**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| NU-PHARM INC.<br>50 Mural Street, Units 1 and 2<br>Richmond Hill, Ontario L4B I E4,<br><br>Plaintiff,<br>v.<br><br>FOOD AND DRUG ADMINISTRATION<br>5600 Fishers Lane<br>Rockville, Maryland 20857,<br><br>MICHAEL O. LEAVITT<br>Secretary of Health and Human Services<br>200 Independence Avenue, S.W.<br>Washington, D.C. 20201, and<br><br>ANDREW C. VON ESCHENBACH, M.D.<br>Commissioner of Food and Drugs<br>5600 Fishers Lane<br>Rockville, Maryland 20857,<br><br>Defendants. | Case No. 08-cv-00070 (RWR) |

**MEMORANDUM IN SUPPORT OF NU-PHARM'S MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**

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Dated: January 15 , 2008

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Nu-Pharm Inc. ("Nu-Pharm") respectfully submits this brief in support of its motion for a temporary restraining order and/or preliminary injunction requiring FDA to immediately award final approval for Nu-Pharm's Abbreviated New Drug Application ("ANDA") No. 77-615 for divalproex sodium delayed-release 500 mg tablets.[1]

## INTRODUCTION

Nu-Pharm is entitled to immediate final approval for its ANDA for divalproex sodium delayed-release 500 mg tablets—a prescription drug currently marketed solely by Abbott under the brand-name Depakote.® Nu-Pharm has satisfied all substantive requirements for final approval under the generic drug approval provisions of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). The FFDCA expressly mandates that FDA "shall" make Nu-Pharm's approval effective immediately upon expiration of the 30-month stay unless the "district court" hearing the "action" that "is brought [within the 45-day period] for infringement of the patent that is the subject of the certification" decides that the patent has been infringed. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Here, Nu-Pharm's 30-month stay of approval has expired, and the district court hearing the only patent infringement action filed against Nu-Pharm for its proposed divalproex sodium product has not issued any substantive rulings of patent validity or infringement. FDA therefore has no lawful basis or authority to deny Nu-Pharm approval.

FDA nonetheless refuses to grant final approval to Nu-Pharm's ANDA, purportedly based on an order entered in a contempt proceeding in a wholly separate patent infringement action involving an entirely different ANDA and an entirely different applicant—

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[1] In the event the Court denies such relief, Nu-Pharm respectfully moves for emergency relief pending appellate review. Specifically, in the event the Court denies Nu-Pharm's request for emergency injunctive relief, Nu-Pharm respectfully requests that any adverse FDA decision be stayed and that Nu-Pharm's 500 mg product be finally approved pending review by, and appeal of this matter to, the United States Court of Appeals for the D.C. Circuit, in order to prevent devastating and irreparable harm to Nu-Pharm.

an action and proceeding to which Nu-Pharm was not a party and did not participate. FDA's decision is arbitrary, capricious, and contrary to law, in clear violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A). Under the only proper construction of the FFDCA, Nu-Pharm's divalproex sodium 500 mg ANDA is entitled to immediate final approval. Indeed, the plain language compels this result. Consequently, Nu-Pharm has a strong likelihood of succeeding on the merits of its claim. Furthermore, Nu-Pharm will suffer severe and irreparable harm absent the requested relief; the balance of harm weighs in favor of granting this relief; and such relief is in the public interest. Accordingly, this Court should enter a temporary restraining order and/or preliminary injunction requiring FDA to award immediate final approval to Nu-Pharm's ANDA for divalproex sodium 500 mg tablets, which will permit Nu-Pharm to begin marketing its lower-priced generic product promptly after the expiration of Abbott's patents on January 29, 2008.[2]

## BACKGROUND

### I. Statutory Background.

This action arises under the FFDCA, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("Hatch-Waxman") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, § 1102(b)(1), Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) ("MMA").

[2] Nu-Pharm does not seek to, and will not, market its product until *after* expiration of Abbott's patents on January 29, 2008. (*See* Rakoczy Decl. Ex. D, Benyak Decl. ¶ 6 n.1.)

**A. Brand Drugs – NDAs And Patent Listing Requirements.**

A company that seeks to sell a new drug must file with FDA a New Drug Application ("NDA"). The applicant must include in its NDA, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results establishing its safety and effectiveness, and labeling describing the use for which approval is requested. *See* 21 U.S.C. § 355(b)(1). The applicant also must submit information to FDA with respect to any patent that "claims the drug for which the application was submitted or which claims a method of using such drug . . . ." *Id.*; *see also* 21 U.S.C. § 355(c)(2). FDA publishes all such patent information in the "Orange Book." *See* 21 C.F.R. § 314.53(e).

**B. Generic Drugs – ANDAs And Patent Certifications.**

Before 1984, a company seeking to market a generic version of an FDA-approved NDA drug had to complete expensive and time-consuming safety and efficacy studies on the drug, even though the NDA-holder already had established the drug's safety and efficacy. In 1984, Congress simplified the procedure for obtaining approval of generic drugs with the Hatch-Waxman Amendments to the FFDCA. Under Hatch-Waxman, "an abbreviated new drug application process allows applicants . . . to proceed more quickly to the marketplace." *Teva Pharms. USA, Inc. v. FDA*, 182 F.3d 1003, 1004 (D.C. Cir. 1999).

An ANDA applicant must establish that its generic drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A). The ANDA also must include a "certification" to any properly-listed Orange Book patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii). The statute provides four certification options, only one of which is relevant here: that the listed patent is invalid and/or will not be infringed by the proposed drug, a so-called "paragraph IV certification." *Id.* With certain exceptions not applicable here, an ANDA applicant seeking FDA approval to market its generic drug prior to the expiration of the Orange Book-listed patent

must submit a paragraph IV certification and notify the patentee and NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B). The submission of an ANDA with a paragraph IV certification constitutes a technical act of infringement under 35 U.S.C. § 271(e)(2)(A), which permits the patent owner to file, and a district court to adjudicate, a suit to determine whether the proposed generic drug infringes the subject patent before the drug has actually been marketed.

The timing of ANDA approval depends, in part, on whether such a suit is filed by the patent owner within 45 days of receiving notice of the ANDA and paragraph IV certification. The statute reads in relevant part:

> If the applicant made a [paragraph IV certification], *the approval **shall** be made effective immediately unless,* before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, *an action is brought for infringement of the patent that is the subject of the certification* and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, *the approval **shall** be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)* or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –
>
> (II) if before the expiration of such period the district court decides that the patent has been infringed . . . .

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added).

Thus, where the applicant submits an ANDA with a paragraph IV certification, FDA "shall" make the approval effective immediately, unless "an action is brought for infringement of the patent that is the subject of the certification." *Id.* If such "action" is brought within the 45-day period after the patent owner and NDA-holder receive notice of the paragraph IV ANDA, "the approval shall be made effective upon the expiration of the thirty-month period

beginning on the date of the receipt of the notice." *Id.* This instruction is mandatory—FDA has no discretion because the approval "*shall* be made effective" upon expiration of the 30-month stay. *Id.* (emphasis added). The only relevant exception is where "the district court" hearing the "action" that "is brought [within the 45-day period] for infringement of the patent that is the subject of the certification" decides that the patent is infringed before the expiration of the 30-month stay.[3] Only in these circumstances may FDA further delay or withhold approval. *See id.*; *see also* Rakoczy Decl. Ex. A, 2004 FDA Draft Guidance at 5)[4] (acknowledging that approval may be delayed based on an order by "the district court hearing a patent infringement suit resulting from a paragraph IV certification"); 21 C.F.R. § 314.94(a)(12)(viii)(A) (requiring ANDA applicant to amend its patent certification "if a final judgment in the action against the applicant is entered finding the patent to be infringed.").

## II. Factual Background.

### A. Abbott's Depakote® (Divalproex Sodium) And Orange Book Patents.

At issue here is the prescription drug divalproex sodium, which Abbott currently markets under the brand-name Depakote®. FDA first approved Depakote® on March 10, 1983, for the treatment of epilepsy. Abbott submitted information to FDA on two patents for listing in the Orange Book in connection with Depakote®: U.S. Patent Nos. 4,988,731 ("the '731 patent") and 5,212,326 ("the '326 patent"). (*See* Rakoczy Decl. Ex. B, Depakote® Orange Book Listing.) Both the '731 and '326 patents naturally expire on January 29, 2008. Abbott also has been

[3] The court may also delay approval based on the parties' failure to cooperate in expediting the action, or if a preliminary injunction is entered, 21 U.S.C. § 355(j)(5)(B)(iii), but neither is applicable here.

[4] All references to "Rakoczy Decl." herein refer to the Declaration of William A. Rakoczy, submitted concurrently herewith.

awarded a period of pediatric exclusivity in connection with its Depakote® products that, to the extent applicable, expires July 29, 2008.[5] (*See id.*)

**B. Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium Delayed-Release Tablets, 500 mg.**

On March 7, 2005, Nu-Pharm submitted ANDA No. 77-615 for divalproex sodium delayed-release tablets in the 500 mg strength.[6] (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 3.) Nu-Pharm has satisfied all substantive requirements for approval. (*Id.*) Nu-Pharm's ANDA contains a paragraph IV certification to both the '731 and '326 patents. (*Id.* ¶ 4.) Nu-Pharm's ANDA also designates and identifies Apotex Inc. of Ontario, Canada, as the contract manufacturer for the finished drug product. (*Id.* ¶ 3.) As required by statute and regulation, Nu-Pharm duly notified Abbott of its paragraph IV certifications, along with the legal and factual bases for its certifications, in a notice letter received by Abbott on May 13, 2005. (*Id.* ¶ 4.) In response, on June 24, 2005, Abbott sued Nu-Pharm for alleged infringement of the '731 and '326 patents under 35 U.S.C. § 271(e)(2)(A) in the United States District Court for the Northern District of Illinois, Eastern Division (hereinafter, "the *Nu-Pharm* action" or "the *Nu-Pharm* Court"). *See Abbott Labs. v. Nu-Pharm Inc.*, No. 05-3714 (N.D. Ill.) (Pallmeyer, J.) This action triggered a 30-month stay of FDA approval of Nu-Pharm's 500 mg tablet ANDA, which expired

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[5] This period of pediatric exclusivity can apply only to ANDAs that do not have final effective approval before the natural expiration of the '731 and '326 patents on January 29, 2008. (*See* Rakoczy Decl. Ex. C, Apr. 18, 2007 FDA Letter to Amlodipine Besylate ANDA Applicants, at 5 n.4 (citing 21 U.S.C. § 355a) (concluding that ANDAs with final approval upon patent expiration are "not blocked by [a brand manufacturer's] pediatric exclusivity . . . under the literal terms of the [pediatric exclusivity] statute")); *see also Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 120-21 (D.D.C. 2007).

[6] Nu-Pharm subsequently amended its divalproex sodium ANDA to also include the 125 mg and 250 mg strengths. Those products, however, are not at issue here and, therefore, are not further addressed.

on November 13, 2007—30 months after Abbott received Nu-Pharm's notice of paragraph IV certification.

The *Nu-Pharm* action is the one and only patent infringement action that Abbott filed in response to the submission of Nu-Pharm's paragraph IV ANDA. The *Nu-Pharm* Court has not entered any substantive rulings or orders on the merits of the patent infringement dispute, and certainly has not made any determination of patent infringement or validity. In fact, as discussed below, on October 16, 2006, the *Nu-Pharm* Court stayed the *Nu-Pharm* action in its entirety pending resolution of contempt proceedings against an unrelated third-party (Apotex) in another matter involving the same patents but a different ANDA, also discussed below. (*See* Rakoczy Decl. Ex. E, Oct. 16, 2006 Docket Entry.) To date, the *Nu-Pharm* action remains stayed. (*See id.* Ex. F, Oct. 31, 2007, Jan. 4, 2008, and Jan. 14, 2008 Docket Entries.)

### C. Contempt Proceedings Against Apotex In *Abbott v. Apotex*, No. 97-7515 (N.D. Ill.), *To Which Nu-Pharm Was Not And Is Not A Party.*

In a contempt proceeding in a wholly separate action against a different generic company (Apotex), *to which Nu-Pharm is not and was* ***not*** *a party*, a different district court "extended" an injunction order involving an entirely different ANDA filed by Apotex (ANDA No. 75-112) to cover Nu-Pharm's ANDA No. 77-615. *See Abbott Labs. v. Apotex, Inc.*, 455 F. Supp. 2d 831, 840 (N.D. Ill. 2006); *see also* Rakoczy Decl. Ex. G, Oct. 6, 2006 Docket Entry and Injunction Order, entered in *Abbott Labs. v. Apotex, Inc.*, No. 97-7515 (N.D. Ill.) (Posner, J.) (hereinafter "the *Apotex* Court" or "the *Apotex* action"). The *Apotex* Court also ordered that the effective date of approval of the Nu-Pharm ANDA No. 77-615 shall not be earlier than expiration of the '731 and '326 patents on January 29, 2008. (*See* Rakoczy Decl. Ex. G, Oct. 6, 2006 Injunction Order.) Significantly, however, Nu-Pharm was not and is not a party to the *Apotex* action in any manner. Nor did the *Apotex* action arise from the filing of Nu-Pharm's

paragraph IV ANDA. Rather, the *Apotex* action involved, and jurisdiction was based on, a completely different paragraph IV ANDA filed by Apotex, ***not*** *Nu-Pharm*.

By way of background, the *Apotex* action arises out of the April 1997 submission of Apotex's ANDA No. 75-112 for divalproex sodium delayed-release tablets. Apotex's ANDA No. 75-112 also included paragraph IV certifications to the '731 and '326 patents. In response, Abbott sued Apotex for alleged infringement in Illinois. After a trial and two appeals, the Apotex ANDA was eventually held to infringe the '731 and '326 patents. *See Abbott Labs. v. TorPharm, Inc.*, 309 F. Supp. 2d 1043, 1054 (N.D. Ill. 2004).[7] As a result, the *Apotex* Court entered an order enjoining the commercial manufacture, sale, and use of the products described in Apotex's ANDA No. 75-112, and also delayed the effective date of approval, until expiration of Abbott's '731 and '326 patents on January 29, 2008. The original order states:

> TorPharm, Inc., Apotex, Inc., and Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing within the United States, or from importing such product into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.
>
> The effective date of any approval by FDA of ANDA No. 75-112, or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,316.

(Rakoczy Decl. Ex. H, March 31, 2004 Injunction Order). But once again, Nu-Pharm was never a party to—and never participated in—the *Apotex* action, which was completed before Nu-Pharm ever submitted its own ANDA.

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[7] The Federal Circuit subsequently affirmed this judgment without opinion on February 14, 2005. *See Abbott Labs. v. TorPharm, Inc.*, 122 Fed. Appx. 511, 2005 WL 406563 at *1 (Fed. Cir. Feb. 14, 2005), *reh'g denied*, Mar. 9, 2005.

After the completion of fact discovery in the current and unrelated *Nu-Pharm* action, NuPharm filed a motion for summary judgment of non-infringement before the *Nu-Pharm* Court. That same day, however, rather than respond to Nu-Pharm's summary judgment motion, Abbott initiated contempt proceedings in the old *Apotex* action against Apotex.[8] In particular, Abbott filed a motion to enforce the prior injunction order against Apotex in the *Apotex* action, and requested that the *Apotex* Court "extend" its injunction over Apotex's old ANDA No. 75-112 to cover and "embrace" Nu-Pharm's wholly separate ANDA No. 77-615. Abbott also filed a motion to stay the *Nu-Pharm* action, which the *Nu-Pharm* Court subsequently granted, and the *Nu-Pharm* action has been stayed ever since. (*See* Rakoczy Decl. Ex. I, Aug. 17, 2006 Docket Entry; *see also id.* Exs. E and F.)

Meanwhile, the *Apotex* Court conducted a one-day summary contempt proceeding in the *Apotex* action, and refused to allow Apotex any time to conduct additional testing and to submit additional evidence. Again, Nu-Pharm was not a party to the *Apotex* action and did not participate in the contempt proceedings to any extent.

On October 6, 2006, despite the fact that Nu-Pharm was not a party to the *Apotex* action or the contempt proceedings, the *Apotex* Court nonetheless granted Abbott's motion, entered a contempt order, and "extend[ed] the injunction" over Apotex's ANDA to cover and "embrace" Nu-Pharm's ANDA as well. *Abbott Labs.*, 455 F. Supp. 2d at 840; Rakoczy Decl. Ex. G, Oct. 6, 2006 Docket Entry. The *Apotex* Court's "extended injunction" states:

> Apotex, Inc., Apotex Corp., and their respective affiliates, successors in interest, and assigns are enjoined from commercially manufacturing, using, selling, or offering to sell generic divalproex sodium which the Court has found to be infringing, including divalproex sodium products synthesized using the processes employed in connection with ANDA No. 77-615, within the United States, or

[8] Abbott clearly did so because Nu-Pharm's summary judgment motion contained unequivocal evidence of non-infringement.

> from importing such products into the United States, until Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326 expire and defendants have received final approval from FDA to market generic divalproex sodium.
>
> The effective date of any approval by FDA of ANDA Nos. 75-112 and 77-615, or any other application concerning defendants' generic divalproex sodium which the Court has found to be infringing, shall be no earlier than January 29, 2008, the date of expiration of Abbott's U.S. Patent Nos. 4,988,731 and 5,212,326.

(Rakoczy Decl. Ex. G, Oct. 6, 2006 Injunction Order.) While this new order does not mention Nu-Pharm by name, it does identify Nu-Pharm's ANDA No. 77-615.

Apotex timely appealed the contempt order and new injunction to the Federal Circuit. On October 11, 2007, the Federal Circuit rightly reversed the *Apotex* Court's finding of contempt against Apotex because the injunction did not preclude or otherwise forbid the filing of another ANDA by Nu-Pharm or Apotex. *See Abbott Labs. v. TorPharm, Inc.*, 503 F.3d 1372, 1382-83 (Fed. Cir. 2007). The Federal Circuit, however, affirmed the extension of the injunction to cover Nu-Pharm's ANDA. *Id.* at 1381. The Federal Circuit recently denied Apotex's petition for rehearing *en banc*. Apotex has filed a petition for a writ of *certiorari* to the United States Supreme Court. That petition remains pending.

### D. FDA Unlawfully Refuses To Award Nu-Pharm Final Approval For Its Divalproex Sodium Delayed-Release 500 mg Tablets.

After the 30-month stay for Nu-Pharm's 500 mg product expired on November 13, 2007, Nu-Pharm requested, and expected to receive, final FDA approval. (*See* Rakoczy Decl. Ex. D, Benyak Decl. ¶ 6.) But on December 11, 2007, the Agency informed Nu-Pharm that it would not grant a final approval based on the order in the *Apotex* action. (*Id.* ¶ 6.) On December 21, 2007, Nu-Pharm made a detailed written submission requesting immediate final approval on the ground that FDA has no lawful basis or authority to withhold final approval where, as here, the 30-month stay has expired and the *Nu-Pharm* Court has not made any finding of infringement or validity. (*See* Rakoczy Decl. Ex. J, Dec. 21, 2007 Ltr. to Buehler). On

January 9, 2008, FDA informed Nu-Pharm that it would not issue such an approval solely based on the *Apotex* Court's order. (*See id.* Ex. D, Benyak Decl. ¶ 6.) Nu-Pharm now challenges this Agency decision.

## ARGUMENT

Courts must weigh four factors in deciding whether to grant a preliminary injunction or temporary restraining order: (1) the likelihood that the moving party will prevail on the merits; (2) the prospect of irreparable injury to the moving party if relief is withheld; (3) the possibility of substantial harm to other parties if relief is granted; and (4) the public interest. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998); *Raymen v. United Senior Ass'n*, No. 05-486(RBW), 2005 WL 607916, at *2 (D.D.C. Mar. 16, 2005) (granting temporary restraining order). The movant "need not prevail on each factor in order to receive injunctive relief." *Raymen*, 2005 WL 607916, at *2. "Rather . . . the factors must be viewed as a continuum, with more of one factor compensating for less of another. If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *Blackman v. Dist. of Columbia*, 277 F. Supp. 2d 71, 77-78 (D.D.C. 2003) (internal quotations and citation omitted) (granting preliminary injunction).

"[I]ssuing an injunction may be justified 'where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury.'" *Raymen*, 2005 WL 607916, at *2 (quoting *Blackman*, 277 F. Supp. 2d at 78). Moreover, "[i]n cases that raise questions 'going to the merits so serious, substantial, difficult and doubtful, as to make them fair ground . . . for more deliberative investigation,' . . . courts should eschew an 'exaggeratedly refined analysis of the merits at an early stage in the litigation.'" *Omar v. Harvey*, 416 F. Supp. 2d 19, 22 (D.D.C. 2006) (quoting *Wash. Metro. Area*

*Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 844 (D.C. Cir. 1977)). Nu-Pharm satisfies this standard here.

## I. Nu-Pharm Has A Substantial Likelihood Of Succeeding On The Merits Of Its Claims.

Under the APA, the Court must set aside FDA's decision because it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As FDA must concede, Nu-Pharm has satisfied all substantive requirements for final approval of its 500 mg product, and the only 30-month stay of FDA approval has expired. Moreover, the only relevant court—namely, the *Nu-Pharm* Court hearing the *Nu-Pharm* action arising out of Nu-Pharm's paragraph IV ANDA—has not entered any substantive orders, much less any finding of infringement. In these circumstances, the statute admits of no discretion, and mandates that FDA "shall" make Nu-Pharm's approval effective immediately. But FDA has withheld Nu-Pharm's final approval solely on the basis of a court order and injunction entered in the *Apotex* action to which Nu-Pharm was not and is not a party, and which arises from a paragraph IV ANDA filed by Apotex, not Nu-Pharm. Under the plain language of the statute and FDA's own precedent, the order entered against Apotex in the *Apotex* action cannot be used to delay Nu-Pharm's approval. FDA's decision therefore is arbitrary, capricious, and contrary to law.

*First*, FDA's decision runs afoul of the plain language of the FFDCA because the statute—properly interpreted in view of its plain language and its underlying purpose—requires FDA to award final approval to a pending ANDA as soon as the 30-month stay has expired, so long as the court hearing that ANDA applicant's patent case has entered no order delaying such approval. *Second*, FDA's decision departs from its own precedent, under which it has construed the statute to delay final ANDA approval based solely on an order from the court hearing the

patent infringement action arising from that applicant's paragraph IV ANDA. Indeed, to Nu-Pharm's knowledge, FDA has *never* found a court decision of either infringement or non-infringement in one ANDA-filer's litigation to open or close the market to other generic ANDA-filers for the same product. *Third*, FDA's decision and interpretation leads to fundamentally absurd and inconsistent results. And *fourth*, FDA's interpretation permits, and indeed encourages, improper gaming and manipulation of the statute. Nu-Pharm, therefore, has a strong likelihood of succeeding on the merits of its case.

### A. Under The Plain Language Of The FFDCA, FDA Has No Lawful Basis For Withholding Final Approval Of Nu-Pharm's ANDA No. 77-615 For Divalproex Sodium 500 mg Tablets.

To determine whether FDA's decision comports with the statute, this Court must determine first "whether Congress has directly spoken to the precise question at issue." *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. "When the statute is clear on its face, resort to the legislative history, much less to the agency's interpretation, is not necessary." *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1525 (D.D.C. 1989); *see also Bd. of Governors of Fed. Reserve Sys. v. Dimension Fin. Corp.*, 474 U.S. 361, 368 (1986) ("The traditional deference courts pay to agency interpretation is not to be applied to alter the clearly expressed intent of Congress."). Where the statute is clear and unambiguous, the Court "do[es] not defer to the agency's interpretation of the statute." *Mova*, 140 F.3d at 1068.

In this case, the intent of Congress could not be clearer: the statute expressly provides that, with certain exceptions not applicable here, if, "before the expiration of [the 45-day period], *an action is brought for infringement of the patent that is the subject of the certification . . . the approval* ***shall*** *be made effective upon the expiration of the thirty-month*

*[stay]*." 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). The only 30-month stay of Nu-Pharm's approval admittedly has expired, and no exception applies. Nu-Pharm therefore is entitled to immediate final approval under the plain and unambiguous language of the statute.

**1. Under the plain language of the FFDCA, FDA may delay approval if, and only if, the *Nu-Pharm* Court enters a finding and order of infringement in the *Nu-Pharm* action.**

"The preeminent canon of statutory interpretation requires [the courts] to presume that the legislature says in a statute what it means and means in a statute what it says there." *BedRoc Ltd., v. United States*, 541 U.S. 176, 183 (2004) (quotations and citation omitted). "When the words of a statute are unambiguous then, this first canon is also the last: judicial inquiry is complete." *Ranbaxy Labs., Ltd. v. Leavitt*, 459 F. Supp. 2d 1, 8 (D.D.C. 2006) (quoting *Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 254 (1992)). Here, Congress has spoken to the issue at hand. As such, this Court's analysis must begin and end with the plain language of the statute. *See Hughes Aircraft Co. v. Jacobson*, 525 U.S. 432, 438 (1999). The relevant provision states:

> If the applicant made a [paragraph IV certification], the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, *an action is brought for infringement of the patent that is the subject of the certification* . . . . If such an action is brought before the expiration of such days, *the* ***approval shall be made effective*** *upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i)* or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that –
>
> (II) if before the expiration of such period the district court decides that the patent has been infringed . . . .

21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added).

Under the plain language of the statute, where, as here, an applicant submits an ANDA with a paragraph IV certification, FDA "shall" make the approval effective immediately,

unless "an action is brought for infringement of the patent that is the subject of the certification." *Id.* If such an action is brought within the 45-day period after the patent owner and NDA-holder receive notice of the paragraph IV ANDA, "the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice." *Id.* This instruction is mandatory—the approval "*shall* be made effective" upon expiration of the 30-month stay. *Id.* (emphasis added).

As the Supreme Court has instructed, "[t]he word 'shall' is ordinarily the language of command." *Alabama v. Boseman*, 533 U.S. 146, 153 (2001) (internal quotations and citation omitted). The D.C. Circuit similarly has held, "[t]he word 'shall' generally indicates a command that admits of no discretion on the part of the person instructed to carry out the directive." *Ass'n of Civilian Technicians, Mont. Air Chapter No. 29 v. FLRA*, 22 F.3d 1150, 1153 (D.C. Cir. 1994); *see also Ass'n of Am. R.R.s v. Costle*, 562 F.2d 1310, 1312 (D.C. Cir. 1977) ("The word 'shall' is the language of command in a statute"). So, too, here. Unless a specific exception applies (and none do here), the statute imposes a mandatory duty and obligation upon FDA to approve the ANDA upon expiration of the 30-month stay.

The only relevant statutory exception, apparently invoked by FDA here, is where the "district court" hearing the "action [that] is brought [within the 45-day period] for infringement of the patent that is the subject of the certification . . . decides that the patent has been infringed." 21 U.S.C. § 355(j)(5)(B)(iii). But this exception does not, and indeed cannot, apply to the facts of this case. Congress went to great lengths to identify the particular "action" and "court" that matter for purposes of delaying approval. The only "action" referred to is the one that "is brought for infringement of the patent that is the subject of the certification," and even more specifically, the "action" brought "before the expiration of 45 days after the date on

which the [paragraph IV notice] is received." *Id.* In other words, for purposes of ANDA approval, the only action that matters is the one brought against the particular ANDA applicant within the 45-day period for infringement of the patent that is the subject of the applicant's paragraph IV certification.

Congress likewise employed specific language and context to identify the exact "court" that matters. It is not just *any* district court or "*a* district court," but rather "*the* district court" hearing the "action" that "is brought for infringement of the patent that is the subject of the certification," and also which is brought "before the expiration of 45 days after the date on which the [paragraph IV notice] is received." 21 U.S.C. § 355(j)(5)(B)(iii). *See SEC v. Nat'l Sec., Inc.*, 393 U.S. 453, 466 (1969) ("The meaning of particular phrases must be determined in context."). "It is a rule of law well established that the definite article 'the' particularizes the subject which it precedes. It is a word of limitation as opposed to the indefinite or generalizing force of 'a' or 'an.'" *Am. Bus Ass'n v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000) (quotation and citation omitted) (finding that agency lacked authority to authorize money damages under unambiguous terms of statute that set forth "the remedies" available to persons subject to discrimination); *see also Gates & Fox Co. v. Occupational Safety & Health Review Comm'n*, 790 F.2d 154, 156 (D.C. Cir. 1986) (Scalia, J.) (stating that, where regulation required self-rescuers on "'*the* haulage equipment,'--the definite article ['the'] suggest[s] that some specific haulage equipment is referred to, rather than merely haulage equipment in general"). In other words, the only relevant "district court" for purposes of delaying the date of effective ANDA approval under the statute is "*the* district court" hearing the patent infringement action filed under 35 U.S.C. § 271(e)(2)(A) by the patent owner and NDA-holder within the 45-day period against the ANDA applicant whose paragraph IV certification and notice gave rise to the suit.

The application of this statutory provision to Nu-Pharm's ANDA is straightforward and simple. Nu-Pharm filed an ANDA containing a paragraph IV certification and provided the requisite notice to Abbott, the NDA-holder and patent owner. Within 45 days of receiving that notice, Abbott filed the *Nu-Pharm* action for infringement of the patents that are the subject of Nu-Pharm's paragraph IV certification. The filing of the *Nu-Pharm* action stayed the approval of Nu-Pharm's ANDA for 30-months from the receipt of Abbott's notice of Nu-Pharm's paragraph IV certification. That 30-month period expired on November 13, 2007. Thus, Nu-Pharm's "approval *shall* be made effective" immediately unless "*the* district court" hearing the "action" that "is brought [within the 45-day period] for infringement of the patent that is the subject of the certification," decides that the patent has been infringed. 21 U.S.C. § 355(j)(5)(B)(iii) (emphasis added). In this case, of course, "the district court" and "action" refer solely to the *Nu-Pharm* Court and the *Nu-Pharm* action, respectively. The *Nu-Pharm* Court is the only court hearing the *Nu-Pharm* action that was brought by Abbott within the 45-day period for infringement of the patents that are the subject of Nu-Pharm's paragraph IV certifications. But the *Nu-Pharm* Court has not decided that the patents are infringed, and in fact has made no substantive rulings of any kind in the *Nu-Pharm* action.

The plain language of the statute, therefore, requires FDA to make Nu-Pharm's approval effective immediately. FDA has no lawful basis or authority to continue delaying Nu-Pharm's approval, and certainly not based on any order entered by the *Apotex* Court in the *Apotex* action. The *Apotex* Court admittedly is not the court hearing the action brought within the 45-day period based on Nu-Pharm's paragraph IV certification. The Agency's refusal to approve Nu-Pharm's ANDA therefore violates the plain and unambiguous language of the FFDCA and must thus be set aside.

**2. Courts have consistently interpreted the statute in accordance with its plain language.**

FDA's refusal to approve Nu-Pharm's 500 mg divalproex sodium tablets also conflicts with the manner in which courts have consistently interpreted the relevant terms of § 355(j)(5)(B)(iii). Indeed, courts always have construed the term "court" to mean the court that is hearing the infringement action that arises out of and is the subject of that particular ANDA applicant's paragraph IV certification. For example, in describing the framework of the statutory provision at issue here, the Eleventh Circuit stated:

> ***If the court hearing the infringement action*** declares the patent invalid or not infringed, this automatic [30-month] delay in FDA approval terminates, 21 U.S.C. § 355(j)(5)(B)(iii)(I), or, if ***the court*** finds the patent valid and infringed, the approval date will be set for a date on or after the patent's expiration, 21 U.S.C. § 355(j)(5)(B)(iii)(II); 35 U.S.C. § 271(e)(4)(A).

*Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1297 (11th Cir. 2003) (emphasis added). The Federal Circuit has interpreted the statute in similar fashion:

> If the patentee files suit within [the 45-day] period, the FDA may not approve the ANDA until the expiration of the patent, judicial resolution of the infringement suit, a judicial determination that the patent is invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever is earliest. ***The court in which the suit is pending*** may order a shorter or longer stay on the approval time, if 'either party to the action fails to reasonably cooperate in expediting the action.' 21 U.S.C. § 355(j)(5)(B)(iii).

*Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1327 (Fed. Cir. 2001) (emphasis added) (internal citation omitted).

The district courts agree. In *Purepac Pharmaceutical Co. v. Thompson*, 238 F. Supp. 2d 191 (D.D.C. 2002), where the proper interpretation of the statutory provisions governing paragraph IV certifications and their legal consequences were directly at issue, the court stated:

> If a suit is initiated, the FDA's approval of the ANDA is automatically stayed for 30 months, a period that can be lengthened or shortened ***by the court hearing the***

> *case* if either party fails to 'reasonably cooperate in expediting the action.' 21 U.S.C. § 355(j)(5)(B)(iii). If, before the expiration of the 30-month stay, ***the court*** finds that the patent is invalid or would not be infringed by the new drug, the FDA's approval of the ANDA becomes effective on the date of that ruling.

238 F. Supp. 2d at 194-95 (emphasis added). Similarly, in *Mylan Laboratories, Inc. v. Thompson*, 332 F. Supp. 2d 106 (D.D.C. 2004), the court explained:

> If the patent holder or NDA is successful in its lawsuit, that is, ***the court hearing the patent infringement litigation concludes that the patent is valid and infringed***, the Patent Code provides that 'the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.' 35 U.S.C. § 271(e)(4)(A).

332 F. Supp. 2d at 112 (emphasis added). Finally, in interpreting § 355(j)(5)(B)(iii) in connection with an ANDA applicant's filing of a paragraph IV certification and notice requirements, another court has stated:

> If the patentee files suit, the FDA may not approve the ANDA until the patent expires, judicial resolution of the infringement action, a judicial determination that the patent is either invalid or unenforceable, or thirty months from the patentee's receipt of notice, whichever occurs first. ***The Court in which the suit is pending has the authority to order a shorter or longer stay on the approval time***, if "either party to the action fail[s] to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

*Astrazeneca AB v. Mutual Pharm. Co.*, 221 F. Supp. 2d 528, 530 (E.D. Pa. 2002) (internal citations omitted) (emphasis added).

In sum, the courts uniformly agree that the only court that matters, and which may be used to delay approval, is the one that is hearing the action brought against the ANDA applicant within the 45-day period for infringement of the patent that is the subject of the certification—here, the *Nu-Pharm* Court hearing the *Nu-Pharm* action. No court has ever interpreted the statute otherwise, and certainly not in any manner that would authorize FDA to delay approval based on an order entered in an action to which Nu-Pharm is not even a party.

The bottom line is that the statute authorizes FDA to delay approval solely based on a determination by the *particular* court hearing the *particular* patent infringement action involving that *particular* ANDA applicant and that *particular* ANDA applicant's proposed product. No such court decision has been rendered in this case; the *Nu-Pharm* Court has entered *no* order of patent validity or infringement, and *no* injunction order. The Agency's refusal to approve Nu-Pharm's 500 mg ANDA therefore violates not only the plain language of the statute, but the courts' interpretation of the statute as well.

### B. FDA's Decision And Interpretation Cannot Be Squared With The Agency's Past Practice And Policies.

To Nu-Pharm's knowledge, FDA has never interpreted the term "court" or "action" in § 355(j)(5)(B)(iii) to mean separate, unrelated actions brought against other ANDA-filers. More specifically, FDA has never delayed one ANDA applicant's approval based on an unfavorable decision in another, unrelated action that did not arise out of that applicant's paragraph IV certification. Nor has FDA ever terminated a 30-month stay and approved one ANDA based on a finding of non-infringement in a separate patent case against another ANDA applicant. Moreover, there is no question that, had the *Apotex* Court rendered a decision in favor of Apotex and found that Apotex's or Nu-Pharm's divalproex sodium products did not infringe Abbott's patents, FDA would not have terminated Nu-Pharm's stay and approved Nu-Pharm's ANDA solely on that basis. For the same reason, FDA cannot lawfully delay Nu-Pharm's approval based solely on an order entered by the *Apotex* Court in the *Apotex* action. FDA's refusal to award final approval to Nu-Pharm's ANDA here is thus arbitrary and capricious in light of its administrative approvals for other ANDAs. *See Teva*, 182 F.3d at 1012 (finding that the Agency's refusal to treat a court dismissal as a trigger "was arbitrary and capricious in light of the FDA's response in another case").

Furthermore, FDA's administrative ruling conflicts directly with the Agency's prior interpretation of the statute, published in its 2004 draft Guidance for Industry and in its own regulations. Specifically, in FDA's October 2004 draft Guidance, entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003," the Agency expressly opined on "[w]hat court decisions and other judicial actions are relevant for lifting 30-month stays of approval on ANDAs." (Rakoczy Decl. Ex. A, 2004 FDA Draft Guidance at 3.) FDA interpreted § 355(j)(5)(B)(iii), in part, as follows:

> ***If the district court hearing a patent infringement suit resulting from a paragraph IV certification*** decides that the patent at issue is infringed, and this decision is not appealed or is affirmed on appeal, the ANDA . . . may be approved based on the district court's ruling in accordance with the patent's expiration and any extension or exclusivity that remains.

(*Id.* at 5) (emphasis added). FDA thus confirmed that the statutory text of § 355(j)(5)(B)(iii), as amended by the MMA, supports just one interpretation: namely, that only a decision of infringement by the district court hearing the patent infringement action resulting from the ANDA-filer's paragraph IV certification may delay final approval of that applicant's ANDA.

This interpretation comports with the plain language of the statute and the manner in which courts have consistently interpreted the terms of this statutory provision. It also comports with the Agency's own implementing regulations, which provide that an ANDA applicant shall amend its patent certification "if a final judgment ***in the action against the applicant*** is entered finding the patent to be infringed." 21 C.F.R. § 314.94(a)(12)(viii)(A) (emphasis added). Once again, the focus is on the district court hearing the infringement action arising out of the ANDA applicant's patent certification—in this case, again, the *Nu-Pharm* Court hearing the *Nu-Pharm* action.

FDA may not depart from its earlier statutory constructions without providing a reasoned basis for doing so. *See Bush-Quayle '92 Primary Comm., Inc. v. Fed. Election Comm'n*, 104 F.3d 448, 453 (D.C. Cir. 1997) ("[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored . . . ." (citation omitted)); *Columbia Broad. Sys., Inc. v. FCC*, 454 F.2d 1018, 1026 (D.C. Cir. 1971) ("[W]hen an agency decides to reverse its course, it must provide an opinion or analysis indicating that the standard is being changed and not ignored, and assuring that it is faithful and not indifferent to the rule of law."). But FDA has provided no basis, much less a reasoned one, for ignoring its prior precedent and interpretation and delaying Nu-Pharm's approval based on the *Apotex* Court's order. FDA's failure to provide justification for its current administrative position in light of its prior statutory construction is arbitrary, capricious, and contrary to law. *See Bush-Quayle '92 Primary Comm.*, 104 F.3d at 453; *Columbia Broad. Sys.*, 454 F.2d at 1026.

### C. FDA's Interpretation Leads To Absurd And Inconsistent Results.

As courts consistently have held, "FDA must interpret the statute to avoid absurd results and further congressional intent." *Teva*, 182 F.3d at 1011; *see also Phillips v. Saratoga Harness Racing, Inc.*, 240 F.3d 174, 179 (2d Cir. 2001) ("[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.") (internal quotations and citation omitted). "In deciding whether a result is absurd, [courts] consider not only whether that result is contrary to common sense, but also whether it is inconsistent with the clear intentions of the statute's drafters—that is, whether the result is absurd when considered in the particular statutory context." *Mova*, 140 F.3d at 1068.

In this case, FDA's interpretation is both: it is contrary to common sense and inconsistent with Congressional intent. By delaying Nu-Pharm's approval based on an order entered in another action to which Nu-Pharm is not even a party, FDA effectively has interpreted the phrase "*the* district court" to mean *any* court, and completely divorced that phrase from the context in which Congress used it in the statute. That, FDA may not do. *See Nat'l Securities, Inc.*, 393 U.S. at 466 ("The meaning of particular phrases must be determined in context."). In addition to impermissible re-writing of the statute, *see Mova*, 140 F.3d at 1068 (finding that through an agency's power to interpret, the "agency does not thereby obtain a license to rewrite the statute"), FDA's interpretation also leads to absurd results that Congress could not possibly have intended. For example, under FDA's interpretation, a judgment of infringement against an ANDA applicant in one action could be used to delay approval of other ANDA applicants in other actions. On the flip-side, FDA could also use a favorable decision for an ANDA applicant in one case to terminate the 30-month stays of other ANDA applicants in other cases. All of this, of course, turns the entire Hatch-Waxman system on its head, and could not have been contemplated or intended by Congress.

In sum, Congress made plain, through unambiguous language, that an applicant's approval is subject to delay solely by its own court action, not the court actions of other ANDA-filers. Likewise, Congress made clear that an NDA-holder's remedy against an ANDA applicant lies in the action against that applicant—*not* in unrelated actions to which that applicant is not a party. FDA's interpretation not only violates the plain language of the statute, but also leads to absurd results and abuses that are "'demonstrably at odds' with Congressional intent." *See Mylan*, 81 F. Supp. 2d at 42.

### D. FDA's Interpretation Permits, And Indeed Encourages, Improper Gaming And Manipulation Of The Statute.

The courts repeatedly have struck down FDA's interpretations of Hatch-Waxman that permit the brand company to manipulate and game the system. *See, e.g., Inwood Labs.*, 723 F. Supp. at 1527 (rejecting FDA's interpretation that "subject[ed] the exclusivity entitlement to the caprices of the patent holder"); *Ranbaxy Labs. v. Leavitt*, 469 F.3d 120, 125-26 (D.C. Cir. 2006) (rejecting FDA policy that "allows an NDA holder, by delisting a patent, to deprive the generic applicant of a period of marketing exclusivity"); *see also Teva*, 182 F.3d at 1009 (questioning statutory interpretation that allows the patentee to "manipulate the system in order to block or delay generic competition"). The Court should do so here as well.

FDA's interpretation allows, and indeed encourages, blatant manipulation and gaming of the system. In particular, FDA effectively has allowed Abbott to forestall generic competition upon expiration of its patents through a contempt proceeding against an unrelated applicant, without ever obtaining an order against Nu-Pharm in the patent litigation that Congress intended for resolution of Hatch-Waxman patent disputes. On its face, the statute already provides NDA-holders with the means of delaying final ANDA approval for a period of up to 30 months just by filing an infringement action against a paragraph IV ANDA-filer within 45 days of receiving notice of the applicant's certification. FDA's interpretation, however, impermissibly rewards an NDA-holder for attempting to escape a finding of non-infringement in the patent infringement action *it filed* against a particular ANDA applicant by running to an entirely different district court to extend an injunction order over an entirely different ANDA-filer and an entirely different ANDA product. Such an outcome would be particularly unjust in this case, as Abbott's scheme was an obvious attempt to avoid Nu-Pharm's summary judgment

motion and a trial on the merits in the *Nu-Pharm* action. The only way to prevent such manipulation is to interpret the statute how it was written and intended by Congress.

## II. Nu-Pharm Will Suffer Substantial And Irreparable Harm If An Injunction Is Not Entered.

"[W]hether or not [Nu-Pharm] has suffered irreparable injury, if it makes out its case under the APA it is entitled to a remedy." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001). Of course, Nu-Pharm has not only made its case on the merits under the APA, but it will suffer irreparable injury absent immediate injunctive relief from this Court.

"[T]imely entry into the market is critical for success in this marketplace." *TorPharm, Inc. v. Shalala*, No. Civ.A. 97-1925(JR), 1997 WL 33472411, at *4 (D.D.C. Sept. 15, 1997) (awarding injunctive relief to ANDA applicant whose approval was withheld under FDA's unlawful construction of the court decision trigger provision); *see also Teva*, 182 F.3d at 1011 n.8 (noting that Teva and Purepac would "face continued harm because of their denied access to the market"). Nu-Pharm can achieve timely entry here—shortly after the expiration of Abbott's patents on January 29, 2008—only with immediate injunctive relief from this Court. Absent such relief, Nu-Pharm's market entry will be delayed for at least another six months, resulting in devastating and unrecoverable financial loss and the effective destruction of Nu-Pharm's only U.S. business opportunity. (*See* Rakoczy Decl. Ex. D, Benyak Decl. ¶¶ 7, 9-10.)

Nu-Pharm is a small Canadian-based pharmaceutical company that markets and sells generic drug products primarily in niche markets in Canada. (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 2.) Nu-Pharm's 500 mg divalproex sodium product is the company's first and only U.S. business opportunity. (*Id.* ¶ 3.) To capitalize on that opportunity, Nu-Pharm requires final approval before the natural expiration of Abbott's patents, which would permit Nu-Pharm to

begin marketing with very few competitors shortly after patent expiration, rather than waiting an additional six months for the expiration of Abbott's pediatric exclusivity. (*Id.* ¶ 7; *see also* Rakoczy Decl. Ex. C, Apr. 18, 2007 FDA Letter to Amlodipine Besylate ANDA Applicants, at 5 n.4 (noting that generic applicant with final approval prior to natural patent expiration is not subject to pediatric exclusivity).)[9] In these circumstances, even with an authorized generic product on the market, in the first year alone, Nu-Pharm expects to generate revenues of at least $139 million if permitted to launch shortly after the expiration of Abbott's patents. (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 8.) This would be, to say the least, an enormous generic opportunity and company-transforming event for Nu-Pharm in the U.S. market. (*Id.* ¶ 7.)

But without such approval before patent expiration, Nu-Pharm will be forced to await the expiration of Abbott's six-month period of pediatric exclusivity. In that event, Nu-Pharm will face generic competition from at least another half dozen generic applicants, most if not all of whom have considerably more market advantages and established relationships with customers, as well as a far larger number of sales representatives, that would effectively eliminate Nu-Pharm's investment and ability to compete in the ultra-competitive U.S. market. (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 7.) Under such a scenario, Nu-Pharm's projected revenues would not exceed $6.5 million—a total loss of over $132.5 million in sales during Nu-Pharm's first full year on the market. (*Id.* ¶ 9.) Such losses are completely unrecoverable from FDA, and in fact will effectively destroy Nu-Pharm's U.S. business. (*Id.*)

Furthermore, apart from the lost opportunity for significant and company-transforming divalproex sodium sales, Nu-Pharm also will suffer unquantifiable losses and harm

[9] Indeed, the pediatric exclusivity statute itself provides that such exclusivity applies if, and only if, ". . . *in the patent infringement litigation resulting from the [paragraph IV] certification* the court determines that the patent is valid and would be infringed . . . ." 21 U.S.C. § 355a(b)(1)(B)(ii) (emphasis added).

to its business and reputation. (Rakoczy Decl. Ex. D, Benyak Decl. ¶ 10.) This is Nu-Pharm's first foray into the ultra-competitive generic market in the United States. Should an injunction not issue, Nu-Pharm will lose access to major customers and contracts, as well as suffer a loss of goodwill that will adversely affect Nu-Pharm's ability to compete in the United States. (*Id.*) Given Nu-Pharm's position as a new-comer to the market, these losses are "so severe as to cause extreme hardship to [Nu-Pharm's] business or threaten its very existence" and constitute imminent, significant and irreparable harm. *See Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26, 32 (D.D.C. 2006) (internal quotation and citation omitted); *see also TorPharm*, 1997 WL 33472411, at *4 (finding that loss in sales contingent upon plaintiff obtaining immediate approval of its ANDA were "imminent, serious, and irretrievable" and sufficed to show irreparable injury).

**III. The Balance Of Harms Weighs In Favor Of Nu-Pharm.**

FDA has no commercial stake in the outcome of this dispute. As a governmental agency, FDA is tasked with carrying out its duties consistent with the faithful and coherent interpretation of the FFDCA. FDA's interests thus are aligned with the public's interest which strongly favors injunctive relief. Yet, absent injunctive relief, Nu-Pharm stands to lose its entire U.S. business, including $132.5 million in sales, goodwill with potential customers, and other significant tangible and intangible benefits.

Moreover, if the Court grants injunctive relief, Abbott will suffer no losses which it would not naturally suffer under a proper interpretation of the statute. Abbott has failed to obtain a court decision of infringement against Nu-Pharm in the *Nu-Pharm* action, which remains pending. Abbott itself moved to stay that action while instead opting to seek relief in the *Apotex* action—all for the express purpose of avoiding any adverse disposition in the *Nu-Pharm* action. Abbott therefore has no cause to complain of harm, especially since its patents and 25-year Depakote® monopoly are set to naturally expire on January 29, 2008, in any case.

Accordingly, the balance of harms tips decidedly in favor of granting Nu-Pharm's request for a temporary restraining order and/or preliminary injunction.

**IV. An Injunction Would Further The Public Interest.**

The public interest is best served by granting the requested injunctive relief. First, the public's interest lies in the "faithful application of the laws," *Mova*, 140 F.3d at 1066, which, here, is served by requiring the Agency to apply the governing statute in a manner that is consistent with its plain language as well as its purpose, which seeks to expedite full generic competition and prevent the patentee from "manipulat[ing] the system in order to block or delay generic competition." *Teva*, 182 F.3d at 1009. Second, injunctive relief comports with FDA's regulations, past practices, and policies. Third, injunctive relief will provide consumers with a generic alternative to a widely-used anti-epileptic for which no generic product has been available for nearly 25 years. Thus, the public interest clearly favors entry of the injunctive relief requested by Nu-Pharm.

**CONCLUSION**

Nu-Pharm has made the requisite showing for immediate injunctive relief. FDA's refusal to award final approval to Nu-Pharm's 500 mg divalproex sodium tablets is based on an absurd and incoherent interpretation of the statute, in contravention of the statute's plain language, the overriding purpose of Hatch-Waxman, and FDA's own precedent. FDA had, and still has, no lawful basis to withhold Nu-Pharm's final approval, and the Agency's decision must be set aside as arbitrary, capricious and contrary to law. Nu-Pharm therefore has made its case on the merits under the APA and is entitled to relief. Nu-Pharm also will suffer devastating and irreparable harm to its U.S. business absent an injunction. Accordingly, the Court should order FDA to immediately award final approval to Nu-Pharm's divalproex sodium delayed-released 500 mg tablets under ANDA No. 77-615.

In the event the Court denies such relief, Nu-Pharm respectfully moves for emergency relief pending appellate review. Specifically, in the event the Court denies Nu-Pharm's request for emergency injunctive relief, Nu-Pharm respectfully requests that any adverse FDA decision be stayed and that Nu-Pharm's 500 mg product be finally approved pending review by, and appeal of this matter to, the United States Court of Appeals for the D.C. Circuit, in order to prevent devastating and irreparable harm to Nu-Pharm.

Dated: January 15, 2008.

Respectfully submitted,

NU-PHARM INC.

By: */s/ William A. Rakoczy*
One of its attorneys

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**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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|---|---|
| NU-PHARM INC.<br>50 Mural Street, Units 1 and 2<br>Richmond Hill, Ontario L4B I E4,<br><br>Plaintiff,<br>v.<br><br>FOOD AND DRUG ADMINISTRATION<br>5600 Fishers Lane<br>Rockville, Maryland 20857,<br><br>MICHAEL O. LEAVITT<br>Secretary of Health and Human Services<br>200 Independence Avenue, S.W.<br>Washington, D.C. 20201, and<br><br>ANDREW C. VON ESCHENBACH, M.D.<br>Commissioner of Food and Drugs<br>5600 Fishers Lane<br>Rockville, Maryland 20857,<br><br>Defendants. | Case No. 08-cv-00070 (RWR) |

**DECLARATION OF WILLIAM A. RAKOCZY**

I, William A. Rakoczy, declare as follows:

1. I am William A. Rakoczy, a partner of Rakoczy Molino Mazzochi Siwik LLP, counsel for Plaintiff Nu-Pharm Inc. ("Nu-Pharm") in this matter.

2. I am a practicing attorney and am a member in good standing of the bars of the District of Columbia (2004) and the State of Illinois (1995), as well as the following courts: United States Supreme Court (2003); the United States Courts of Appeals for the Fourth Circuit (2005), the Third Circuit (2003), the District of Columbia Circuit (1999), the Federal Circuit (1999), and the Seventh Circuit (1995); and the United States District Courts for the District of

Columbia (2005), the Western District of Wisconsin (2001), and Northern District of Illinois (1995).

3. I submit this Declaration in support of Nu-Pharm's Motion for Temporary Restraining Order and/or Preliminary Injunction, and, in particular, to authenticate and provide to the Court certain exhibits cited and referenced in Nu-Pharm's Motion and Memorandum of Points and Authorities.

4. I have personal knowledge of the facts stated in this Declaration and am competent to testify to the same.

5. Attached hereto at Exhibit A is a true and correct copy of FDA's October 2004 draft Guidance For Industry, entitled "Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

6. Attached hereto at Exhibit B is a true and correct copy of the electronic Orange Book listing for Depakote® (divalproex sodium) delayed-release tablets, 500 mg.

7. Attached hereto at Exhibit C is a true and correct copy of an April 18, 2007 Letter from Gary J. Buehler, Director, Office of Generic Drugs, to ANDA Applicants for Amlodipine Besylate Tablets.

8. Attached hereto at Exhibit D is a true and correct copy of the Declaration of Richard Benyak, President of Nu-Pharm Inc.

9. Attached hereto at Exhibit E is a true and correct copy of the October 16, 2006 Docket Entry granting Abbott Laboratories' motion to stay proceedings in *Abbott Laboratories v. Nu-Pharm Inc.*, No. 05 C 3714 (N.D. Ill.) (Pallmeyer, J.).

10. Attached hereto at Exhibit F is a true and correct copy of the October 31, 2007 Docket Entry stating that a stay of proceedings remains in place in *Abbott Laboratories v. Nu-Pharm Inc.*, No. 05 C 3714 (N.D. Ill.) (Pallmeyer, J.). Also attached at Exhibit F are true and correct copies of the January 4, 2008 Docket Entry in the same matter resetting the January 8 status hearing to January 14, 2008, and the January 14, 2008 Docket Entry noting that a status hearing was held and that another status hearing is set for April 17, 2008. To date, no substantive rulings on patent infringement or validity have been rendered, and a stay remains in place, in *Abbott Laboratories v. Nu-Pharm Inc.*, No. 05 C 3714 (N.D. Ill.) (Pallmeyer, J.).

11. Attached hereto at Exhibit G is a true and correct copy of the October 6, 2006 Docket Entry and Injunction Order entered in *Abbott Laboratories v. Apotex, Inc.*, No. 97 C 7515 (N.D. Ill.) (Posner, J.).

12. Attached hereto at Exhibit H is a true and correct copy of the March 31, 2004 Judgment and Injunction Order entered in *Abbott Laboratories v. Apotex, Inc.*, No. 97 C 7515 (N.D. Ill.) (Posner, J.).

13. Attached hereto at Exhibit I is a true and correct copy of the August 17, 2006 Docket Entry entering a stay of proceedings in *Abbott Laboratories v. Nu-Pharm Inc.*, No. 05 C 3714 (N.D. Ill.) (Pallmeyer, J.).

14. Attached hereto at Exhibit J is a true and correct copy of the December 21, 2007 letter to Gary Buehler, Director, Office of Generic Drugs, requesting final effective approval of Nu-Pharm's divalproex sodium delayed-release 500 mg tablets under ANDA No. 77-615.

15. The foregoing facts are true and correct as I verify and believe.

Dated this 15th day of January, 2008.

I, WILLIAM A. RAKOCZY, hereby declare, under penalty of perjury under 28 U.S.C. § 1746 and the laws of the United States of America, that the foregoing Declaration is true and correct.

*/s/ William A. Rakoczy*
William A. Rakoczy