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. 1:08-CV-00798 (RBW)

SUPPLEMENTAL 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
Minaksi Bhatt, D.C. Bar No. 434448
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 9, 2008

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

Cobalt respectfully submits this brief supplement in support of its May 8, 2008 motion for a temporary restraining order.[1]

DISCUSSION

FDA asserts that Cobalt forfeited its exclusivity under the so-called "failure to market" forfeiture provision, which provides:

> (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

[1] Because FDA waited until well after close of business on May 7, 2008 to notify Cobalt that the Agency simultaneously stripped Cobalt of its statutory right to exclusivity and approved one of its competitors, FDA left Cobalt with no choice but to submit an immediate TRO motion. Cobalt did so just 20 or so hours after receiving FDA's administrative decision. Consequently, Cobalt did not have sufficient time to flesh out all of the reasons why the Agency's administrative ruling is arbitrary, capricious, and contrary to law. With this supplemental submission, Cobalt provides additional detail regarding one of its arguments.

> 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) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

21 U.S.C. § 355(j)(5)(D)(i)(I).

According to FDA, the failure to market forfeiture provision "directs that a forfeiture event occurs when the first applicant fails to market the drug by the later of two dates." (Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 6).[2] One event is "calculated under item (aa) by determining the earlier of a date that is either 75 days after the first applicant's ANDA is approved (subitem (AA)) or 30 months after the date of submission of the first applicant's ANDA (subitem (BB)). (*Id.*). According to FDA, the "earlier of" date, and thus the date under item (aa), with respect to Cobalt's ANDA is September 22, 2007. (*Id.*).

Item (bb) looks to events with respect to the listed patents to which the first applicant submitted a paragraph IV certification. According to FDA, "[t]hese events include, very generally, when a court enters a final decision that the patent is invalid or not infringed, a court signs a settlement order or consent decree entering final judgment that includes a finding that the patent is invalid or not infringed, or the patent information for the listed drug is withdrawn by the NDA holder." (*Id.* at 7). The Agency then goes on to explain why the court decision and settlement order/consent decree provisions (subitems (AA) and (BB)) are

[2] "Rakoczy Decl." refers to the Declaration of William A. Rakoczy submitted on May 8, 2008.

inapplicable in this case. (*Id.*). FDA then states that it received a delisting request from the NDA holder at issue here on April 16, 2007. (*Id.*). Even if this Court believes all of FDA's assertions to this point, what happens next is fatal to FDA's administrative ruling. Specifically, FDA asserts:

> Under section 505(j)(5)(D)(i)(I)(bb) of the Act, the applicable date for calculating whether a failure to market forfeiture event has occurred is 75 days after the patent information is withdrawn by the NDA holder. In this case, the date that is 75 days after the NDA holder withdrew the information on the '796 patent, i.e., April 16, 2007, was June 30, 2007.

(*Id.*). From this unlawful statutory construction, FDA concludes that the date under item (bb) is June 30, 2007. And from this, FDA ruled that the "later of" date under the failure to market provision is September 20, 2007, and thus that Cobalt forfeited its exclusivity. (*Id.* at 7-8). FDA is flat wrong. Item (bb) does ***not*** calculate the relevant date simply as 75 days from one of the enumerated patent events, as FDA asserts. Not at all. Far from it.

What FDA pays lip service to, and then immediately attempts to sidestep (*id.* at 6 n.11), is the key phrase that proceeds the 75-day language. Specifically, before the 75-day clock starts to run, a subsequent ANDA applicant must have "***received tentative approval***." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (introductory clause) (emphasis added). Congress included this 75-day period precisely so that a first applicant would not immediately forfeit after the occurrence of an event over which it had no control. But this is precisely what FDA has done in this case.

The plain language of item (bb) does more than "reasonably anticipate[] that a first applicant will not forfeit its exclusivity unless another applicant has met the technical and scientific requirements for approval of its ANDA," as FDA claims. (Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 6 n.11). It expressly requires the other applicant to have "received tentative approval." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb) (introductory clause). "Tentative

approval" is not some malleable administrative concept that FDA can shape to fit the needs of the moment. It is defined statutory term:

> The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

21 U.S.C. § 355(j)(5)(B)(iv)(II)(dd)(AA). In this case, FDA has conceded that no other ANDA applicant had tentative approval as of the date the NDA holder requested to have the '769 patent delisted. Indeed, by FDA's own admission, no other ANDA applicant was even eligible for tentative approval until May 7, 2008.[3]

On May 7, 2008, FDA concluded that some acarbose ANDA applicants were eligible for tentative approval. Under the plain language of item (bb), Cobalt had 75 days from that date to begin commercial marketing or risk a forfeiture. Indeed, even if FDA lawfully could use some lesser standard than the statutory definition of "tentative approval" when it comes to the approval status of a subsequent applicant (which FDA cannot), the Agency cannot lawfully ignore the 75-day requirement, which attaches to one of the three enumerated patent events only

[3] By its own admission, FDA only makes exclusivity determinations "in the context of specific ANDAs that are otherwise eligible for approval." (Rakoczy Decl. Ex. D, 5/7/08 Buehler Ltr. at 1 n.1). From this admission, this Court knows that until May 7, no acarbose ANDA applicant was otherwise eligible for final approval. Acarbose ANDAs became otherwise eligible for approval yesterday solely because in addition to ruling on Cobalt's right to generic exclusivity, FDA also issued a separate administrative ruling in a different citizen petition docket, Docket 2007P-0448. The 2007P-0448 petition challenged "as inadequate and inappropriate the in vitro bioequivalence recommendations" FDA previously had provided to acarbose ANDA applicants. (*Id.* at 3). It "triggered [at the Agency] a reassessment of appropriate in vitro and in vitro [sic] bioequivalence methodologies for acarbose tablets." (*Id.*). By FDA's own admission, the Agency "delayed approval of the acarbose ANDAs" during this reassessment. (*Id.*). On May 7, 2008, FDA granted in part and denied in part the 2007P-0448 submission, finding that it could approve any ANDAs satisfying the appropriate approval criteria. (*Id.*). Again, by FDA's own admission, it was this administrative decision that cleared the way for ANDA approvals and thus, according to the Agency, necessitated a determination regarding Cobalt's right to exclusivity. (*Id.*).

after a subsequent applicant has received tentative ANDA approval. Because Cobalt started to commercially market on May 8, there has been no forfeiture of its exclusivity under the failure to market provision. Any other result would violate the plain language of the statute; impermissibly run afoul of Congressional intent; and unlawfully lead to absurd results. FDA's administrative decision must be set aside because it is arbitrary, capricious, and contrary to law.

CONCLUSION

For the reasons set forth here and in Cobalt's May 8, 2008 motion papers, Cobalt is entitled to the requested immediate injunctive relief.

Dated: May 9, 2008.

Respectfully submitted,

COBALT LABORATORIES INC. and
COBALT PHARMACEUTICALS, INC.

By: Minaksi Bhatt
One of their attorneys

E. Anthony Figg, D.C. Bar No. 345124
Daniel L. Shores, D.C. Bar No. 495389
Minaksi Bhatt, D.C. Bar No. 434448
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

The undersigned hereby certifies that the foregoing **SUPPLEMENTAL MEMORANDUM IN SUPPORT OF COBALT'S MOTION FOR TEMPORARY RESTRAINING ORDER** was electronically filed this 9th day of May, 2008. Notices of filing will be sent to all parties by operation of the court's electronic filing system. Parties may access this filing through the Court's System.

In addition, the undersigned hereby certifies that the foregoing **SUPPLEMENTAL MEMORANDUM IN SUPPORT OF COBALT'S MOTION FOR TEMPORARY RESTRAINING ORDER** was served via hand delivery and electronic mail upon the following:

Gerald Kell, Esq.
Senior Trial Counsel
U.S. Department of Justice
Office of Consumer Litigation
Liberty Square Building
Room 6318 South
450 5th Street, N.W.
Washington, DC 20001
E-mail: gerald.kell@usdoj.gov
Counsel for the Federal Defendants

Minaksi Bhatt

Minaksi Bhatt
Counsel for Cobalt Laboratories Inc. and Cobalt Pharmaceuticals Inc.