRICK J. FITZGERALD
United States Attorney

By: /s David R. Lidow
DAVID R. LIDOW
Assistant United States Attorney
Northern District of Illinois
219 South Dearborn Street, Suite 500
Chicago, Illinois 60604
(312) 886-1390

MARK JOSEPHS
Trial Attorney
Office of Consumer Litigation
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
Tel: 202-305-3630
mark.josephs@usdoj.gov