

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029**

IN RE:	)	DOCKET NO. FIFRA-03-2017-0027
	)	
ANGELINI PHARMA, INC.	)	CONSENT AGREEMENT
8322 HELGERMAN COURT	)	NOTABLY LATE OR NON REPORTING
GAITHERSBURG, MARYLAND 20877	)	
	)	
Respondent	)	

**EXPEDITED CONSENT AGREEMENT**

1. This Expedited Consent Agreement is entered into by the Director of the Land and Chemicals Division, U.S. Environmental Protection Agency - Region III (“EPA” or “Complainant”) and Angelini Pharma, Inc. (“Respondent”), pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), *as amended*, 7 U.S.C. § 136l(a), and Sections 22.13(b) and .18(b) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. § 22.13(b) and .18(b). This Consent Agreement (“CA”) and the attached Final Order (hereinafter jointly referred to as the “CAFO”) resolve Complainant's civil penalty claims against the Respondent under FIFRA arising from the violation of FIFRA alleged herein.

2. Section 7(c) of FIFRA, 7 U.S.C. § 136e(c), requires any producer operating a registered pesticides-producing establishment to inform EPA of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides, which it is producing, which it has produced during the past year, and which it has sold or distributed during the past year. The information required by this paragraph shall be kept current and submitted to the Administrator annually as required by such regulations as the Administrator may prescribe. The regulation found at 40 C.F.R § 167.85(d) requires such pesticides report to be filed annually on or before March 1, even if the producer has produced no pesticidal products for that reporting year.

3. The EPA is authorized to enter into this CAFO, pursuant to Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, *as amended*, 7 U.S.C. § 136l(a) (“FIFRA”), 40 C.F.R. § 167.85 and 40 C.F.R. § 22.13(b) and in accordance with the July 22, 2014 *FIFRA Section 7 Expedited Settlement Agreement Pilot Program*, which has been extended by the EPA until January 22, 2017.

4. EPA finds that Respondent is a “person,” a “producer” and operates an “establishment”, as those terms are defined in Sections 2(s), (w), and (dd) of FIFRA, 7 U.S.C. §§ 136(s), (w), and

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(dd), and 40 C.F.R. § 167.3, at 8322 Helgerman Court, Gaithersburg, Maryland 20877. This Establishment is registered with EPA under Establishment Number 65787-MD-001.

5. Respondent has failed to comply with Section 7(c) of FIFRA, 7 U.S.C. § 136e(c), and with the regulations found at 40 C.F.R. § 167.85(d) in that it did not file the 2015 annual pesticides report for the above facility by March 1, 2016, as required.

6. For purposes of this proceeding, Respondent admits the jurisdictional allegations set forth in this CAFO.

7. Except as provided in Paragraph 6 herein, for purposes of this proceeding, Respondent neither admits nor denies the factual allegations and legal conclusions set forth in this CAFO.

8. Respondent agrees not to contest the jurisdiction of EPA with respect to the execution of this CA, the issuance of the attached Final Order, or the enforcement of this CAFO.

9. For purposes of this proceeding only, Respondent hereby expressly waives any right to contest any issue of law or fact set forth in this CA and any right to appeal the attached Final Order.

10. Respondent consents to the issuance of this CAFO and agrees to comply with its terms and conditions.

11. Each Party to this CAFO shall bear its own costs and attorney's fees.

12. By its signature below, Respondent certifies, subject to civil and criminal penalties for making a false statement to the United States Government, that to the best of Respondent's knowledge, it is presently in compliance with all requirements of FIFRA, 7 U.S.C. *et seq.*, and all regulations promulgated thereunder.

13. The parties enter into this Consent Agreement in order to settle the civil violation(s) alleged above. Pursuant to the Consolidated Rules of Practice, and in consideration of the statutory factors set forth in FIFRA Section 14(a)(4), 7 U.S.C. Section 136l(a)(4), EPA's *Enforcement Response Policy for FIFRA Section 7(c) Establishment Reporting Requirements* ("ERP"), updated May 2010, 40 C.F.R. Part 19, and the July 22, 2014 *FIFRA Section 7 Expedited Settlement Agreement Pilot Program*, extended until January 22, 2017, EPA has determined that an appropriate civil penalty to settle this action is **\$1200**.

14. Respondent agrees that within 30 days of the effective date of this CAFO (the date it is filed with the Regional Hearing Clerk), Respondent shall submit a check payable to "**United States Treasury**" with the case name, address and docket number of this CAFO (FIFRA-03-2017-0027), for the amount specified above, to U.S. Environmental Protection Agency, Fines and Penalties, Cincinnati Finance Center, P.O. Box 979077, St. Louis, MO 63197-9000. Copies

of the check shall be sent simultaneously to:

Ms. Holly Raguza, Enforcement Officer  
U.S. Environmental Protection Agency  
Region III (Mail Code 3LC62)  
1650 Arch Street  
Philadelphia, PA 19103-2029

and

Ms. Lydia Guy, Regional Hearing Clerk  
U.S. Environmental Protection Agency  
Region III (Mail Code 3RC00)  
1650 Arch Street  
Philadelphia, PA 19103-2029.

15. This CAFO settles EPA's civil penalty claims against Respondent for the violations specified above. EPA does not waive its right to take enforcement action against Respondent for any other past, present, or future violations of FIFRA or any other federal statute or regulation.

16. Nothing in this CAFO is intended to, nor shall be construed to operate in any way to resolve, any criminal liability of Respondent, and nothing in this CAFO shall be construed to limit EPA's authority to undertake any action against Respondent in response to conditions that may present an imminent and substantial endangerment.

17. This CAFO is binding on the parties signing below. Upon signature of the parties and approval by the Regional Judicial Officer, this CAFO shall be filed with the Regional Hearing Clerk. In accordance with 40 C.F.R. 22.31(b), this CAFO is effective upon filing with the Regional Hearing Clerk.

18. The undersigned representative certifies that he is fully authorized to execute this Consent Agreement and to legally bind Angelini Pharma, Inc. to this CAFO.

In the Matter of Angelini Pharma, Inc.

EPA Docket No. FIFRA-03-2017-0027

**APPROVED BY:**

Name (Print): Hippolitus Odukwu

Title (Print): Director, Regulatory Affairs

Signature:  Date: 11/21/16

**FOR COMPLAINANT:**

Holly A. Ragusa Date: 11/29/2016  
Holly Ragusa  
Pesticides Enforcement Officer  
U.S. EPA Region III

Accordingly, the Land and Chemicals Division, United States Environmental Protection Agency, Region III, recommends that the Regional Administrator, or his designee, issue the Final Order set forth below.

12.9.16  
Date

  
John A. Armstead, Director  
Land and Chemicals Division

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029**

**In the Matter of:**

**ANGELINI PHARMA, INC.  
8322 HELGERMAN COURT  
GAITHERSBURG, MARYLAND 20877**

**Respondent.**

**EPA Docket No. FIFRA-03-2017-0027**

**FINAL ORDER**

**Proceeding under Section 14(a) of the  
Federal Insecticide, Fungicide and  
Rodenticide Act, 7 U.S.C. § 136l(a)**

**FINAL ORDER**

Complainant, the Director of the Land and Chemicals Division, U.S. Environmental Protection Agency, Region III, and Respondent, have executed a document entitled “Expedited Consent Agreement,” which I hereby ratify as a Consent Agreement in accordance with the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (“Consolidated Rules of Practice”), 40 C.F.R. Part 22 (with specific reference to Sections 22.13(b) and 22.18(b)(2) and (3)). The terms of the foregoing Consent Agreement are accepted by the undersigned and incorporated into this Final Order as if fully set forth at length herein.

Based upon the representations of the parties in the attached Consent Agreement, the penalty agreed to therein is based upon consideration of, *inter alia*, EPA’s December 2009 *FIFRA Enforcement Response Policy Federal Insecticide, Fungicide, Rodenticide Act*, and the

and the statutory factors set forth in Section 14(a)(4) of FIFRA, 7 U.S.C. § 136l(a)(4).

**NOW, THEREFORE, PURSUANT TO** Section 14(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136l(a), and Section 22.18(b)(3) of the Consolidated Rules of Practice, **IT IS HEREBY ORDERED** that Respondent pay a civil penalty in the amount of ONE THOUSAND, TWO HUNDRED DOLLARS (**\$1200.00**), in accordance with the payment provisions set forth in the Consent Agreement, and comply with the terms and conditions of the Consent Agreement.

The effective date of the attached Consent Agreement and this Final Order is the date on which this Final Order is filed with the Regional Hearing Clerk.

Dec 13, 2016  
Date

  
\_\_\_\_\_  
Joseph J. Lisa  
Regional Judicial and Presiding Officer  
U.S. EPA Region II

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Region III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029

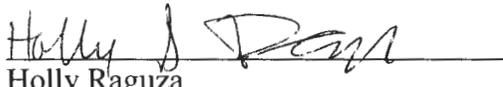
IN RE: :  
: :  
ANGELINI PHARMA, INC. : DOCKET NO. FIFRA-03-2017-0027  
8322 HELGERMAN COURT : :  
GAITHERSBURG, MD 20877 : :  
: :  
**Respondent** :

**CERTIFICATE OF SERVICE**

I hereby certify that the original of the foregoing Expedited Consent Agreement and Final Order for the above-referenced matter were hand-delivered to the Regional Hearing Clerk, EPA Region III, and that true and correct copies were mailed via certified mail to the following person(s):

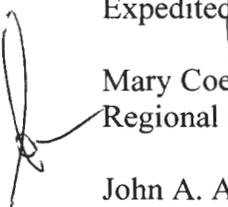
Hippolitus Odukwu  
Directory of Regulatory Affairs and Quality Assurance  
Angelini Pharma, Inc.  
8322 Helgerman Court  
Gaithersburg, MD 20877

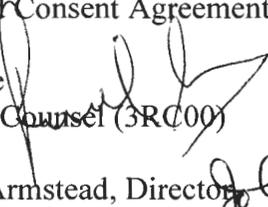
12/14/16  
Date

  
Holly Ragusa  
Enforcement Officer  
U.S. Environmental Protection Agency, Region III

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
1650 Arch Street  
Philadelphia, Pennsylvania 19103-2029

Subject: Federal Insecticide, Fungicide, and Rodenticide Act  
Angelini Pharma, Inc.  
Docket No. FIFRA-03-2017-0027  
Expedited Consent Agreement and Final Order

From:  Mary Coe  
Regional Counsel (3RC00) 12/7/16

 John A. Armstead, Director  
Land and Chemicals Division (3LC00) 12.9.16

To:  Joseph J. Lisa  
Regional Judicial Officer (3RC00) 12/13/2016

The attached Expedited Consent Agreement has been negotiated pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, and the Revocation/Termination or Suspension of Permits (“Consolidated Rules”), 40 C.F.R. Part 22, with specific reference to 40 C.F.R. § 22.18(b)(2), in settlement of an alleged violation of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136 *et seq.*, by Angelini Pharma, Inc.

The FIFRA Expedited Settlement Agreement program was extended for an additional six (6) months by email dated Wednesday, July 20, 2016 6:25 PM, from Greg Sullivan, Acting Director Waste and Chemical Enforcement Division, U.S. EPA, OECA, OCE. The policy is in effect until January 22, 2017.

The terms of the settlement include a civil penalty of ONE THOUSAND, TWO HUNDRED DOLLARS (\$1200.00), calculated in accordance with the statutory factors of FIFRA Section 14(a), EPA’s *Enforcement Response Policy for FIFRA Section 7(c) Establishment Reporting Requirements (“ERP”)*, updated May 2010, and 40 C.F.R. Part 19.

We concur with the terms of the attached Expedited Consent Agreement and we recommend that you sign the Final Order; in accordance with the Consolidated Rules at 40 C.F.R. § 22.18(b)(3).

Respondent’s contact information is as follows:  
Name: Hippolitus Odukwu, Directory of Regulatory Affairs and Quality Assurance  
Phone: (800) 726-2308  
Email: [hodukwu@angelini-us.com](mailto:hodukwu@angelini-us.com)

cc: Hippolitus Odukwu, Directory of Regulatory Affairs and Quality Assurance  
Angelini Pharma, Inc.