

LANCE R. LEFLEUR
DIRECTOR



ROBERT J. BENTLEY
GOVERNOR

Alabama Department of Environmental Management
adem.alabama.gov

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Montgomery, Alabama 36130-1463
(334) 271-7700 ■ FAX (334) 271-7950

February 04, 2014

CERTIFIED MAIL # 91 7199 9991 7032 3110 8803

Ms. Alane Barnes
Vice President, General Counsel & Corporate Secretary
BioCryst Pharmaceuticals, Inc.
4505 Emperor Boulevard, Suite 200
Durham, NC 27703

RE: **Consent Order No. 14-037-CHW**
BioCryst Pharmaceuticals, Inc. (d/b/a BioCryst Discovery Center of Excellence)
2190 Parkway Lake Drive
Birmingham, AL 35244
EPA Identification Number ALD983190786

Dear Ms. Barnes:

Enclosed is an original copy of the Consent Order No. 14-037-CHW, which constitutes an agreement between BioCryst Pharmaceuticals, Inc. and the Alabama Department of Environmental Management. This Order requires BioCryst Pharmaceuticals, Inc. to take certain actions at the facility in regard to alleged violations of the Alabama Hazardous Wastes Management and Minimization Act of 1978. This Order was signed by ADEM's Director and became effective as of February 04, 2014. As described in Order Item A, BioCryst Pharmaceuticals, Inc. has forty-five days from that date to pay the civil penalty assessed therein.

Should you have any questions, please feel free to contact Srinivas Pochana of my staff at 334-271-7769.

Sincerely,

A handwritten signature in black ink, appearing to read "Phillip D. Davis", is written over a horizontal line.

Phillip D. Davis, Chief
Land Division

PDD/SP/nbf

Enclosure

CC via email: Cesar Zapata, EPA Region 4
Paula Whiting, EPA Region 4
Jerome Hand, ADEM Office of Public Affairs
Chris Sasser, ADEM Office of General Counsel
Thomas L. Johnston, ADEM Office of General Counsel

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Birmingham Branch
110 Vulcan Road
Birmingham, AL 35209-4702
(205) 942-6168
(205) 941-1603 (FAX)

Decatur Branch
2715 Sandlin Road, S. W.
Decatur, AL 35603-1333
(256) 353-1713
(256) 340-9359 (FAX)



Mobile Branch
2204 Perimeter Road
Mobile, AL 36615-1131
(251) 450-3400
(251) 479-2593 (FAX)

Mobile-Coastal
4171 Commanders Drive
Mobile, AL 36615-1421
(251) 432-6533
(251) 432-6598 (FAX)

**ALABAMA DEPARTMENT OF
ENVIRONMENTAL MANAGEMENT**

IN THE MATTER OF:

**BioCryst Pharmaceuticals, Inc.
Birmingham, Jefferson County, Alabama
USEPA ID NUMBER ALD983190786**

ORDER NO. 14-037-CHW

PREAMBLE

This Special Order by Consent is made and entered into by the Alabama Department of Environmental Management (hereinafter “the Department” or “ADEM”) and BioCryst Pharmaceuticals, Inc. (hereinafter “BioCryst”) pursuant to the provisions of the Alabama Environmental Management Act, Ala. Code §§ 22-22A-1 to 22-22A-16 (2006 Rplc. Vol.), and the Alabama Hazardous Wastes Management and Minimization Act (hereinafter “AHWMMA”), Ala. Code §§ 22-30-1 to 22-30-24 (2006 Rplc. Vol.), and the regulations promulgated pursuant thereto.

STIPULATIONS

1. BioCryst Pharmaceuticals, Inc. (hereinafter “BioCryst”) operates a pharmaceutical development facility with EPA Identification Number ALD983190786, located at 2190 Parkway Lake Drive, Birmingham, Jefferson County, Alabama. BioCryst submitted notifications to the Department identifying itself as a large quantity generator on August 15, 2012 and July 29, 2013.
2. The Department is a duly constituted department of the State of Alabama pursuant to Ala. Code §§ 22-22A-1 to 22-22A-16 (2006 Rplc. Vol.).
3. Pursuant to Ala. Code § 22-22A-4(n) (2006 Rplc. Vol.), the Department is the state agency responsible for the promulgation and enforcement of solid and hazardous waste regulations in accordance with the federal Solid Waste Disposal Act §§ 1002 to 11012, 42 U.S.C. §§ 6901 to 6992k, as amended. In addition, the Department is authorized to administer

and enforce the provisions of the AHWMMMA, Ala. Code §§ 22-30-1 to 22-30-24 (2006 Rplc. Vol.).

DEPARTMENT'S CONTENTIONS

4. On September 14, 2012 and February 7, 2013, a representative of the Department conducted compliance evaluation inspections (hereinafter "CEIs") of BioCryst. The CEIs and a review of BioCryst's compliance showed the following:

Pursuant to ADEM Admin. Code r. 335-14-3-.03(5)(b), a large quantity generator who accumulates hazardous waste for more than 90 days is an operator of a storage facility and is subject to the requirements of 335-14-5 and 335-14-6, and the permit requirements of 335-14-8 unless he has been granted an extension to the 90-day period. ADEM Admin. Code r. 335-14-8-.01(1)(c) requires a permit for the "storage" of any "hazardous waste" as identified or listed in Chapter 335-14-2.

BioCryst accumulated hazardous waste on site for more than ninety days, thereby subjecting BioCryst to the requirements of ADEM Admin. Code ch. 335-14-5 and 335-14-6 and the permit requirements of ADEM Admin. Code ch. 335-14-8. During the September 14, 2012 inspection, a BioCryst employee informed the Department's representative that BioCryst had declared the contents of a 55-gallon container labeled with the words "Tetrahydrofuran" (but no accumulation start date) as an ignitable hazardous waste in February 2012. The container was located in the facility's 90-day hazardous waste container storage area. A review of Department records revealed that BioCryst has not applied for or received a hazardous waste storage facility permit from the Department.

5. As a result of the September 14, 2012 and February 7, 2013 CEIs, the Department issued to BioCryst a Notice of Violation (dated March 4, 2013), which cited violations of the hazardous waste regulations that were discovered during the CEIs.

6. On April 26, 2013, the Department received BioCryst's response to the March 4, 2013 Notice of Violation.

7. Pursuant to Ala. Code § 22-22A-5(18) (2006 Rplc. Vol.), in determining the amount of any penalty, the Department must give consideration to the seriousness of the violation(s), including any irreparable harm to the environment and any threat to the health or safety of the public; the standard of care manifested by such person; the economic benefit which delayed compliance may confer upon such person; the nature, extent, and degree of success of such person's efforts to minimize or mitigate the effects of such violation(s) upon the environment; such person's history of previous violations; and the ability of such person to pay such penalty. Any civil penalty assessed pursuant to this authority shall not exceed \$25,000.00 for each violation, provided however, that the total penalty assessed in an order issued by the department shall not exceed \$250,000.00. Each day such a violation continues shall constitute a separate violation.

8. In arriving at the civil penalty assessed in this Order, the Department has considered the following:

(a) **SERIOUSNESS OF THE VIOLATIONS:** Accumulation of hazardous waste beyond the allowable time period without requesting an extension or obtaining a storage permit constitutes a significant deviation from the applicable regulatory requirements. However, the Department is not aware of any threat to the health or safety of the public or of any irreparable harm to the environment resulting from the violation.

(b) **THE STANDARD OF CARE:** The violation described in Paragraph 4. was easily avoidable. According to the facility's training documents, the required facility personnel had received hazardous waste management training, which included information about hazardous waste accumulation time limits. Consequently, BioCryst did not exhibit a standard of care commensurate with applicable regulatory requirements.

(c) **ECONOMIC BENEFIT WHICH DELAYED COMPLIANCE MAY HAVE CONFERRED:** The Department is not aware of any evidence indicating that BioCryst received any significant economic benefit from the violation.

(d) EFFORTS TO MINIMIZE OR MITIGATE THE EFFECTS OF THE VIOLATION UPON THE ENVIRONMENT: There are no known environmental effects to mitigate as a result of the alleged violations.

(e) HISTORY OF PREVIOUS VIOLATIONS: Based on Department records, BioCryst does not have a history of noncompliance with respect to ADEM Admin. Code div. 335-14.

(f) THE ABILITY TO PAY: BioCryst has not alleged an inability to pay the civil penalty.

(g) OTHER FACTORS: It should be noted that this Consent Order is a negotiated settlement and, therefore, the Department has compromised the amount of the penalty that is warranted in this matter in the spirit of cooperation and the desire to resolve this matter amicably, without incurring the unwarranted expense of litigation (see Attachment A, which is made a part of the Department's contentions).

8. The Department neither admits nor denies BioCryst's contentions, which are set forth below. The Department has agreed to the terms of this Consent Order in an effort to resolve the alleged violations cited herein without the unwarranted expenditure of State resources in further prosecuting the above violations. The Department has determined that the terms contemplated in this Consent Order are in the best interest of the citizens of Alabama.

BIOCRYST'S CONTENTIONS

9. BioCryst employs individuals who work and live in Jefferson County, Alabama and the surrounding areas. BioCryst is committed to conducting its operations in a responsible manner that is protective of the health and safety of its employees and of the environment in which it operates. BioCryst takes the allegations of the Department's March 4, 2013, Notice of Violation and this Consent Order very seriously, but BioCryst believes it is important to recognize that the Department has concluded that there was no threat to the

health or safety of the public or of any irreparable harm to the environment that resulted from BioCryst's alleged violations.

10. BioCryst neither admits nor denies the Department's contentions. BioCryst consents to abide by the terms of this Consent Order.

ORDER

THEREFORE, without admitting that it has violated any statutes or regulations, BioCryst, along with the Department, desires to resolve and settle the alleged violation cited above. The Department has carefully considered the facts available to it and has considered the six penalty factors enumerated in Ala. Code § 22-22A-5(18)c., as amended, as well as the need for timely and effective enforcement; the Department believes that the following conditions are appropriate to address the violation alleged herein. Therefore, the Department and BioCryst agree to enter into this Consent Order with the following terms and conditions:

A. Pursuant to Ala. Code § 22-22A-5(18)a., as amended, BioCryst agrees to pay to the Department a civil penalty in the amount of \$11,000 in settlement of the violation alleged herein within forty-five days from the effective date of this Consent Order. Failure to pay the civil penalty within forty-five days from the effective date may result in the Department's filing a civil action in the Circuit Court of Montgomery County to recover the civil penalty.

B. BioCryst agrees that all penalties due pursuant to this Consent Order shall be made payable to the Alabama Department of Environmental Management by certified or cashier's check or other payment methods acceptable to the Department and shall be remitted to:

Office of General Counsel

Alabama Department of Environmental Management

P.O. Box 301463

Montgomery, Alabama 36130-1463

Any payment submitted to the Department pursuant to this Order shall reference BioCryst's name and address, and the ADEM Administrative Order number of this action.

C. BioCryst agrees that, independent of this Consent Order, BioCryst shall comply with all terms, conditions, and limitations of the AHWMMMA, Ala. Code §§ 22-30-1 to 22-30-24 (2006 Rplc. Vol.), and the regulations promulgated pursuant thereto.

D. The Department and BioCryst (hereinafter the "parties") agree that this Consent Order shall apply to and be binding upon both parties, their directors, officers, and all persons or entities acting under or for them. Each signatory to this Consent Order certifies that he or she is fully authorized by the party he or she represents to enter into the terms and conditions of this Consent Order, to execute the Consent Order on behalf of the party represented, and to legally bind such party.

E. The parties agree that, subject to the terms of these provisions and subject to provisions otherwise provided by statute, this Consent Order is intended to operate as a full resolution of the violations cited in the Department's March 4, 2013, Notice of Violation and this Consent Order.

F. BioCryst agrees that it is not relieved from any liability if it fails to comply with any provision of this Consent Order.

G. For purposes of this Consent Order only, BioCryst agrees that the Department may properly bring an action to compel compliance with the terms and conditions contained herein in the Circuit Court of Montgomery County.

H. The parties agree that the sole purpose of this Consent Order is to resolve and dispose of all allegations and contentions stated herein and in the Department's March 4, 2013, Notice of Violation. Should additional facts and circumstances be discovered in the future which would constitute possible violations not addressed in the March 4, 2013, Notice of Violation or this Consent Order, then such future violations may be addressed in Orders as may be issued by the Director, litigation initiated by the Department, or such other

enforcement action as may be appropriate; BioCryst agrees not to object to such future orders, litigation, or enforcement action based on the issuance of this Consent Order if future orders, litigation, or other enforcement action address new matters not raised in the March 4, 2013, Notice of Violation or this Consent Order.

I. The parties agree that this Consent Order shall be considered final and effective immediately upon signature of all parties. This Consent Order shall not be appealable, and BioCryst does hereby waive any hearing on the terms and conditions of this Consent Order.

J. The parties agree that this Consent Order shall not affect BioCryst's obligation to comply with any Federal, State, or local laws or regulations.

K. The parties agree that final approval and entry into this Consent Order are subject to the requirements that the Department give notice of proposed Orders to the public, and that the public have at least thirty days within which to comment on the Consent Order.

L. The parties agree that, should any provision of this Consent Order be declared by a court of competent jurisdiction or the Environmental Management Commission to be inconsistent with Federal or State law and therefore unenforceable, the remaining provisions hereof shall remain in full force and effect.

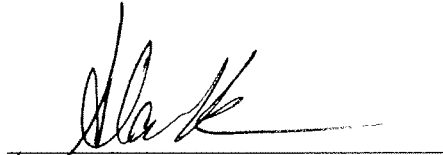
M. The parties agree that any modifications of this Consent Order must be agreed to in writing signed by both parties.

N. The parties agree that, except as otherwise set forth herein, this Consent Order is not and shall not be interpreted to be a permit or modification of an existing permit under Federal, State or local law, and shall not be construed to waive or relieve BioCryst of its obligations to comply in the future with any permit.

Executed in duplicate, with each part being an original.

BioCryst Pharmaceuticals, Inc.

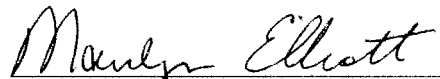
ALABAMA DEPARTMENT OF
ENVIRONMENTAL MANAGEMENT


(Signature of Authorized Representative)

Alene Barnes
(Printed Name)

VP General Counsel - Capital
(Printed Title)

12-5-13
(Date Signed)


Lance R. LeFleur
Director

02 - 04 - 2014
(Date Executed)

Attachment A
Civil Penalty Synopsis

BioCryst Pharmaceuticals, Inc.
Birmingham, Jefferson County, Alabama
EPA ID NUMBER ALD983190786

Violation*	Number of Violations*	Seriousness of Violation & Base Penalty*	Standard of Care*	History of Previous Violations*
Accumulation of hazardous waste beyond 90 days	1	\$10,000	\$1,000	\$0
Totals:	1	\$10,000	\$1,000	\$0

Economic Benefit:	\$0
Mitigating Factors:	\$0
Ability to Pay:	\$0
Other Factors:	
Civil Penalty:	<hr/> \$11,000

*See the "Department's Contentions" portion of the Order for a detailed description of each violation and the penalty factors