



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

June 25, 2009

VIA OVERNIGHT MAIL

S. Khurshaid Kazmi
Vice President, Administration/Operation
Pharmaceuticals International, Inc.
10819 Gilroy Road
Hunt Valley, MD 21031

CAA-03-2011-0308

Re: Pharmaceuticals International, Inc., Docket No. CAA-III-11-0308

Dear Stan:

Enclosed, please find the final Consent Agreement and Consent Order resolving the above-referenced matter. Pursuant to the Consent Order, payment of the penalty plus interest shall be made within thirty (3) days of the effective date of the Order. The effective date of the Order is the date on which the Order was filed with the Regional Hearing Clerk, in this case September 30, 2011.

Payment of the penalty shall be made as specified in paragraph IV.D. of the Consent Agreement. At the same time that any payment is made, mail copies of any corresponding check, or written notification confirming any electronic wire transfer to Lydia A. Guy, Regional Hearing Clerk (3RC00), U.S. EPA, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103-2029 and to me at the above-referenced address. The written notification to the Regional Hearing Clerk and to me should reference the above case caption and docket number.

Thank you for your cooperation in settling this matter. If you have any questions, I can be reached at (215) 814-2607.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel E. Boehmcke".

Daniel E. Boehmcke
Senior Assistant Regional Counsel
EPA Region III

Enclosure

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

RECEIVED
 2011 SEP 30 PM 3:05
 REGIONAL HEARING CLERK
 EPA REGION III PHILADELPHIA

IN RE: :
 :
 : EPA Docket No. CAA-III-11-0308
 :
 Pharmaceuticals International, Inc. :
 :
 10819 Gilroy Road :
 :
 Hunt Valley, MD 21031 :
 :
 : Proceeding under Sections 113 (a) and
 :
 and :
 :
 : of the Clean Air Act,
 :
 : 42 U.S.C. § 7413(a) and (d)
 :
 103 Beaver Court :
 :
 Cockeysville, MD 21030 :
 :
 :
 :
 Respondent :
 :

CONSENT AGREEMENT

I. Preliminary Statement

A. This Consent Agreement is entered into by and between the Complainant, the Director of the Air Protection Division, United States Environmental Protection Agency, Region III (“EPA” or “Complainant”), and Pharmaceuticals International, Inc. (the “Respondent”), pursuant to Sections 113(a) and (d) of the Clean Air Act (“CAA”), 42 U.S.C. §§ 7413(a)(3) and (d), and the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits, 40 C.F.R. Part 22, (the “Consolidated Rules of Practice”). The Consolidated Rules of Practice, at 40 C.F.R. § 22.13 provide, in pertinent part, that where the parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding may be commenced and concluded simultaneously by the issuance of a consent agreement and final order pursuant to 40 C.F.R. §§ 22.18(b)(2) and (3).

B. The violations cited herein pertain to Respondent’s alleged failure to comply with the CAA, and provisions of the underlying Maryland State Implementation Plan (“SIP”) at Respondent’s pharmaceutical coating operations located at two (2) separate closely situated locations at 10819 Gilroy Road Hunt Valley, Maryland 21031 (the “Gilroy Road Facility”), and 103 Beaver Court, Cockeysville, Maryland 21030 (the “Beaver Court Facility”) (collectively the “Facilities”).

C. In accordance with Sections 22.13(b), and 22.18(b)(2) and (3) of the Consolidated

Rules of Practice, 40 C.F.R. §§ 22.13(b), and 22.18(b)(2) and (3), Complainant hereby simultaneously commences and resolves, as part of the settlement set forth herein, the claims identified Section III (“Findings of Fact and Conclusions of Law”) of this Consent Agreement

II. General Provisions

A. For purposes of this proceeding, Respondent admits the jurisdictional allegations set forth in this Consent Agreement and the accompanying Final Order (hereinafter collectively referred to as (“this CAFO”).

B. Respondent neither admits nor denies the specific factual allegations and conclusions of law set forth in this CAFO, except as provided in Paragraph II.A., above.

C. Respondent agrees not to contest EPA’s jurisdiction with respect to the execution of this CAFO, the issuance of the accompanying Final Order or the enforcement of this CAFO.

D. For the purpose of this proceeding only, Respondent hereby expressly waives its rights to a hearing pursuant to Section 113 of the CAA, 42 U.S.C. § 7413, concerning the finality or validity of this CAFO, or with respect to any issue of law or fact set forth in this CAFO. Respondent also waives any right to appeal the accompanying Final Order.

E. Respondent consents to the issuance of this CAFO and agrees to comply with the terms of this CAFO.

F. By signing this Consent Agreement, Respondent certifies to EPA that, upon investigation and to the best of its knowledge, it is in compliance at the Facilities with the requirements of the Clean Air Act and the Maryland SIP.

G. Each party to this action agrees to pay its own costs and attorney fees.

H. Nothing in this CAFO shall relieve Respondent of its obligation to comply with all applicable federal, state, and local laws and regulations.

I. This CAFO shall apply to and be binding upon Respondent, its officers, directors, successors and assignees.

III. Findings of Fact and Conclusions of Law

A. Complainant has determined that Respondent has violated certain requirements of the CAA and the Maryland SIP. In accordance with the Consolidated Rules of Practice, Complainant alleges the following findings of fact and conclusions of law:

1. On May 25, 2010, duly authorized representatives of the EPA conducted an inspection at the Facilities. The report of this inspection was sent to Respondent via letter dated July 14, 2010.
2. On July 14, 2010, EPA issued a CAA information request to Respondent pursuant to EPA's authority under Section 114 of the Act, 42 U.S.C. § 7414. EPA received a response to the July 14, 2010 CAA information request from Respondent via letter dated July 30, 2010.
3. EPA's review of the inspection findings and Respondent's response to the July 14, 2010 CAA information request indicates that Respondent violated requirements of the applicable Maryland State Operating Permits for various units at the Facilities.
4. Under Part B, Paragraph 2.e of Maryland State Operating Permits No. 005-2637-6-2949, 2951, 2952, 2953, & 2954, volatile organic compound ("VOC") emissions from facility operations are required to be limited to less than 20lb/day, unless such VOC emissions are treated by control technology which reduces those emissions by 85% or more overall.
5. According to Respondent's response to the July 14, 2010 CAA information request, Respondent's coating operations at the Gilroy Road Facility which use the O'Hara Coating Pan emit 164.323 kg (361.51lbs) of VOC when producing Respondent's designated batch number 14301. They emit 115.271 kg (253.59 lbs) when producing batch number 14302. They emit 150kg (330 lbs) when producing batch number 10PII0163-020. Respondent produced batch number 14301 on May 21, 2008, July 1, 2009 and October 7, 2009. Respondent produced batch number 14302 on August 19, 2008 and April 13, 2009. Respondent produced batch number 10PII0163-020 on July 2, 2010. Respondent claimed in its response to the July 14, 2010 CAA information request that 10% of the solvent is absorbed in the product in any given batch. As a result, the daily emissions for the dates mentioned would be 325.36 lbs. for batch 14301, 228.2 lbs. for batch 14302, and 297 lbs. for batch 10PII0163-020.
6. The O'Hara coating process unit uses a dust collector as a control device (AAF International Model 3RC6 serial number OP070067). According to the manufacturer, the Model 3RC6 dust collector is a cartridge collector capable of using the following media: cellulose, polyester, glass (and blends of these), carbon impregnated, oleophobic and PFTE membrane. Respondent uses ethyl alcohol/ethanol as a solvent in the production of batches 14301 and 14302. This dust collector unit is not an appropriate control technology for ethanol emissions. The control technology did not reduce VOC emissions by 85% or more overall, as required by Respondent's state operating permit, which constitutes a violation of Sections 113(a) and (d) of the CAA, 42 U.S.C. § 7413(a) and (d).
7. According to Respondent's calculations submitted in response to EPA's information requests, the drying operations at the Gilroy Road Facility which use the Gruenberg Oven, Serial Number 21822, emit 14.0 kg (30.8lbs) of VOC when producing batch numbers 14301 and 14302. They emit 16.266 kg (35.8lbs) when producing batch number 17001. Respondent produced batch number 14301 on May 21, 2008, July 1, 2009 and October 7, 2009. Respondent produced

batch number 14302 on August 19, 2008 and April 13, 2009. Respondent produced batch number 17001 on March 11, 2009, April 30, 2009 and June 10, 2009. Respondent claimed in its response to the July 14, 2010 CAA information request that 10% of the solvent is absorbed in the product of any given batch. As a result, the daily emissions for the dates noted would be 27.72 lbs. for batches 14301 and 14302, and 32.2 lbs. for batch 17001.

8. The Gruenberg Oven unit uses a filter as a control device. According to a memorandum from Respondent to the Maryland Department of the Environment ("MDE"), this unit's filter has a removal efficiency of 70%. Respondent uses ethyl alcohol/ethanol as a solvent in the production of batches 14301 and 14302. A filter is not an appropriate control technology for ethanol emissions. Even if this filter was the appropriate control device, its rated efficiency is less than 85% as required by Respondent's state operating permit, which constitutes a violation of Sections 113(a) and (d) of the CAA, 42 U.S.C. § 7413(a) and (d).

9. According to Respondent's calculations, operations using the Glatt 50 Liter Fluid Bed, S/N 3039. ("Glatt 50") at the Gilroy Road Facility emit 16.26 kg (35.7lbs) of VOC when producing batch number 12202. Respondent produced batch number 12202 on February 1, 2008, February 11, 2008, February 12, 2008 and February 18, 2008. Respondent claimed in the response to the July 14, 2010 CAA information request that 10% of the solvent is absorbed in the product in any given batch. As a result, the daily emissions would be 32.1 lbs. for each date batch 12202 is produced.

10. The Glatt 50 uses a filter as a control device. Respondent uses acetone and propyl alcohol as a solvent in the production of batch 12202. A filter is not an appropriate control technology for acetone and propyl-alcohol emissions. The control technology did not reduce VOC emissions by 85% or more overall, as required by Respondent's state operating permit, which constitutes a violation of Sections 113(a) and (d) of the CAA, 42 U.S.C. § 7413(a).

12. Part C, Paragraph 8 of Maryland State Operating Permit No. 005-6-2955, 005-7-0696 (Beaver Court), requires that the combustion zone temperature of the thermal oxidizer in use at the Beaver Court Facility be maintained to a minimum of 1400°F whenever a fluid Bed Dryer is in operation at that Facility.

13. Additionally, Part D, Paragraph 2.a of Permit No. 005-6-2955, 005-7-0696 requires Respondent to maintain records of the combustion temperature and gas flow to the combustion chamber for the thermal oxidizer.

14. At the time of the May 25, 2010 EPA inspection, Respondent was unable to provide any of the records described in paragraph 13, above. EPA requested such records in its July 14, 2010 CAA information request letter issued to Respondent. No responsive information was provided. According to Respondent's response, the thermal oxidizer has been used to control emission for the Fluid Bed Dryer located at Beaver Court since 2009. At least 14 batches emitting VOCs were manufactured in 2009. Respondent therefore failed, at a minimum, to maintain required

temperature records for at least the 14 days that Respondent operated the thermal oxidizer in 2009, which constitutes a violation of Sections 113(a) and (d) of the CAA, 42 U.S.C. § 7413(a) and (d).

15. Maryland State Operating Permits are issued pursuant to a State Operating Permit Program which has been approved by EPA as part of the Maryland SIP, see 40 C.F.R. § 52.1100. Accordingly, Respondent's violations of the applicable Maryland State Operating Permits constitute violations of the federally enforceable Maryland SIP, and are enforceable by EPA pursuant to Sections 113(a) and (d) of the CAA, 42 U.S.C. § 7413(a) and (d).

16. Since at least February 1, 2008, Respondent has been in violation of the Maryland SIP as set forth above. These violations of the Maryland SIP constitute violations of Sections 113(a) and (d) of the CAA, 42 U.S.C. §§ 7413(a) and (d).

IV. Settlement Recitation, Settlement Conditions And Civil Penalty

A. Complainant and Respondent enter into this Consent Agreement, and the attached Final Order, in order to fully settle and resolve all allegations set forth in Section III, "Findings of Fact and Conclusions of Law," above, and all claims for civil penalties pursuant thereto.

B. In full settlement of the violations alleged in Section III, above, and in consideration of Sections 113(a) and (d) of the CAA, 42 U.S.C. §§ 7413(a) and (d), and other relevant factors, Complainant has determined that a civil penalty of thirty seven thousand, nine hundred and sixty five dollars (\$37,965) is appropriate. This penalty amount is based upon EPA's consideration of a number of factors, including but not limited to the statutory factors set forth in Section 113(e) of the CAA, 42 U.S.C. § 7413(e), which are: the seriousness of the violations, the duration of the violations, and Respondent's compliance history and good faith efforts to comply. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA's *Clean Air Act Stationary Source Civil Penalty Policy*, adjusted for inflation pursuant to 40 C.F.R. Part 19.

C. In settlement of the violations set forth in Section III, above, Respondent hereby consents to the assessment of a thirty seven thousand, nine hundred and sixty five dollars (\$37,965) civil penalty.

D. Payment of the civil penalty as required by paragraph IV.C., above, shall be made by either cashier's check, certified check, or electronic wire transfer, in the following manner:

1. All payments by the Respondent shall include Respondent's full name and address and the EPA Docket Number of this Consent Agreement (CAA-III-11-0308).
2. All checks shall be made payable to "United States Treasury";

3. All payments made by check and sent by regular mail shall be addressed to:

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
PO Box 979077
St. Louis, MO 63197-9000

Contact: Eric Volck 513-487-2105

4. All payments made by check and sent by overnight delivery service shall be addressed for delivery to:

U.S. Bank
Government Lockbox 979077
U.S. EPA Fines & Penalties
1005 Convention Plaza
Mail Station SL-MO-C2GL
St. Louis, MO 63101

Contact 314-418-1028

5. All payments made by check in any currency drawn on banks with no USA branches shall be addressed for delivery to:

Cincinnati Finance
U.S. EPA, MS-NWD
26 W. M.L. King Drive
Cincinnati, OH 45268-0001

6. All payments by electronic funds transfer ("EFT") shall be directed to:

Federal Reserve Bank of New York
ABA No. 021030004
Account No. 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York NY 10045

Field Tag 4200 of the Fedwire message should read
"D 68010727 Environmental Protection Agency"

7. All payments made through the automatic clearinghouse (“ACH”), also known as Remittance Express (“REX”), shall be directed to:

U.S. Treasury REX/Cashlink ACH Receiver
ABA No. 051036706
Account 310006, Environmental Protection Agency
CTX Format Transaction Code 22 – checking

Physical Location of U.S. Treasury facility:
5700 Rivertech Court
Riverdale, MD 20737

Contact, Jesse White, 301-887-6548 or REX, 1-866-234-5681

8. On-line Payment Option:

WWW.PAY.GOV/PAYGOV

Enter “sfo 1.1” in the search field. Open and complete the form.

Additional payment guidance is available at:

http://www.epa.gov/ocfo/finservices/make_a_payment.htm

- E. At the time of payment, Respondent simultaneously shall send a notice of such payment, including a copy of the check or electronic fund transfer, as applicable, to:

Ms. Lydia Guy
Regional Hearing Clerk (3RC00)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029;

and

Daniel E. Boehmcke
Senior. Assistant Regional Counsel (3RC10)
U.S. EPA, Region III
1650 Arch Street
Philadelphia, PA 19103-2029.

F. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 13.11, EPA is entitled to assess interest, administrative costs and late payment penalties on outstanding debts owed to the United States and a charge to cover the costs of processing and handling a delinquent claim, as more fully described below. Accordingly, Respondent's failure to make timely payment or to comply with the conditions in this CAFO shall result in the assessment of late payment charges including interest, penalties, and/or administrative costs of handling delinquent debts.

G. Interest on the civil penalty assessed in this CAFO will begin to accrue on the date that a true and correct copy of this CAFO is mailed or hand-delivered to Respondent. However, EPA will not seek to recover interest on any amount of the civil penalty that is paid within thirty (30) calendar days after the date on which such interest begins to accrue. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 40 C.F.R. § 13.11(a).

H. The costs of the Agency's administrative handling of overdue debts will be charged and assessed monthly throughout the period a debt is overdue. 40 C.F.R. § 13.11(b). Pursuant to Appendix 2 of EPA's Resources Management Directives - Cash Management, Chapter 9, EPA will assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the first thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) days the penalty remains unpaid.

I. A late payment penalty of six percent (6%) per year will be assessed monthly on any portion of the civil penalty that remains delinquent more than ninety (90) calendar days. 40 C.F.R. § 13.11(c). The late payment penalty on any portion of the civil penalty that remains delinquent more than ninety days shall accrue from the first day payment is delinquent. 31 C.F.R. § 901.9(d).

J. Respondent agrees not to deduct for federal tax purposes the civil penalty amount paid pursuant to this Consent Agreement and the attached Final Order.

V. Effect of Settlement

Payment of the penalty specified in Section IV, above, in the manner set forth in Section IV, above, and payment of any applicable interest, handling costs and/or late payment charges, as set forth in Section IV, above, shall constitute full and final satisfaction of all civil claims for penalties for the specific violations alleged in Section III, above. Compliance with this CAFO shall not be a defense to any action commenced at any time for any other violation of any federal laws and regulations administered by EPA.

VI. Reservation of Rights

This CAFO resolves only the civil claims for the specific violations alleged in Section III, above. Respondent understands that EPA retains the right to reinspect any and all of Respondent's facilities and that the discovery of additional violations may lead to further enforcement action, including the possible imposition of civil penalties. EPA reserves the right to commence action against any person, including Respondent, in response to any condition which EPA determines may present an imminent and substantial endangerment to the public health, public welfare, or the environment. In addition, this settlement is subject to all limitations on the scope of resolution and to the reservation of rights set forth in Section 22.18(c) of the Consolidated Rules of Practice, 40 C.F.R. § 22.18(c). Further, EPA reserves any rights and remedies available to it under the CAA, the regulations promulgated thereunder, and any other federal laws or regulations for which EPA has jurisdiction, to enforce the provisions of this CAFO, following its filing with the Regional Hearing Clerk.

VII. Effective Date

The effective date of this Consent Agreement and the accompanying Final Order is the date on which the Final Order is filed with the Regional Hearing Clerk of U.S. EPA, Region III.

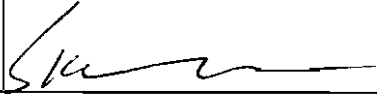
VIII. Entire Agreement

This CAFO constitutes the entire agreement and understanding of the parties concerning settlement of all claims pertaining to the specific violations alleged herein and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this CAFO.

IX. Execution

The undersigned representative for Respondent certifies that he or she is fully authorized by Respondent to execute this Consent Agreement and to legally bind Respondent to this Consent Agreement.


**FOR THE RESPONDENT
PHARMACEUTICS INTERNATIONAL, INC.:**



S. Khurshaid Kazmi,
Vice President, Administration/Operation
Pharmaceutics International, Inc.

Date 09/22/2011


**FOR THE COMPLAINANT:
UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY, REGION III**



Daniel E. Boehmcke
Senior Assistant Regional Counsel
U.S. EPA, Region III

Date 9/27/11

The Air Protection Division, United States Environmental Protection Agency, Region III, recommends that the Regional Administrator of U.S. EPA Region III, or his designee, issue the accompanying Final Order.



Diana Esher, Director
Air Protection Division

Date 9/29/11

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

Subject: In Re: Pharmaceutic International, Inc.
EPA Docket No. CAA-III-11-0308
CAA Consent Agreement and Final Order

From: *CM* Marcia E. Mulkey *Robert Yonick*
Regional Counsel (3RC00)

Diana Esher, Director *Christopher B. Collofer*
Air Protection Division (3AP00)

To: Renée Sarajian
Regional Judicial Officer (3RC00)

In accordance with 40 C.F.R. §§ 22.13(b), and 22.18(b)(2) and (3) of the Consolidated Rules of Practice, the attached Consent Agreement and Final Order (“CAFO”) simultaneously commences and resolves claims against Pharmaceutics International, Inc. (“Respondent”). The basis of the CAFO is Respondent’s failure to comply with the CAA, and provisions of the underlying Maryland State Implementation Plan (“SIP”) at Respondent’s pharmaceutical coating operations located at two (2) separate closely situated locations at 10819 Gilroy Road, Hunt Valley, Maryland 21031 (the “Gilroy Road Facility”), and 103 Beaver Court, Cockeysville, Maryland 21030 (the “Beaver Court Facility”) (collectively the “Facilities”).

The specific provisions alleged to have been violated include Respondent’s violation of the emissions limitations contained in Part B, Paragraph 2.e of Maryland State Operating Permits No. 005-2637-6-2949, 2951, 2952, 2953, & 2954, which limit volatile organic compound (“VOC”) emissions from facility operations to less than twenty pounds per day, unless such VOC emissions are treated by control technology which reduces those emissions by 85% or more overall; and Respondent’s failure to comply with Part C, Paragraph 8 of Maryland State Operating Permit No. 005-6-2955, 005-7-0696 (Beaver Court), which requires that the combustion zone temperature of the thermal oxidizer in use at the Beaver Court Facility be maintained to a minimum of 1400°F whenever a fluid Bed Dryer is in operation at that Facility, and with Part D, Paragraph 2.a of Permit No. 005-6-2955, 005-7-0696 which requires Respondent to maintain records of the combustion temperature and gas flow to the combustion chamber for the thermal oxidizer.

For purposes of achieving full settlement of the violations alleged in Section III, EPA has determined that a civil penalty of thirty seven thousand, nine hundred and sixty five dollars

(\$37,965) is appropriate. As explained in Section IV of the CAFO, this penalty is based upon EPA's consideration of a number of factors, including but not limited to the statutory factors set forth in Section 113(e) of the CAA, 42 U.S.C. § 7413(e), which include: the seriousness of the violations, the duration of the violations, and Respondent's compliance history and good faith efforts to comply. These factors were applied to the particular facts and circumstances of this case with specific reference to EPA's Clean Air Act Stationary Source Civil Penalty Policy, and adjusted for inflation pursuant to 40 C.F.R. Part 19.

Based on the foregoing, we recommend that you sign the attached Final Order and return it to the Daniel Boehmcke of the Office of Regional Counsel for further processing.

Attachment

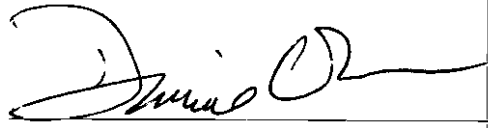
cc: Pamela Kelberer, Pharmaceuticals International, Inc.

CERTIFICATE OF SERVICE

I, the undersigned, hereby certify that, on the date provided below, the original and one true and correct copy of the foregoing Consent Agreement and Final Order were hand-delivered to and filed with the Regional Hearing Clerk (3RC00), U.S. EPA, Region III, 1650 Arch Street, Philadelphia, PA, and that a true and correct copy was served via USPS Certified Mail, upon the following persons:

S. Khurshaid Kazmi
Vice President, Administration/Operation
Pharmaceutics International, Inc.
10819 Gilroy Road
Hunt Valley, MD 21031

Date 9 / 30 / 11



Daniel E. Boehmcke
Senior Assistant Regional Counsel
U.S. EPA , Region III
(215) 814-2607

RECEIVED
2011 SEP 30 PM 3:06
REGIONAL HEARING CLERK
EPA REGION III PHILA, PA