IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COBALT LABORATORIES INC. 24840 South Tamiami Trail Bonita Springs, Florida 34134, and COBALT PHARMACEUTICALS, INC. 6500 Kitimat Road Mississauga, Ontario, Canada, L5N 2B8 Plaintiffs, v. FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, Maryland 20857, MICHAEL O. LEAVITT Secretary of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201, and ANDREW C. VON ESCHENBACH, M.D. Commissioner of Food and Drugs 5600 Fishers Lane Rockville, Maryland 20857, Defendants.	)	Case No.

COBALT'S MOTION FOR TEMPORARY RESTRAINING ORDER

Pursuant to Rule 65(b) of the Federal Rules of Civil Procedure and LCvR 65.1, Cobalt Laboratories Inc. and Cobalt Pharmaceuticals, Inc. ("Cobalt") hereby respectfully move for a temporary restraining order against the Food and Drug Administration ("FDA"); Michael O. Leavitt, in his official capacity as Secretary of Health and Human Services; and Andrew C. von Eschenbach, M.D., in his official capacity as Commissioner of Food and Drugs (collectively,

the "Federal Defendants")—pending briefing, hearing and resolution of a motion for preliminary injunction—as follows:

(a) Enjoining FDA from approving all other acarbose abbreviated new drug applications ("ANDAs") until natural expiration of Cobalt's statutory right to exclusivity for its acarbose ANDA No. 77-532;

(b) Requiring FDA to immediately stay and/or withdraw approval of any acarbose ANDA to which the Agency has already granted final approval, including the May 7, 2008 approval of Roxane Laboratories, Inc.'s ("Roxane") acarbose ANDA, until natural expiration of Cobalt's statutory right to 180-day exclusivity; and

(c) Requiring FDA to immediately order a recall of all acarbose products already shipped and/or sold by Roxane.

In the event the Court denies such relief, Cobalt respectfully moves for immediate emergency relief pending appellate review. Specifically, in the event the Court denies Cobalt's request for emergency injunctive relief, Cobalt respectfully requests immediate entry of a temporary restraining order staying or withdrawing approval of all acarbose ANDAs, except Cobalt's ANDA, pending review by the United States Court of Appeals for the D.C. Circuit of FDA's May 7, 2008 administrative decision, in order to prevent devastating and irreparable harm to Cobalt.

The grounds for this motion are fully set forth in the accompanying Memorandum in support of Cobalt's motion, and the Declarations of William A. Rakoczy, Robert Sanzen and Donna Hillier, filed contemporaneously herewith.

Pursuant to LCvR 65.1(a), Cobalt certifies that in advance of this filing, Cobalt informed the Federal Defendants of its intent to seek a temporary restraining order in this matter, as well as the time of the making of the application, and has provided the Federal Defendants with copies of this motion and all supporting papers, including the proposed order. The Federal Defendants have declined to consent to entry of the requested temporary restraining order, and consultation pursuant to LCvR 7(m) has failed to narrow the areas of disagreement.

Dated: May 8, 2008.

Respectfully submitted,

COBALT LABORATORIES INC. and
COBALT PHARMACEUTICALS INC.

By: _____
One of their attorneys

E. Anthony Figg, D.C. Bar No. 345124
Daniel L. Shores, D.C. Bar No. 495389
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K Street, N.W.
Suite 800
Washington, D.C. 20005
(202) 783-6040
(202) 783-6031 (facsimile)
efigg@rfem.com

William A. Rakoczy, D.C. Bar No. 489082
Christine J. Siwik
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60610
(312) 222-6301
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com

Counsel for Cobalt Laboratories Inc. and
Cobalt Pharmaceuticals Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COBALT LABORATORIES INC. 24840 South Tamiami Trail Bonita Springs, Florida 34134, and COBALT PHARMACEUTICALS, INC. 6500 Kitimat Road Mississauga, Ontario, Canada, L5N 2B8 Plaintiffs, v. FOOD AND DRUG ADMINISTRATION 5600 Fishers Lane Rockville, Maryland 20857, MICHAEL O. LEAVITT Secretary of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201, and ANDREW C. VON ESCHENBACH, M.D. Commissioner of Food and Drugs 5600 Fishers Lane Rockville, Maryland 20857, Defendants.	)	Case No.

MEMORANDUM IN SUPPORT OF COBALT'S
MOTION FOR TEMPORARY RESTRAINING ORDER

William A. Rakoczy, D.C. Bar No. 489082
Christine J. Siwik
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, Illinois 60610
(312) 222-6301
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com

E. Anthony Figg, D.C. Bar No. 345124
Daniel L. Shores, D.C. Bar No. 495389
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K Street, N.W., Suite 800
Washington, D.C. 20005
(202) 783-6040
(202) 783-6031 (facsimile)
efigg@rfem.com

Dated: May 8, 2008

Counsel for Cobalt Laboratories Inc. and Cobalt Pharmaceuticals, Inc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

FEDERAL STATUTES

FEDERAL REGULATIONS

OTHER AUTHORITIES

Cobalt respectfully submits this memorandum in support of its motion for a temporary restraining order: (1) enjoining FDA from approving subsequent acarbose abbreviated new drug applications ("ANDAs") during Cobalt's 180-day exclusivity period for its acarbose ANDA No. 77-532; (2) requiring FDA to immediately stay or withdraw approval of any other ANDA to which the Agency has granted final approval, including the approval granted to Roxane Laboratories, Inc. on May 7, 2008; and (3) requiring FDA to order a recall of any acarbose product shipped or sold by Roxane, pending full briefing, hearing and resolution of a preliminary injunction motion.

INTRODUCTION

Immediate emergency relief is necessary here because of the tactics that the U.S. Food and Drug Administration ("FDA") employed when ruling on Cobalt's right to 180-day generic exclusivity. After 6:00 EDT p.m. last evening (May 7, 2008), without any advanced warning, FDA blindsided Cobalt by faxing its counsel a 14-page administrative ruling advising Cobalt for the first time that Cobalt purportedly had "forfeited" its statutory right to generic exclusivity. At the same time, FDA approved the ANDA of a subsequent generic applicant. The Agency owed Cobalt better.

Back in September 2007, FDA opened a public docket and requested comments on the issue of Cobalt's right to generic exclusivity. Cobalt made two lengthy submissions and had numerous calls with the Agency over the course of several months on this topic. Cobalt repeatedly made clear that it would seek judicial review of any adverse ruling. But knowing that its ruling cannot withstand judicial scrutiny, FDA has attempted to strip Cobalt of the opportunity to obtain meaningful judicial review and relief. The Agency did so by waiting until after close of business to not only advise Cobalt of its adverse administrative ruling, but to tell

Cobalt that FDA already had gone ahead and approved one of Cobalt's competitors.[1] Accordingly, absent immediate injunctive relief from this Court, Cobalt's right to generic exclusivity will be eliminated entirely. This Court should grant that relief to prevent unrecoverable and irreparable harm to Cobalt, and to permit briefing, argument and resolution of a preliminary injunction. Indeed, such relief is required if this Court, or any court, is to have an opportunity to review FDA's arbitrary, capricious, and unlawful administrative ruling, which raises critical issues of statutory construction—critical both to the generic industry and the consumers that count on that industry to bring affordable medicines to market.

BACKGROUND

Cobalt indisputably submitted the first application seeking approval to market generic acarbose tablets. Cobalt's application contained a so-called "paragraph IV certification" to the relevant patent for the branded counterpart, making Cobalt the "first applicant" for this product. As discussed below, because it filed the first paragraph IV ANDA, Cobalt is statutorily entitled to 180 days of generic marketing exclusivity—exclusivity that Congress created as the reward and incentive for undertaking the risk and expense of mounting the first challenge to the patents protecting branded drug products from generic competition. Cobalt's exclusivity begins to run upon commercial marketing of its ANDA product. But because FDA improperly delayed approving Cobalt's ANDA, Cobalt did not launch until today (May 8, 2008) and, consequently, Cobalt's exclusivity has not yet expired. As a result, FDA cannot lawfully approve any subsequent generic application for this product, but this is precisely what the Agency has done—

[1] While FDA's administrative ruling came unannounced to Cobalt, it apparently did not come as a surprise to Roxane. Cobalt was told by potential customers earlier today that Roxane began entering contracts to sell its generic acarbose product several hours before Cobalt received FDA's administrate ruling.

unlawfully approved one of Cobalt's competitors in violation of Federal Food, Drug, and Cosmetic Act ("FFDCA") and the Administrative Procedure Act ("APA"). Emergency injunctive relief is the only way to obtain meaningful review of this administrative decision, which involves FDA's first interpretation of several aspects of the critical 180-day exclusivity forfeiture provisions, and to prevent irreparable harm to Cobalt.

I. Statutory Background.

A. New Drugs And Patent Listing Requirements.

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

B. Abbreviated New Drug Applications And Patent Certification Requirements.

Before 1984, a company seeking to market a generic version of an FDA-approved drug had to repeat the expensive and time-consuming safety and efficacy studies that already were conducted for the NDA drug. *See SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1018 (N.D. Ill. 2003). In 1984, Congress simplified the procedure for obtaining approval of generic drugs with the Hatch-Waxman Amendments to the FFDCA. Hatch-Waxman permits a company to file an ANDA that relies on information from the NDA. *Id.* at 1018-19.

An ANDA applicant must establish, *inter alia*, that its drug product is bioequivalent to the NDA drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). The ANDA must also include a "certification" to any patent information listed in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii). While Hatch-Waxman provides four certification options, only the "paragraph IV certification" is relevant here. With certain exceptions not relevant here, if an ANDA applicant seeks FDA approval to market its drug product before expiration of the Orange-Book listed patent, the applicant must submit a paragraph IV certification to that patent. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The ANDA applicant must notify the patentee and the NDA-holder of the factual and legal bases for that certification. *See* 21 U.S.C. § 355(j)(2)(B).

Submitting an ANDA containing a paragraph IV certification has two significant consequences. First, submitting a paragraph IV certification constitutes a technical act of infringement, vesting the district courts with subject matter jurisdiction over a patent infringement lawsuit brought by the patentee against the ANDA applicant. *See* 35 U.S.C. § 271(e)(2)(A). If the patentee brings a patent infringement lawsuit within 45 days after receiving the ANDA applicant's notice of its paragraph IV certification, FDA cannot finally approve the ANDA for 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Second, the first company to submit an ANDA for a drug product containing a paragraph IV certification to any patent listed in the Orange Book is entitled to market its generic product free from generic competition for 180 days. *See* 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is at the heart of the dispute in this case.

C. First-Filer 180-Day Generic Exclusivity, And The Criticality Of This Exclusivity Period To Hatch-Waxman.

The 180-day generic exclusivity period is critical to the purpose of Hatch-Waxman, and to the continued viability of the generic pharmaceutical industry. Congress

recognized this fact in 1984 when creating that incentive in the first place. Congress re-emphasized its importance in 2003 when it created generic exclusivity forfeiture provisions – provisions that protect the first-filer's right to enjoy the benefits Congress intended to flow during this 180-day period.

In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Congress passed Hatch-Waxman in order to "make available more low cost generic drugs" to the public. *Apotex, Inc. v. Shalala*, 53 F. Supp. 2d 454, 461 (D.D.C. 1999), *aff'd*, No. 99-5231, 1999 WL 956686 (D.C. Cir. Oct. 8, 1999) (quotation marks and citations omitted). The 180-day exclusivity period is critical to carrying out Congress' goal of "get[ting] generic drugs into the hands of patients at reasonable prices–fast." *In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991).

Congress recognized that challenging the many patents purportedly protecting branded drug products from competition requires generic drug companies to assume considerable risks and costs. But Congress also recognized that the public will never have access to lower-priced generic drugs before the expiration of brand patents unless generic companies challenge the suspect and overbroad patents that commonly prevent immediate generic competition. To encourage such patent challenges, Congress created a *quid pro quo*: expend the resources to mount the first patent challenge in exchange for "the right to sell [the generic] drug without competition for 180 days." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) (citing 21 U.S.C. § 355(j)(5)(B)(iv)). Congress created the 180-day generic marketing exclusivity period by preventing FDA from approving competing generic products until 180 days

after the earlier of two so-called "triggering" events—"the commercial marketing trigger" and "the court decision trigger". 21 U.S.C. § 355(j)(5)(B)(iv) (2002).[2]

As the courts repeatedly have acknowledged, the 180-day generic exclusivity period is *the sole* incentive that Congress created in order to facilitate its goal of expediting consumer access to lower-priced drug products. *See Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005) ("This provision provides an economic incentive for generic manufacturers to challenge the validity of listed patents and to 'design around' patents to find alternative, non-infringing forms of patented drugs."), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007); *Mylan Pharms., Inc. v. Shalala*, 81 F. Supp. 2d 30, 33 (D.D.C. 2000) (stating that Congress created the 180-day exclusivity provision to "encourage generic drug makers to incur the potentially substantial litigation costs associated with challenging pioneer drug makers' patents"); *Apotex*, 53 F. Supp. 2d at 461 (noting that the "purpose of the exclusivity incentive and the entire ANDA regime is to make available more low cost generic drugs" (internal quotation and citation omitted)).

FDA itself also has recognized the importance of the generic exclusivity period to the patent challenge process. *See* 64 Fed. Reg. 42,873, 42,877 (Aug. 6, 1999) (acknowledging that the 180-day period is "the incentive created by Congress for ANDA applicants to challenge patents"). Indeed, the fact that Hatch-Waxman cannot carry out Congress' goal of increased access to affordable medicines without a strong 180-day generic exclusivity incentive became all

[2] The generic exclusivity provision changed in 2003 when Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 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"). The two-trigger statutory scheme governs generic exclusivity for products where the first ANDA containing a paragraph IV certification was submitted prior to December 8, 2003. *See* MMA § 1102(b)(1). The statutory scheme discussed, *infra*, governs ANDAs, like Cobalt's here, where the first paragraph IV was filed after December 8, 2003.

the more clear in 2003 when Congress revisited the 1984 Hatch-Waxman Amendments as part of the MMA. More specifically, Congress expressly revisited the 180-day generic exclusivity incentive when enacting the MMA. Had Congress believed that incentive no longer necessary to encourage companies to challenge suspect and overbroad brand patents, Congress easily could have eliminated it. Some, in fact, encouraged Congress to do precisely that. But Congress did not do so. To the contrary, Congress revised the triggering provisions and enacted a series of so-called "forfeiture" provisions designed to ensure that a first applicant cannot be prematurely or unfairly stripped of its statutory right to generic market exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i). The generic exclusivity provisions, including the forfeiture provisions, must be construed against this backdrop.

D. The Forfeiture Provisions Implicated By FDA's Decision With Respect To Cobalt's Exclusivity For Acarbose.

On September 26, 2007, FDA published a letter soliciting comments from all acarbose ANDA applicants regarding "how the 180-day generic exclusivity forfeiture provisions at Section 505(j)(5)(D) of the Federal Food, Drug and Cosmetic Act (the Act) apply" to acarbose ANDAs. That letter raised the idea that Cobalt had forfeited its exclusivity under the so-called "failure to market" and "failure to obtain tentative approval" forfeiture provisions. Those provisions read in relevant part:

> (D) Forfeiture of 180-day exclusivity period-
>
> > (i) Definition of forfeiture event - In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:
> >
> > > (I) ***Failure to market*** - The first applicant fails to market the drug by the later of-
> > >
> > > > (aa) the earlier of the date that is-
> > > >
> > > > > (AA) 75 days after the date on which the approval of the

application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) is withdrawn by the holder of the application approved under subsection (b).

* * *

(IV) ***Failure to obtain tentative approval*** - The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

21 U.S.C. §§ 355(j)(5)(D)(i)(I), (IV) (emphasis added). Although Congress enacted the MMA in 2003, FDA has yet to publish implementing regulations.

II. Factual Background.

The facts surrounding FDA's delay in reviewing and approving Cobalt's acarbose ANDA are critical in light of the Agency's stated basis for attempting to strip Cobalt of its right to generic exclusivity. For example, as discussed in detail, FDA's actions (and inactions)

without question delayed Cobalt's approval. Indeed, FDA acknowledges that its actions delayed Cobalt's ability to obtain tentative approval within 30 months of ANDA submission, and thus the Agency found no forfeiture under the tentative approval forfeiture provision. Incredibly, FDA nevertheless turned around and found a forfeiture under the failure to market provision because Cobalt failed to obtain final approval and launch within 30 months of its ANDA submission. The Agency simply cannot forfeit Cobalt's exclusivity when FDA's actions (and inactions) delayed Cobalt's approval, as well as for the other reasons set forth herein.[3]

A. The NDA Product.

The NDA product at issue here is Bayer's prescription medication, Precose® (acarbose) Tablets 25 mg, 50 mg, and 100 mg. FDA first approved Precose® (acarbose) on September 6, 1995, pursuant to NDA No. 20-482, for, among other things, the treatment of type 2 diabetes. (*See* Rakoczy Decl. Ex. A, Precose® Label.)[4] Bayer submitted information to FDA on one patent for listing in the Orange Book in connection with Precose® and NDA No. 20-482: U.S. Patent No. 4,904,769 ("the '769 patent"). (*See id.*, Ex. B, Precose® Electronic Orange Book Listing.) The '769 patent expires on September 6, 2009. (*See id.*) To date (May 8, 2008), the '769 patent remains listed in the Orange Book, and has not been "withdrawn" from that publication by the Agency. (*Id.*) As such, all ANDA applicants seeking to market a generic

[3] As discussed below, FDA's actions delayed approval in at least two material ways. First, as the Agency concedes, it changed the approval requirements after Cobalt submitted its ANDA, which delayed Cobalt's approval. Second, the Agency's failure to timely inspect Cobalt's contract research organization also delayed Cobalt's approval. Indeed, based on FDA's interpretation of when the relevant 30-month period begins, FDA's failure to timely inspect this facility is the reason the Agency refused to approve Cobalt's ANDA in time for Cobalt to avoid a forfeiture under FDA's impermissible statutory construction.

[4] "Rakoczy Decl." refers to the Declaration of William A. Rakoczy submitted herewith.

acarbose product prior to expiration of the '769 patent have been—and still are—required to submit a paragraph IV certification to such patent.

B. Cobalt's First-Filed Paragraph IV ANDA For Acarbose.

Cobalt began its development of a generic acarbose product in early 2003, with a view toward compiling the information necessary to submit an ANDA. (Rakoczy Decl. Ex. C, Hillier Decl. ¶ 3.) To that end, Cobalt researched the potential ways to establish bioequivalence ("BE") to the brand product. As part of that process, with its contract research organization ("CRO"), Cobalt developed a detailed protocol for establishing BE to the NDA product. (*Id.*)

On August 27, 2003, Cobalt formally sought the Agency's confirmation regarding the BE requirements and parameters for an appropriate study to support an ANDA for acarbose. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 4.) On March 5, 2004, after hearing nothing from FDA, Cobalt again sought confirmation regarding its BE study, and included an even more detailed protocol from its CRO. (*Id.*) By January 2005—well over *sixteen* months since its original correspondence—Cobalt had received no response of any kind from FDA. (*See id.* ¶ 5.) On January 10, 2005, Cobalt submitted ANDA No. 77-532 to FDA for acarbose tablets in 25 mg, 50 mg, and 100 mg strengths. (*See id.* ¶ 6.) Cobalt's ANDA included a paragraph IV certification to the '769 patent, as well as the results of the *in vivo* BE study conducted by Cobalt's CRO—the very same CRO that Cobalt had identified back in August 2003—according to the protocols that Cobalt provided FDA on August 27, 2003, and again on March 5, 2004. (*Id.*) On January 11, 2005, the day *after* Cobalt submitted its ANDA, Cobalt received a letter from the Agency. (*See id.* ¶ 7.) The Agency essentially ignored Cobalt's prior BE study design, and instead established and imposed new BE requirements for acarbose. FDA completely changed the rules of the game *after* the submission of Cobalt's ANDA, and more than sixteen months after Cobalt originally contacted the Agency.

On March 9, 2005, FDA informed Cobalt that its ANDA purportedly was not "sufficiently complete to merit a critical technical review" for several reasons—none of which were related to Cobalt's BE study or CRO. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 8.) On March 18, 2005, Cobalt submitted an amendment to its ANDA that sufficiently addressed all of FDA's concerns. (*Id.*) On April 28, 2005, in an "acceptance-for-filing" letter, FDA acknowledged receipt of Cobalt's ANDA, as well as the March 18, 2005 amendment. (*See id.* ¶ 9.) FDA further informed Cobalt that the Agency had accepted Cobalt's ANDA for filing and substantive review as of March 22, 2005. (*Id.*) This is the first day that a substantially complete ANDA for acarbose, together with a paragraph IV certification, was submitted to FDA. (*See id.*, Ex. D, 05/07/08 Ltr. from G. Buehler to W. Rakoczy ("Buehler Ltr.") at 2.)

C. FDA Delays Its Review Of Cobalt's ANDA, And Fails To Timely Inspect Cobalt's CRO.

On June 30, 2005, FDA issued a BE deficiency to Cobalt. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 11.) The Agency's deficiency never mentioned FDA's January 2005 BE letter, nor did the Agency mention anything about Cobalt's CRO. (*Id.*) Cobalt responded to FDA on September 27, 2005 by, *inter alia*, identifying the study protocol and reports from its original ANDA, which clearly identify the CRO that conducted the BE study. (*Id.*)

After receiving Cobalt's response, FDA said nothing regarding BE for well over a year. On October 24, 2005, FDA did, however, issue a minor deficiency. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 12.) FDA once again made no mention of its January 2005 letter to Cobalt or any problems or delays in inspecting the facilities identified in Cobalt's ANDA, including its CRO. (*Id.*) Cobalt responded to FDA's minor deficiency on February 27, 2006. (*Id.*) Cobalt reasonably assumed that FDA would, consistent with its statutory and regulatory obligations, timely conduct any necessary inspections of the facilities identified in Cobalt's ANDA. (*Id.*)

Cobalt did not hear from FDA again for over a year, until August 8, 2006, when FDA raised the additional study requirements first mentioned its January 6, 2005 correspondence. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 13.) The Agency, of course, failed to mention that it did not communicate these new BE requirements to Cobalt until *after* Cobalt's CRO conducted the pivotal BE study and *after* Cobalt filed its ANDA. (*Id.*) Nor did FDA acknowledge its failure to raise these new BE requirements in the Agency's earlier June 2005 BE deficiency. (*Id.*) On September 20, 2006, Cobalt responded to FDA's August 8, 2006 letter. (*Id.*) Among other things, Cobalt submitted data on an additional study conducted by its CRO, just as FDA had requested. (*Id.*)

Once again, FDA waited nearly a year to respond back to Cobalt. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 14.)[5] On June 8, 2007, FDA issued another BE deficiency letter. (*See id.* ¶ 15.) On June 18, 2007, Cobalt promptly requested a telephone conference to discuss the letter. (*See id.* ¶ 16.) On June 28, 2007, representatives of FDA and Cobalt conducted a telephone conference to discuss these issues. (*Id.*) In particular, the parties agreed, among other things, that Cobalt would conduct a new pivotal BE study. (*Id.*) During that call, FDA specifically inquired as to which CRO Cobalt would be using to conduct the new pivotal BE study. (*Id.*) Cobalt responded that it would use the same CRO that conducted the prior two studies, which FDA said would be acceptable. (*Id.*) FDA never stated or otherwise implied that the CRO was not acceptable because it had not been inspected. (*Id.*) Nor did FDA mention that, after more than two years, FDA still had not inspected the CRO. (*Id.*)

[5] In the interim, Cobalt made numerous oral contacts to determine the status of the Agency's BE review. (*Id.*) At no time during this period did FDA ever inform Cobalt that the Agency had not inspected Cobalt's CRO, even though the Agency had known about this CRO since at least August 2003, and no later than the submission of Cobalt's ANDA in 2005. (*Id.*)

On September 3, 2007, Cobalt formally responded to FDA's June 8, 2007 BE deficiency. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 17.) With that response, Cobalt submitted the results from another pivotal BE study conducted by its CRO. (*Id.*) FDA orally confirmed to Cobalt that there were no substantive issues with the new pivotal BE study. (*Id.*) But on September 24, 2007, FDA orally informed Cobalt that the Agency refused to approve Cobalt's ANDA solely because FDA had never inspected Cobalt's CRO, and that such an inspection could not occur for at least another month. (*Id.*)

FDA waited until November 28, 2007 before contacting Cobalt's CRO to arrange for an inspection of its facilities. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 18.) Surprisingly, FDA requested that such inspection be conducted by telephone rather than in-person. (*Id.*) FDA provided no explanation to Cobalt or to Cobalt's CRO as to why, if an inspection could have been conducted by telephone, the Agency had failed to perform such an inspection in the over two and a half years that Cobalt's ANDA has been pending, much less why FDA had waited over two months to schedule such an inspection since informing Cobalt that an inspection was the only hurdle standing between Cobalt's acarbose ANDA and approval. (*Id.*)

FDA finally conducted its telephone inspection of Cobalt's CRO over five days, December 3-7, 2007. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 19.) Following the inspection, Cobalt's CRO was informed that the FDA inspector was recommending approval of Cobalt's ANDA. (*Id.*) But on December 17, 2007, FDA's Office of Generic Drugs ("OGD") informed Cobalt that its ANDA still would not receive final approval due to certain issues that the Agency was evaluating relating to all acarbose tablet ANDAs. (*Id.*)

D. Bayer's Alleged "Delisting" Request.

On or about April 16, 2007, according to FDA, Bayer allegedly requested that the '769 patent be "delisted" from the Orange Book. (*See* Rakoczy Decl. Ex. E, 9/26/07 Buehler

Ltr.) By its own admission, FDA failed to publish notice of this delisting request until September 25, 2007. (*See id.* Ex. D, 5/7/08 Buehler Ltr. at 7.) FDA repeatedly refused to provide Cobalt with any evidence of such delisting request. Indeed, FDA still has never provided the requested proof. Moreover, information concerning the '769 patent remains in the Orange Book and, at least as of the filing of this submission, has not been withdrawn in any fashion. (*See id.* Ex. B, Precose® Electronic Orange Book Listing.)

E. FDA's Request For Comment And Its Late-Night Ambush Of Cobalt.

On or about September 26, 2007, FDA posted a letter requesting comment on certain 180-day exclusivity forfeiture issues concerning acarbose. According to FDA:

> As of the date of this letter, which is more than 30 months from March 22, 2005, no first applicant's ANDA has been approved. Also, on April 16, 2007, Bayer requested that the '769 patent be "delisted" as to Precose, i.e., they withdrew the patent information. On September 26, 2007, FDA indicated in [the Orange Book] that the request to delist this patent had been submitted on April 16, 2007.
>
> To determine whether any ANDA referencing Precose is eligible for final approval, the agency must consider how the 180-day generic drug exclusivity forfeiture provisions at section 505(j)(5)(D) of the [FFDCA] apply to this set of facts. As part of the process for making such a determination, we are seeking your views regarding the applicability of sections 505(j)(5)(D)(i)(IV) -- failure to obtain tentative approval within 30 months -- and 505(j)(5)(D)(i)(I)(aa)(BB) -- failure to market by 30 months. We also are interested in your views regarding the applicability of section 505(j)(5)(D)(i)(I)(bb)(CC) -- relating to the delisting of a patent.

(*See* Rakoczy Decl. Ex. E, 9/26/07 Buehler Ltr.)

After sitting on these critical issues for over seven months, on May 7, 2008, FDA waited until after close of business to fax Cobalt's counsel a 14-page administrative ruling stripping Cobalt of its statutory right to generic exclusivity under the failure to market forfeiture provision, but not under the failure to obtain tentative approval provision. (*See* Rakoczy Decl. ¶ 18.) At the same time, FDA approved a subsequent applicant, Roxane, that promptly launched its acarbose products during Cobalt's exclusivity. (*See id.* Ex. F, Roxane Press Release.) FDA's

decision interprets several aspects of the critical 180-day exclusivity forfeiture provisions for the first time. It is imperative that this Court carefully review and consider these statutory construction rulings because they are fatally flawed and unlawful. If left undisturbed, FDA's impermissible ruling will not only irreparably harm Cobalt, but will destroy the carefully-crafted balance that Congress struck with Hatch-Waxman to the detriment of the generic drug industry and the consumers that rely on that industry.

ARGUMENT

In this Circuit, to obtain temporary injunctive relief from the Court, Cobalt must demonstrate:

> 1) a substantial likelihood of success on the merits, 2) that it would suffer irreparable injury if the injunction is not granted, 3) that an injunction would not substantially injure other interested parties, and 4) that the public interest would be furthered by the injunction.

Mova Pharm. Corp. v. Shalala, 140 F.3d 1060, 1066 (D.C. Cir. 1998) (citation omitted); *see also 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). These four factors "interrelate on a sliding scale and must be balanced against each other." *Davenport v. Int'l Bhd. of Teamsters*, 166 F.3d 356, 361 (D.C. Cir. 1999). Thus, while this Court must consider each of these four factors, Cobalt need not prevail on each: "If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *CityFed Fin. Corp. v. Office of Thrift Supervision*, 58 F.3d 738, 747 (D.C. Cir. 1995); *see also Cuomo v. United States Nuclear Regulatory Comm'n*, 772 F.2d 972, 974 (D.C. Cir. 1985) (concluding that an injunction may issue "with either a high probability of success and some injury, or vice versa"); *Raymen*, 2005 WL 607916, at *2 (the movant "need not prevail on each factor in order to receive injunctive relief").

In this case, each of these factors weighs heavily in Cobalt's favor. First, Cobalt has a strong likelihood of success on the merits. Second, Cobalt unquestionably will suffer irreparable harm if FDA's unlawful decision is not reversed and the approval issued yesterday (May 7) immediately stayed. Third, FDA will not be harmed if required to properly apply the statute, and no subsequent acarbose ANDA applicant can legitimately claim any harm from being excluded from the market until Cobalt enjoys its full rights to exclusivity because these applicants have no right to market during that period. Finally, the public interest will be served by honoring the *quid pro quo* that Congress enacted to encourage companies like Cobalt to challenge patents on brand drugs. Accordingly, Cobalt's request for emergency injunctive relief should be granted.

I. Cobalt Has A Substantial Likelihood Of Success On The Merits Because Finding A Forfeiture Of Cobalt's Exclusivity Is Arbitrary, Capricious And Contrary To Law.

A. The Forfeiture Provisions Must Be Construed Consistent With The Statute As A Whole, Congress' Purpose, And The Policy For Hatch-Waxman.

When construing the exclusivity forfeiture provisions, this Court must be faithful to Congressional intent, *both based on the statute's plain language, as well as its purpose and intent. See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter . . . ."). The Supreme Court itself has cautioned that reviewing courts must look not only to the plain text, "but look to the provisions of the whole law, and to its object and policy" as well. *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (citation and internal quotation marks omitted); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." (internal quotations and citation omitted)), *aff'g*, 153 F.3d 155 (4th Cir. 1998); *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991) (recognizing that

"statutory language must always be read in its proper context"); *Offshore Logistics, Inc. v. Tallentire*, 477 U.S. 207, 220-21 (1986); *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956) (rejecting literal interpretation of words read in complete isolation from their context in the Act); *Bell Atl. Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) ("The literal language of a provision taken out of context cannot provide conclusive proof of congressional intent, any more than a word can have meaning without context to illuminate its use.").

Indeed, in *Public Citizen v. United States Department of Justice*, the Supreme Court made clear that "reliance on the plain language . . . alone is not entirely satisfactory." 491 U.S. 440, 452 (1989). The Court explained:

> Even though, as Judge Learned Hand said, "the words used, even in their literal sense, are the primary, and ordinarily the most reliable, source of interpreting the meaning of any writing," nevertheless "it is one of the surest indexes of a mature and developed jurisprudence not to make a fortress out of the dictionary; but to remember that statutes always have some purpose or object to accomplish, whose sympathetic and imaginative discovery is the surest guide to their meaning." Looking beyond the naked text for guidance is perfectly proper when the result it apparently decrees is difficult to fathom or where it seems inconsistent with Congress' intention, since the plain-meaning rule is "rather an axiom of experience than a rule of law, and does not preclude consideration of persuasive evidence if it exists."

Id. at 454-55 (citations omitted). Consequently, policy evaluation is important because considering the policy behind a statute routinely "shed[s] new light on congressional intent, notwithstanding statutory language that appears superficially clear." *Natural Res. Def. Council, Inc. v. Browner*, 57 F.3d 1122, 1127 (D.C. Cir. 1995) (citation and quotation marks omitted); *see also* Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 515 (1989) (stating that "[p]olicy evaluation is . . . part of the traditional judicial tool-kit that is used in applying the first step of *Chevron*," adding that courts should look "not merely

[to the] text and legislative history but also, quite specifically, [to a] consideration of policy consequences").

A review of Hatch-Waxman's purpose, language and context makes clear that Congress intended the 180-day exclusivity period to incentivize early generic competition because generic competition is the only way to bring affordable medicines to market. But the only way that the 180-day exclusivity period operates as an incentive is if it truly provides the first-filer with a period of marketing exclusivity. Congress understood this and, consistent with its express intent, used language to carry out this goal. Consequently, it should not come as a surprise that the courts (and FDA) have recognized that the generic exclusivity provision must be interpreted and enforced:

- "in a manner consistent with 'the statute's interest in affording market access and incentives for both generic and non-generic makers,' and to maintain 'an incentive for the parties to fulfill the purposes of Hatch-Waxman'"; and
- to "avoid interpreting Hatch-Waxman so the decision on whether a generic applicant is entitled to exclusivity rests entirely in the patent holder's hands."

(Rakoczy Decl. Ex. G, FDA 02/06/01 Admin. Ruling in Docket No. 2000P-1446, at 5 (quoting *Mylan Pharms., Inc. v. Henney*, 94 F. Supp. 2d 36, 53-54 (D.D.C. 2000), *vacated as moot by*, *Pharmachemie B.V. v. Barr Labs., Inc.*, 276 F.3d 627 (D.C. Cir. 2002))).

In fact, FDA, as well as the courts, repeatedly have interpreted Hatch-Waxman's exclusivity provisions to effectuate Congress' purpose and intent, even where such interpretation went beyond the purportedly "plain language" of the statutory provision. For instance, as originally enacted, Hatch-Waxman provided that exclusivity will only be triggered by a court decision finding the patent-in-suit "invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002). Despite the seemingly clear nature of the plain language, both FDA and the courts have held a court decision of patent unenforceability to be a triggering decision. *See* 21 C.F.R.

§ 314.107(c)(1)(ii); *see also Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1009 (D.C. Cir. 1999). Similarly, FDA interprets the generic exclusivity provision to allow for the "selective waiver" of that exclusivity, despite the fact that the plain language of the exclusivity provision says nothing about such waivers. (*See* Rakoczy Decl. Ex. H, FDA 07/02/04 Admin. Ruling in Docket No. 2004P-0227.) FDA does so in order to effectuate Congress' intent that the first-filer benefit from its market exclusivity, concluding that the exclusivity provision must be construed in a manner "favorable to those for whom a statutory benefit is chiefly intended." (*Id.* at 6-7.) As FDA recognized, "[a]llowing waiver and relinquishment helps maintain the value of the exclusivity for the beneficiary, strengthening the incentive to challenge patents and, thereby, promote competition." (*Id.* at 9.) Significantly, FDA further acknowledged:

> Where, as here, statutory language compelling government action has the effect of benefiting specific private entities (in this case, granting 180 days of marketing exclusivity to eligible ANDA applicants), *judicial precedent . . . supports inferring from silence a legislative intent to allow an alternative course of action more favorable to the beneficiary of the government act . . . .*

(*Id.* at 4 (emphasis added)).

Applying the well-established principles of statutory construction here, no forfeiture event has occurred, and FDA cannot approve a subsequent ANDA for acarbose until Cobalt's exclusivity expires.

B. No "Failure To Market" Forfeiture Has Occurred.

Under a proper and lawful analysis of the failure to market provision, Cobalt has not forfeited its exclusivity, and FDA's finding to the contrary is arbitrary, capricious and contrary to law, for at least the following reasons:

- First, by FDA's own admission, the Agency's actions (and inaction) prevented Cobalt from being able to launch its generic product by the date FDA has declared the relevant forfeiture date.

- Second, information on the '769 patent has not been, and cannot lawfully be, "withdrawn" from the Orange Book.

- Third, the second prong of the failure to market forfeiture provision, relating to patent dispute resolution and delisting, comes into play if, and only if, a subsequent acarbose ANDA applicant has received tentative approval. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (introductory clause). By FDA's own admission, no subsequent ANDA applicant had tentative approval at the time FDA found Cobalt's exclusivity to be forfeit.

1. FDA's Delay Cannot Cause An Exclusivity Forfeiture.

FDA cannot lawfully forfeit Cobalt's exclusivity under the failure to market provision because, as the Agency readily admits, its delay prevented Cobalt from entering the market in time. Any other result turns the statute on its head and unlawfully runs afoul of the statutory text and Congressional intent.

The tentative approval forfeiture provision of § 355(j)(5)(D)(i)(IV) provides that exclusivity may be forfeited if the applicant fails to obtain tentative approval "unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed." Why? To prevent penalizing ANDA applicants when FDA changes, or considers changing, the rules of the game. This is precisely what occurred here. By FDA's own admission, FDA changed and/or reviewed the BE requirements for acarbose, and communicated those requirements to Cobalt only after Cobalt already conducted its pivotal BE study and submitted its ANDA. Significantly, by FDA's own admission, the Agency's action delayed Cobalt's ability to obtain tentative approval by September 22, 2007.[6] (*See* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 11.) Consequently, by

[6] FDA calculated September 22, 2007 under its impermissible interpretation of when the 30-month period referenced in both the failure to obtain tentative approval and failure to market forfeiture provisions begins. (*Compare* Rakoczy Decl. Ex. N, 10/17/07 Rakoczy Ltr. at 15-17, *with* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 11-12). Cobalt reserves the right to fully brief this issue.

FDA's own admission, its actions delayed Cobalt's ability to obtain the final approval needed to commercially launch product by September 22, 2007. Yet, FDA found Cobalt's exclusivity to be forfeit because Cobalt did not receive final approval and launch by this date. FDA's decision simply cannot stand.

According to FDA, the 30-month period referenced in section (I)(aa)(BB) of the failure to market provision starts running from the same date as the 30-month period referenced in section (IV) of the tentative approval provision. (*See* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 6 & n.10; 9-10 & n.15.) Applying that interpretation here, FDA calculated the relevant date under both provisions to be September 22, 2007. (*Id.*) FDA concedes that "because FDA changed the requirements for the bioequivalence study," Cobalt could not obtain tentative approval by September 22, 2007 and, as a result, that Cobalt did not forfeit exclusivity under the failure to obtain tentative approval provision. (*Id.* at 11.) For FDA to turn around and find that Cobalt forfeited because it failed to obtain final approval and launch its product by the same date is arbitrary, capricious and unlawful. There simply is no lawful, let alone logical, basis for FDA to find otherwise. This is particularly true given that FDA's ruling barely scratches the surface of the approval delays caused by the Agency's failure to carry out its statutory obligations.

As of September 22, 2007, FDA withheld approval of Cobalt's ANDA solely because the Agency had failed to timely conduct an inspection that it deemed necessary for receiving such approval. (*See* Rakoczy Decl. Ex. C, Hillier Decl. ¶ 17.) Specifically, according to FDA, Cobalt's acarbose ANDA was approvable, but for an inspection of Cobalt's CRO—an inspection that FDA, and FDA alone, is charged with initiating and conducting. (*Id.*) FDA delayed inspecting the CRO for over *two and a half years*, even though it has known about this CRO since at least August 2003, and no later than submission of Cobalt's ANDA. (*See id.*

¶¶ 17-19.) FDA's admitted delays and failure to timely inspect the CRO violated not only the Agency's statutory mandate for reviewing and approving ANDAs, but also FDA's own internal policies and procedures. FDA cannot lawfully find that Cobalt forfeited its exclusivity by failing to launch by September 22, 2007 when, by FDA's own admission, the only reason Cobalt could not launch is because the Agency failed to carry out an inspection that FDA alone is charged with doing.

The result is all the more egregious and unlawful given the fact that FDA should not have withheld Cobalt's approval based upon this inspection. In the FFDCA, Congress specifically directed that "[n]o action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug." 21 U.S.C. § 355(j)(3)(F). The message and mandate from Congress is clear—approvals should not be held up by things like inspections, and certainly not by FDA's failure to follow its own statutory obligations and procedures for initiating and completing such routine inspections.[7]

[7] Additionally, the Agency has developed and published its own Compliance Program Guidance Manual (CPGM) specifically for inspections of CROs that conduct BE studies for ANDAs (*See* Rakoczy Decl. Ex. I, FDA CPGM, Compliance Program 7348.001 – Bioresearch Monitoring: Human Drugs – In Vivo Bioequivalence). According to FDA's CPGM, "*[f]acilities where bioequivalence studies are conducted are to be inspected under this compliance program.*" (*Id.* at 5 (emphasis added)). Additionally, FDA's Office of Generic Drugs ("OGD")—which is charged with reviewing and approving ANDAs—has developed and published its own Manual of Policies and Procedures (MAPP) governing "Inspections of Clinical Facilities and Analytical Laboratories Conducting Bioequivalence Studies in ANDAs." (*See* Rakoczy Decl. Ex. J, MAPP 5210.7 (Dec. 15, 2000)). OGD's MAPP emphasizes the importance of BE studies to approval of an ANDA, and sets forth the policies and procedures for identifying when an inspection of a CRO is necessary and should be initiated. (*See id.* at 1-3.) Most pertinent here, OGD must request "a routine inspection of clinical facilities or analytical laboratories conducting BE studies included in an unapproved ANDA if: A clinical facility or analytical testing site is identified in the ANDA that has no inspection history". (*Id.* at 3.) The process for initiating the inspection begins when the ANDA is accepted for filing: "*[w]hen an ANDA is accepted for filing*," OGD must determine if any of the inspection criteria in this MAPP apply. (*Id.* at 4 (emphasis added)).

FDA's administrative ruling tries to diminish the importance of the inspection issue. (*See* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 3.) The Agency's efforts fail because FDA cannot avoid the fact that but for its delay inspecting Cobalt's CRO, Cobalt would have obtained the approval needed to avoid a forfeiture under FDA's interpretation of this provision. The purpose of the forfeiture provisions is to ensure that ANDA applicants actively work towards approval and do not wait indefinitely to launch their products. Congress most assuredly did not enact these provisions to punish first applicants for delays at the Agency, nor can these forfeiture provisions be lawfully construed in a manner that leads to such an absurd result. Indeed, any other result turns the statute on its head, and leads to impermissibly inconsistent and absurd results. It would penalize first applicants by causing numerous exclusivity forfeitures based on circumstances within FDA's control, but which clearly are outside the first applicant's control.[8] Accordingly, FDA's decision to forfeit Cobalt's exclusivity unlawfully runs contrary to the statute and Congressional intent.

2. FDA's Forfeiture Of Cobalt's Exclusivity Based On Bayer's Mere "Request For Patent Delisting" Is Arbitrary, Capricious And Contrary To Law.

Under FDA's interpretation, a mere "request for patent delisting" by the NDA-holder constitutes the "withdrawal" of patent information under § 355(j)(5)(D)(i)(I)(bb)(CC) that triggers a forfeiture event (*see* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 7 n.13)—regardless

---

If so, OGD must issue an inspection request and take the necessary steps to initiate an inspection of the facility by field personnel. (*Id.* at 4-5.)

[8] Consider, for example, the significant approval delays and backlogs that FDA already is experiencing due to increased ANDA filings and decreased Agency resources. FDA had a backlog of over 1,100 ANDAs at the end of fiscal year 2006, compared to 780 for 2005 and just 374 for 2001. (*See* Rakoczy Decl. Ex. K, CHAIN DRUG REVIEW 4-23-07, vol. 29, issue 8, *available at* 2007 WLNR 11400759.) By June 2007, the backlog of pending ANDAs reached nearly 1,300 applications. (*See id.*, Ex. L, CHAIN DRUG REVIEW 8-20-07, vol. 29, issue 14, *available at* 2007 WLNR 16535267.)

of whether the information is actually withdrawn from the Orange Book, and regardless of whether FDA provides any timely notice of such delisting request to the interested first applicant. FDA's interpretation violates the plain language of the statute; runs afoul of Congressional intent by allowing brand companies to manipulate, if not eliminate, the exclusivity incentive; and ignores binding D.C. Circuit precedent.

a. FDA's Interpretation Violates The Plain Language Of The Statute.

First, and most importantly, construing this provision to include the mere "request for patent delisting" impermissibly runs afoul of and conflicts with the plain language of the statute. The provision, on its face, requires that "[t]he patent information submitted under subsection (b) or (c) [be] ***withdrawn*** by the holder of the application approved under subsection (b)." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) (emphasis added). It says nothing about a mere "request for patent delisting," such as Bayer made here. A significant and material substantive difference exists between asking to have patent information delisted and actually having that information withdrawn. FDA cannot ignore this clear language and material distinction. *See Mova*, 140 F.3d at 1068-74 (rejecting and invalidating FDA's interpretation of the 180-day exclusivity provisions in light of explicit statutory language to the contrary); *Purepac Pharm.*, 354 F.3d at 884-85 (refusing to grant deference to FDA's action when it is "irreconcilable with the language and intent of the FDCA").

This is true even where the result seems "absurd" to the Agency because "the delay of approval of subsequent ANDAs will never end." *Inwood Labs., Inc. v. Young*, 723 F. Supp. 1523, 1527 (D.D.C. 1989). In *Inwood*, FDA sought to condition generic exclusivity on whether the first-filer had been sued for patent infringement. *Id.* at 1525. The Agency argued that such a statutory interpretation was necessary because it was the only way to avoid a situation

where the first applicant's exclusivity delayed approval of all subsequent applications. *Id.* at 1527. The court rejected FDA's interpretation, stating that although "th[e] problem warrants consideration by Congress," it "does not give the FDA or this Court a license to read into the present, clear language of section 355(j)([5])(B)(iv)(I) a requirement of a suit for patent infringement that is simply not there." *Id.* The D.C. Circuit echoed this conclusion a decade later in *Purepac Pharmaceutical Co. v. Friedman*, 162 F.3d 1201 (D.C. Cir. 1998). In that case, it was once again argued that FDA should require an infringement suit as a condition for receiving generic exclusivity. *Id.* at 1204. Once again, it was further argued that such a requirement is necessary to prevent approval delays for subsequent ANDA filers:

> If a first applicant is never sued for patent infringement, it is possible that neither of two "triggers" for the running of the 180 days of market exclusivity—commercial marketing or a judicial decision—would ever occur. Without a lawsuit there would be no judicial decision. If the applicant never begins marketing its product, the 180 days would never run and all later generic applicants would be barred from bringing their products to market.

Id. at 1205. The D.C. Circuit rejected this as a basis for deviating from the plain language of the statute, which does not require the first-filer to be sued for patent infringement in order to obtain the generic exclusivity incentive. *Id.* at 1204-05.

Here again, the plain language of that statute requires that the patent information be actually withdrawn from the Orange Book, not merely the submission of a request for patent delisting. FDA has not even attempted to support its contrary interpretation. The fact is, FDA cannot lawfully override the plain language even if it believes that the plain language will lead to approval delays for subsequent ANDA filers. Had Congress intended for a mere delisting request to satisfy this provision, it easily could have said so. That Congress did not do so speaks volumes about Congressional intent which, as discussed below, is fully consistent with its plain language.

b. FDA's Interpretation Runs Afoul Of Congressional Intent And Allows Brand Companies To Manipulate, and Indeed Eliminate, The Generic Exclusivity Incentive.

Second, FDA cannot permissibly construe § 355(j)(5)(D)(i)(I)(bb)(CC) as being satisfied by the mere "request for patent delisting" because doing so would run afoul of Congressional intent—such an interpretation would impermissibly allow brand companies to manipulate, and indeed eliminate, the generic exclusivity incentive altogether. Under FDA's interpretation, a brand company admittedly could unilaterally trigger a forfeiture event at any time, and completely control and manipulate whether a first applicant ever enjoys exclusivity.

Congress could not possibly have contemplated or intended this absurd result. Congress created the generic exclusivity incentive to encourage generic companies to undertake the considerable risk and expense of challenging brand patents. In the MMA, Congress sought to strengthen, not weaken, that incentive. It certainly never intended to give brand companies the power to manipulate and eliminate that critical incentive entirely. Indeed, the D.C. Circuit already has rejected an interpretation of the generic exclusivity period under which "the patent holder could manipulate the system" as, among other things, inconsistent with Congressional intent. *Teva*, 182 F.3d at 1009; *id.* at 1011. Other courts have consistently reached the same conclusion, rejecting an FDA "interpretation [that] places the decision as to whether a generic manufacturer will be entitled to exclusivity entirely in the hands of the patent holder". *Mylan Pharms.*, 94 F. Supp. 2d at 54; *see also Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120, 125-26 (D.C. Cir. 2006) (rejecting FDA policy that "allows an NDA holder, by delisting its patent, to deprive the generic applicant of a period of marketing exclusivity"); *Inwood Labs.*, 723 F. Supp. at 1527 (striking down FDA's statutory interpretation because "[b]y subjecting the exclusivity entitlement to the caprices of the patent holder, the FDA's interpretation would seem to affect

adversely the incentives that Congress sought to create in providing for 180 days of exclusivity for the manufacturers of generic drugs.").

So, too, should this Court.[9]

c. FDA's Decision Squarely Violates The D.C. Circuit's Ruling In *Ranbaxy v. Leavitt* That Precludes The Agency From Depriving An Applicant Of Exclusivity By Removing A Patent From The Orange Book.

FDA's decision also runs afoul of the D.C. Circuit's decision in *Ranbaxy Labs. Ltd. v. Leavitt*, 469 F.3d 120 (D.C. Cir. 2006), *aff'g*, 459 F. Supp. 2d 1 (D.D.C. 2006). There, in connection with the drug simvastatin, FDA removed two patents from the Orange Book after ANDA applicants had submitted applications containing paragraph IV certifications to those patents, thus qualifying those applicants for exclusivity. After removing the patents from the Orange Book, FDA determined that the applicants were no longer entitled to exclusivity. FDA justified its decision by citing to a regulation that permitted the Agency to remove patents unless litigation ensued as a result of the paragraph IV certification. Because there was no litigation over the two simvastatin patents, the Agency concluded that it could remove them from the Orange Book, even though doing so would deprive the first applicants of their statutory right to 180-day generic exclusivity. The first applicants brought suit challenging FDA's decision.

Both the district court and the D.C. Circuit struck down the Agency's decision to delist the simvastatin patents and deprive the first-filers of exclusivity as arbitrary, capricious and unlawful agency action. In so ruling, the D.C. Circuit recognized, among other things, that

[9] In fact, Congress expressly enacted provisions, such as the declaratory judgment provisions, as part of the MMA precisely to prevent brand manipulation of the generic exclusivity period. *See* 149 CONG. REC. S15,885 (daily ed. Nov. 25, 2003) (statement of Sen. Kennedy) ("[W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could trigger the 'failure to market' provision and force the first generic to market.").

FDA's delisting policy "diminishes the incentive for a manufacturer of generic drugs to challenge a patent listed in the Orange Book in the hope of bringing to market a generic competitor for an approved drug without waiting for the patent to expire," and that the Agency may not lawfully "change the incentive structure adopted by the Congress, for the agency is bound 'not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.'" *Ranbaxy*, 469 F.3d at 126 (quoting *MCI Telecomms. Corp. v. AT & T Co.*, 512 U.S. 218, 231 n.4 (1994)).

FDA's decision here squarely violates the binding principles in *Ranbaxy* by depriving Cobalt of exclusivity and diminishing the incentive to challenge listed patents. FDA's attempt to distinguish *Ranbaxy* on the ground that it was a pre-MMA decision rings hollow. (*See* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 8.) The binding principles enunciated by the D.C. Circuit in *Ranbaxy*, which had everything to do with preserving the incentives enacted by Congress, are no less applicable here. (*See also* Rakoczy Decl. Ex. O, 11/6/07 Rakoczy Ltr.). If anything, FDA's conduct here is all the more egregious where the patent information was never actually taken out of the Orange Book, and FDA did not even provide notice of this purported delisting request to Cobalt until over 5 months after receiving it.[10] By forfeiting Cobalt's exclusivity based on a mere request for patent delisting, the Agency has not only impermissibly

[10] In fact, despite Cobalt's repeated requests, FDA has not provided any evidence of Bayer's alleged delisting request, which allegedly was submitted by Bayer back in April 2007, or over a year ago. As such, neither Cobalt nor this Court can confirm the existence of such a request, much less evaluate whether it was a proper request that satisfies the statutory criteria for delisting. As a matter of fundamental due process, FDA cannot deprive a company of its statutory entitlement to exclusivity based on the contents of a supposed delisting request that the Agency will not even divulge, and which Cobalt was never even given notice of until after the forfeiture of its exclusivity. The opportunity for abuse of process is manifest. For this reason alone, applying this provision here is unlawful.

changed the incentive structure adopted by the Congress, but opened the door to eliminating it altogether.

Nor is it true (or an answer to *Ranbaxy*), as FDA suggests, that 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) is applicable to "all patent withdrawals," regardless of how they come about, including a voluntary request for patent delisting. (*See* Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 8-9.) As FDA well knows, the MMA provides for one, and only one, mechanism for delisting and withdrawing patent information from the Orange Book for a patent to which an applicant has submitted a paragraph IV certification; namely, a delisting counterclaim filed in patent litigation against the brand company seeking a court order that the patent be delisted. *See* 21 U.S.C. § 355(j)(5)(C)(ii). In these circumstances, a court may order that the patent be delisted. These are precisely, and indeed the only, circumstances under which the withdrawal provision in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(CC) comes into play. When these provisions are read together, as they must be, it is clear that Congress intended to trigger a forfeiture in these limited circumstances, and not whenever a brand company feels like doing so. FDA's interpretation, on the other hand, reads the withdrawal provision in § 355(j)(5)(D)(i)(I)(bb)(CC) in a vacuum without regard for the remainder of the MMA, and destroys the carefully crafted symmetry of these provisions.

3. The "Failure To Market" Forfeiture Provision Does Not—And Cannot—Apply Here Because No Subsequent Applicant Had Received Tentative Approval.

A "failure to market" forfeiture takes place on the "later of" two specific events. 21 U.S.C. § 355(j)(5)(D)(i)(I). The second prong of that provision requires a subsequent ANDA filer to have received "tentative" ANDA approval. *Id.* § 355(j)(5)(D)(i)(I)(bb). As FDA buries in a footnote of its administrative ruling, no subsequent applicant for acarbose had tentative approval at the time FDA issued its forfeiture decision. (Rakoczy Decl. Ex. D, 5/7/08 Buehler

Ltr. at 6 n.11.) The lack of tentative approval by a subsequent filer means no forfeiture under this provision is possible under the plain and ambiguous language.

II. Cobalt, Without Question, Will Suffer Irreparable Harm If This Court Does Not Enter An Injunction Preventing FDA From Approving Subsequently-Filed Acarbose ANDAs.

The courts have long-recognized that "the earliest generic drug manufacturer in a specific market has a distinct advantage over later entrants." *Mova Pharm. Corp. v. Shalala*, 955 F. Supp. 128, 131 (D.D.C. 1997). Indeed, this is precisely the reason that Congress created an "officially sanctioned head start" in the form of the 180-day generic exclusivity provision—because such a head start is the only way to provide the incentive needed for companies to challenge suspect drug patents. *Id.*

Many benefits flow to the first generic market entrant. The first entrant, for example, satisfies the immediate market demand for a generic product by filling the distribution channels, thereby achieving significant sales revenue that a subsequent entrant does not achieve. (Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 7.) The first entrant also has the opportunity to capture significant market share over time by entering into longer term contracts with drug wholesalers, chain pharmacies, hospitals, and other pharmaceutical purchasers, which results in long-term revenue. (*Id.* ¶ 8.) These opportunities are far more abundant for the first entrant than for each subsequent entrant. (*Id.*) Additionally, almost all customers practice "a right of first refusal" process, which allows the first entrant to maintain the business on a specific product even after subsequent manufacturers launch, thereby guaranteeing a long term revenue stream and dominant market share for the product. (*Id.*) Moreover, most customers typically carry only one generic product. (*Id.*) Thus, obtaining these long term contracts is essential to maintaining some market share once subsequent generic products enter the market. Again, the opportunities are far

more abundant for the first entrant and are presented less and less for each subsequent entrant. (*Id.*)

Cobalt estimates that, with exclusivity, it will generate sales of about $9 million during the 180-day exclusivity period. (Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 12.) Cobalt also estimates that it will be able to capture significant market share during the exclusivity period, which will result in a higher market share after that period expires. (*Id.*) Moreover, Cobalt estimates that if it receives the 180-day exclusivity period, and Bayer does not market a so-called "authorized generic" in the first full year after the 180-day exclusivity period, Cobalt projects new revenues of more than $1.6 million and that it will capture a significant amount of the total acarbose market. (*Id.* ¶ 16.)[11] If, however, other acarbose ANDAs are permitted to remain on the market during Cobalt's exclusivity, as Roxane already is, the exclusivity advantages that Congress intended Cobalt to have will be destroyed.

If deprived of exclusivity, Cobalt believes that its profitability and market share will plummet dramatically. (Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 5.) Once multiple generic companies enter the market, profitability drops often as much as 90% within the first few months. (*Id.* ¶ 9.) Indeed, Cobalt projects that, if other subsequent ANDAs are allowed to market during Cobalt's exclusivity, Cobalt's revenues will amount to no more than about $276,000 for the first full year of generic marketing. (*Id.* ¶ 17.) Moreover, the loss of any part of the 180 days of exclusivity due to entry of a new generic product will cause significant revenue losses beyond just the sales lost to the new entrant. (*Id.* ¶¶ 9-10.) These losses diminish the resources of smaller drug companies such as Cobalt, and thus make it more difficult and less

[11] An "authorized generic" is a product manufactured under the brand company's NDA, but marketed under its generic name to compete with the true generic ANDA product. Even if Bayer launches an authorized generic, Cobalt projects revenues exceeding $646,000 over the same period. (*Id.* ¶ 16.)

attractive to develop new generic products. (*Id.* ¶¶ 10-11.) And the difficulty in developing new products is compounded when a generic drug company cannot be certain that it will receive exclusivity even when it files the first paragraph IV ANDA. (*Id.* ¶ 10.)

Given these realities, it is not surprising that the courts have long-recognized that the loss of the advantages flowing from market exclusivity constitutes significant, and often irreparable, harm. *See Mova*, 140 F.3d at 1067 n.6 (confirming that Mova's loss of its "officially sanctioned head start . . . suffices to show a severe economic impact to Mova," for purposes of satisfying the irreparable harm standard (internal quotation omitted)); *Bracco Diagnostics, Inc. v. Shalala*, 963 F. Supp. 20, 29 (D.D.C. 1997) (stating that "there is a significant economic advantage to receiving first approval and being the first company to enter the market, an advantage that can never be fully recouped through money damages or by 'playing catch-up'" and that a loss of market share to competitors establishes irreparable harm); *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 2 (D.D.C. 1997) (recognizing that losing "the advantage of being the first to market" amounts to significant harm for purposes of balancing hardships); *TorPharm, Inc. v. Shalala*, No. Civ.A. 97-1925(JR), 1997 WL 33472411, at *4 (D.D.C. Sept. 15, 1997) (recognizing that "early market entry is critical to success in the [relevant pharmaceutical] market because competitors will vie for a small number of long-term contracts"); *Stein Indus., Inc. v. Jarco Indus., Inc.*, 934 F. Supp. 55, 58 (E.D.N.Y. 1996) (finding irreparable harm and granting preliminary injunction where sales of patented products would lead to sales of other products).

Further, even if Cobalt could be compensated by money damages (it cannot), Cobalt cannot recover its significant losses from FDA for refusing to grant the exclusivity to which Cobalt is statutorily entitled. *See Minn. Mining & Mfg. Co. v. Barr Labs, Inc.*, 289 F.3d

775, 777 (Fed. Cir. 2002) (recognizing no private cause of action created under Hatch-Waxman); *Mylan Pharms., Inc. v. Thompson,* 268 F.3d 1323, 1332 (Fed. Cir. 2001) (same). This fact further compounds the irreparable nature of the harm that Cobalt will suffer if this Court does not grant injunctive relief. *See World Duty Free Ams., Inc. v. Summers*, 94 F. Supp. 2d 61, 67 (D.D.C. 2000) (stating that the "significant losses are further compounded by the fact that such losses are not likely to be recovered given the" nature of the movant's business); *Express One Int'l, Inc. v. United States Postal Serv.*, 814 F. Supp. 87, 91 (D.D.C. 1992) (finding irreparable harm supported where "[t]he *non-recoverable* monetary losses [movant] faces are therefore real and present" and damages exist "for which there is no recourse"); *Rum Creek Coal Sales, Inc. v. Caperton,* 926 F.2d 353, 361 (4th Cir. 1991) (recognizing injunctive relief favored where, among other things, "[n]o other form of redress appears available").

The 180-day generic exclusivity period also involves several very important intangible benefits. (*See* Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 18.) Being the first-filer and obtaining the 180-day exclusivity period is a significant and important part of Cobalt's overall business plan. (*Id.*) In many instances, the majority of revenue that a company earns on a generic product will be generated during that exclusivity period. (*Id.*) The money made during this period is used, among other things, to fund research and development of new products, including funding new patent challenges. (*Id.*) Thus, loss of exclusivity can negatively impact future opportunities. And as noted, this is one of Cobalt's only first-filer opportunities that the company is counting on for the development of future generic products. The loss of this opportunity could destroy much of Cobalt's future pipeline. (*Id.*)

Further, being the first filer also provides the ability to foster good will with customers by providing them a generic product that no one else offers; the ability to form

relationships with new customers as the only provider of the generic product; the ability to cement those relationships prior to entry of a new generic product; and improved market position and prestige. (*See* Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 19.) As a new company, Cobalt has limited opportunities and distribution, since customers do not want to open up new accounts with new companies. (*Id.* ¶ 20.) But an exclusive first-filer opportunity like acarbose gives Cobalt full distribution—customers will want a new generic product like acarbose that they cannot get anywhere else. (*Id.*) Therefore, this exclusive opportunity opens up channels that were not otherwise available to Cobalt. This opportunity goes well beyond just sales of this particular product—it gives Cobalt visibility, opportunities to bid on future products, and credibility that will provide long-term benefits, future growth and sustainability. (*Id.*)

Cobalt's well-deserved image as an important supplier of generic pharmaceuticals has been established due to its ability to bring lower cost alternatives of important pharmaceuticals to the market. (*See* Rakoczy Decl. Ex. M, Sanzen Decl. ¶ 21.) If Cobalt loses its sole exclusivity for its generic acarbose product, Cobalt will lose that prestige and its business reputation will be severely and irreparably be damaged. (*Id.*) In the end, as a relatively new and small company, Cobalt has had very few first-filer opportunities. Cobalt must therefore capitalize on this opportunity now, or else risk never having the necessary resources to secure and enjoy the exclusivity again.

Finally, even if Cobalt were not facing irreparable harm (it certainly is as a result of Roxane's commercial launch), the injunction should still issue in light of Cobalt's significant likelihood of success on the merits: "If the arguments for one factor are particularly strong, an injunction may issue even if the arguments in other areas are rather weak." *CityFed*, 58 F.3d at 747; *accord Cuomo*, 772 F.2d at 974 (finding injunction appropriate where there is "either a high

probability of success and some injury, or vice versa"). Because Cobalt has demonstrated a significant likelihood of success on the merits, and will undoubtedly suffer injury for which it cannot be recompensed, this Court should grant Cobalt's motion.

III. The Requested Injunction Will Not Substantially Harm Any Other Interested Party.

Others will not be substantially harmed if this Court grants Cobalt's request for injunctive relief. The FDA has no commercial stake in the outcome of this lawsuit. Indeed, FDA's only legitimate interest concerns the proper interpretation and implementation of the FFDCA. Accordingly, injunctive relief requiring FDA to follow the clearly expressed intent of Congress will not harm FDA.

The same is true for all other acarbose ANDA filers. At the time that they prepared and filed their ANDAs, all filers knew that the statute awarded exclusivity to another ANDA applicant. Consequently, each and every ANDA filer knew that approval of its product necessarily would be delayed by the 180-day generic exclusivity period. Thus, subsequent ANDA filers cannot legitimately claim any harm other than the loss of a windfall due to FDA's unlawful forfeiture provision interpretation, particularly since FDA's interpretation is so obviously contrary to the plain language of the statute. Accordingly, the balance of harms clearly favors Cobalt. *See Mova*, 955 F. Supp. at 131 (concluding that the significant likelihood of success on the merits outweighed any harm suffered by the subsequent ANDA applicant).

IV. The Requested Injunction Fosters The Public Interest.

Finally, the public interest would be served by an injunction in this case. The public has a considerable interest in the faithful application of the law. *See Mova*, 955 F. Supp. at 131; *accord Bracco*, 963 F. Supp. at 30 ("Requiring [FDA] to act lawfully is . . . very much in the public interest."). Moreover, Congress already has determined what is in the public interest—encouraging challenges to brand-name patented drug monopolies through the reward of

180-day generic exclusivity. Because generic exclusivity is the only incentive Congress created for companies to challenge drug patents, a statutory interpretation that destroys or diminishes the value of that exclusivity necessarily will cause generic companies to forego new patent challenges. Fewer patent challenges will, in turn, harm the public by forcing consumers to pay unnecessarily high prices for drug products, in direct contravention of Congressional intent. *See In re Barr Labs.*, 930 F.2d at 76 (observing that Congress designed Hatch-Waxman "to get generic drugs into the hands of patients at reasonable prices–fast."). Thus, as with all of the other factors, the public interest weighs in favor of granting Cobalt's motion for immediate injunctive relief.

CONCLUSION

Cobalt, therefore, has a strong likelihood of succeeding on the merits of its suit against FDA. Furthermore, Cobalt will be irreparably harmed if any other ANDA applicant is permitted to continue to encroach on any of Cobalt's 180 days of exclusivity. This harm can be prevented only by enjoining FDA from granting final approval to any generic acarbose ANDA until Cobalt's exclusivity period has expired and the Agency is immediately required to stay or withdraw any and all previously-granted approvals until expiration of Cobalt's exclusivity. The Court therefore should enjoin FDA from forfeiting Cobalt's exclusivity and approving any subsequent acarbose ANDAs until the natural expiration of such exclusivity, and require FDA to immediately stay or withdraw the approval of any and all other acarbose ANDAs. The Court also should require FDA to order a recall of all acarbose product sold or shipped by Roxane during Cobalt's exclusivity period. This order should remain in place until this Court has the opportunity to rule on a fully-briefed preliminary injunction motion.

Dated: May 8, 2008.

Respectfully submitted,

COBALT LABORATORIES INC. and
COBALT PHARMACEUTICALS, INC.

By: _____
One of their attorneys

E. Anthony Figg, D.C. Bar No. 345124
Daniel L. Shores, D.C. Bar No. 495389
ROTHWELL, FIGG, ERNST & MANBECK, P.C.
1425 K Street, N.W.
Suite 800
Washington, D.C. 20005
(202) 783-6040
(202) 783-6031 (facsimile)
efigg@rfem.com

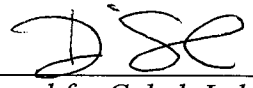
William A. Rakoczy, D.C. Bar No. 489082
Christine J. Siwik
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60610
(312) 222-6301
(312) 222-6321 (facsimile)
wrakoczy@rmmslegal.com

Counsel for Cobalt Laboratories Inc. and
Cobalt Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

I, the undersigned, HEREBY CERTIFY that on this 8th day of May 2008, a true and correct copy of: (a) Cobalt's Motion for Temporary Restraining Order; (b) Memorandum in Support of Cobalt's Motion for Temporary Restraining Order; (c) Proposed Order; (d) Certificate of Counsel Pursuant to Local Rule 65.1(a); (e) Declaration of William A. Rakoczy and all exhibits thereto; and all other papers filed in this matter were served via hand delivery and electronic mail upon the following:

Gerald Kell
Senior Trial Counsel
Office of Consumer Litigation
Civil Division
US Department of Justice
PO Box 386
Washington, DC 20044
gerald.kell@usdoj.gov
Counsel for the Federal Defendants



Counsel for Cobalt Laboratories Inc. and Cobalt Pharmaceuticals Inc.