

UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 6  
DALLAS, TEXAS

FILED  
2017 AUG -9 AM 10: 53  
REGIONAL HEARING CLERK  
EPA REGION VI

IN THE MATTER OF:

Professional Compounding Centers of  
America, Inc.,

Houston, Texas

Respondent

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Consent Agreement and Final Order  
Docket No. RCRA-06-2017-0936

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CONSENT AGREEMENT AND FINAL ORDER

I. PRELIMINARY STATEMENT

1. The Director, Compliance Assurance and Enforcement Division, United States Environmental Protection Agency, Region 6 ("EPA" and "Complainant") and Professional Compounding Centers of America, Inc. ("PCCA" or "Respondent") agree that settlement of this proceeding is in the public interest and that entry of this Consent Agreement and Final Order ("CAFO") without further litigation is the most appropriate means of settling this matter. Therefore, before taking any testimony, without any adjudication of issues of law or fact herein, and upon consent and agreement of the parties, it is hereby ordered and adjudged as follows:

2. This CAFO is entered into by EPA and Respondent, and concerns the facility located at 9901 South Wilcrest Drive, Houston, Texas, 77099 (the "Facility").

3. Notice of this action has been given to the State of Texas, under Section 3008(a)(2) of the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6901 et seq. ("RCRA"). See 42 U.S.C. § 6928(a)(2).

4. For the purpose of these proceedings, Respondent admits the jurisdictional allegations herein. Notwithstanding the foregoing or anything to the contrary contained in this CAFO, Respondent neither admits nor denies the specific factual allegations and conclusions of law contained herein. This CAFO states a claim upon which relief may be granted.

5. Respondent explicitly waives any right to contest the allegations or to appeal the proposed final order contained in this CAFO, and waives all defenses that have been raised or could have been raised to the claims set forth in this CAFO.

6. This CAFO resolves all RCRA violations alleged herein from 2012 through the effective date of this CAFO (the "Review Period").

7. The Respondent consents to the issuance of the CAFO hereinafter recited, consents to the assessment and payment of the stated civil penalty in the amount and by the method set out in this CAFO, and consents to the specific stated compliance order.

## II. JURISDICTION

8. This CAFO is issued by EPA pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), as amended by the Hazardous and Solid Waste Amendments of 1984 and is simultaneously commenced and concluded through the issuance of this CAFO under 40 C.F.R. §§ 22.13(b), 22.18(b)(2) and (3).

9. Respondent agrees to undertake and complete all actions required by the terms and conditions of this CAFO. In any action by the EPA or the United States to enforce the terms of this CAFO, Respondent agrees not to contest the authority or jurisdiction of the EPA to issue or enforce this CAFO, and agrees not to contest the validity of this CAFO or its terms or conditions.

### III. FINDINGS OF FACT AND CONCLUSIONS OF LAW

10. Respondent is a corporation authorized to do business in the State of Texas.

11. Respondent owns and operates the Facility, which operates as a pharmaceutical ingredient repackaging and distribution facility.

12. Respondent is a “person” within the meaning of Section 1004(15) of RCRA, 42 U.S.C. § 6903(15); and 30 TEX. ADMIN. CODE § 3.2(25), [40 C.F.R. § 260.10].

13. The Facility is a “facility” within the meaning of 30 TEX. ADMIN. CODE § 335.1(59), [40 C.F.R. § 260.10].

14. From 2015 through 2017, EPA conducted an investigation and records review relating to Respondent’s performance as a generator of hazardous waste in Texas during the Review Period, including a review of information voluntarily provided to EPA by Respondent (the “Investigation”).

15. During the Investigation, EPA discovered that Respondent, at times during the Review Period, generated and offered for transport, treatment, and/or hazardous waste streams, including, but not limited to, the following:

- a. Ignitable hazardous waste (D001);
- b. Corrosive hazardous waste (D002);
- c. Reactive hazardous waste (D003);
- d. Toxic hazardous waste (D007, D009, D0018, D0022, D0024, and D0026);
- e. Listed hazardous waste (U188); and
- f. Acute hazardous waste (P022, P042 and P075).

16. Respondent is a “generator” of “hazardous wastes” at the Facility, as those terms are defined in RCRA §§ 1004(5), (6), 42 U.S.C. §§ 6903(5), (6), and 30 TEX. ADMIN. CODE §§ 335.1(65), (69), [40 C.F.R. § 260.10].

17. As a generator of hazardous waste, Respondent is subject to RCRA §§ 3002 and 3010, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth at 30 TEX. ADMIN. CODE Chapter 335, Subchapter C and F, [40 C.F.R. §§ 262 and/or 270].

**Claim 1: Failure to Comply with Notification Requirements**

18. The allegations in Paragraphs 1-17 are re-alleged and incorporated herein by reference.

19. Within the meaning of 30 TEX. ADMIN. CODE § 335.1 and 40 C.F.R. § 260.10, PCCA is a “generator” and has been engaged in the “treatment,” “storage,” and/or “disposal” of hazardous waste.

20. Pursuant to Section 3010(a) of RCRA, 42 U.S.C. § 6930(a), any person generating a characteristic or listed hazardous waste shall file with the Administrator or authorized State a notification stating the location and general description of such activity and the identified or listed hazardous wastes handled by such person.

21. At times during the Review Period, PCCA did not file with the Administrator or with the authorized State an adequate notification of hazardous waste activities in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

**Claim 2: Managing Hazardous Waste without a Generator Identification**

**Number**

22. The allegations in Paragraphs 1-21 are re-alleged and incorporated herein by reference.

23. Pursuant to 30 TEX. ADMIN. CODE § 335.63(a), [40 C.F.R. § 262.12(a)], a generator must not treat, store, dispose of, transport, or offer for transportation hazardous waste without receiving an EPA identification number from the Administrator.

24. At times during the Review Period, Respondent did not obtain an EPA identification number for the Facility.

25. At times during the Review Period, Respondent treated, stored, disposed of, and/or offered for transportation hazardous waste without having received an EPA identification number from the Administrator for the Facility in violation of 30 TEX. ADMIN. CODE § 335.63(a), [40 C.F.R. § 262.12(a)].

**Claim 3: Failure to Operate Within Proper Generator Status**

26. The allegations in Paragraphs 1-25 are re-alleged and incorporated herein by reference.

27. Pursuant to 30 TEX. ADMIN. CODE § 335.78(b) and 40 C.F.R. § 261.5(b), as long as a conditionally exempt small quantity generator (“CESQG”) complies with the applicable requirements under 30 TEX. ADMIN. CODE §§ 335.78(f), (g) and (j) and 40 C.F.R. §§ 261.5(f), (g) and (j) then the generator’s hazardous waste is not subject to regulations under 30 TEX. ADMIN. CODE Chapter 335, Subchapters C-H and O; 40 C.F.R. Parts 262 through 268; 40 C.F.R. Parts 270 and 124; and the requirements of Section 3010 of RCRA, 42 U.S.C. § 6930.

28. At times during the Review Period, PCCA exceeded its CESQG status and operated as a small quantity generator (“SQG”) and/or large quantity generator (“LQG”) in violation of the regulations set forth at 30 TEX. ADMIN. CODE Chapter 335, Subchapters C and/or F and 40 C.F.R. Parts 262 and/or 270.

29. At times during the Review Period, PCCA failed to comply with one or more of the requirements for SQGs and/or LQGs under 30 TEX. ADMIN. CODE Chapter 335, Subchapter C and/or F, [40 C.F.R. § 262 and/or 270], with such requirements including, but not limited to, properly maintaining contingency plans, emergency procedures, and training documents in accordance with the SQG and/or LQG regulations.

**Claim 4: Failure to Make Adequate Hazardous Waste Determinations**

30. The allegations in Paragraphs 1-29 are re-alleged and incorporated herein by reference.

31. 30 TEX. ADMIN. CODE § 335.62, [40 C.F.R. § 262.11], requires all persons generating solid waste to determine if that waste is a hazardous waste.

32. At times during the Review Period, PCCA did not conduct and/or adequately document the review of its solid waste streams to determine if such solid waste streams were hazardous in violation of the hazardous waste determination and classification requirements set forth in 30 TEX. ADMIN. CODE §§ 335.62 and 335.504, [40 C.F.R. § 262.11].

**Claim 5: Failure to Comply with Manifest Requirements**

33. The allegations in Paragraphs 1-32 are re-alleged and incorporated herein by reference.

34. 30 TEX. ADMIN. CODE § 335.10 requires all persons generating solid waste to comply with the manifest requirements in 40 C.F.R. § 262.20.

35. At times during the Review Period, PCCA did not comply with certain manifest requirements found in 30 TEX. ADMIN. CODE § 335.10 and/or 40 C.F.R. 262.20,

including, but not limited to, preparing a manifest with an appropriate EPA identification number before offering hazardous waste for transport.

**Claim 6: Failure to Comply with Recordkeeping Requirements**

36. The allegations in Paragraphs 1-35 are re-alleged and incorporated herein by reference.

37. All generators of hazardous wastes must follow the appropriate Land Disposal Restriction determination and documentation requirements (“LDR Requirements”) as identified in 30 TEX. ADMIN. CODE § 335.431, [40 C.F.R. § 268.7(a)].

38. At times during the Review Period, PCCA did not meet the LDR Requirements in violation of 30 TEX. ADMIN. CODE § 335.431, [40 C.F.R. § 268.7(a)].

**IV. COMPLIANCE ORDER**

39. Pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Respondent is hereby ordered to take the actions described in this section and, within ninety (90) calendar days of the effective date of this Order, provide in writing, a certification that Respondent has complied with the following with regard to the Facility:

- A. Respondent shall certify that it has assessed all its solid waste streams to determine that accurate waste codes are in use and Respondent has developed and implemented Standard Operating Procedures (“SOP”) to ensure that Respondent is operating in compliance with RCRA and the regulations promulgated thereunder, including, but not limited to, procedures for: (a) making hazardous waste determinations; (b) managing hazardous wastes; and (c) reporting, transporting, and disposing of hazardous waste; and

B. Respondent shall certify that it has accurately and adequately complied with its RCRA Section 3010 Notification requirements.

40. In all instances in which this CAFO requires written submission to EPA, the submittal made by Respondent shall be signed by an owner or officer of Respondent and shall include the following certification:

“I certify under the penalty of law that this document and all its attachments were prepared by me or under my direct supervision in accordance with a system designed to assure that qualified personnel properly gathered and evaluated the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.”

Copies of all documents required by the CAFO shall be sent to the following:

U.S. Environmental Protection Agency  
Compliance Assurance and Enforcement Division  
Waste Enforcement Branch  
Waste Compliance II Section (6EN-H2)  
1445 Ross Avenue  
Dallas, TX 75202-2733  
Attn: Debra Pandak

## V. TERMS OF SETTLEMENT

### A. Penalty Provisions

41. Pursuant to the authority granted in Section 3008 of RCRA, 42 U.S.C. § 6928, and upon consideration of the entire record herein, including the above referenced Findings of Fact and Conclusions of Law, which are hereby adopted and made a part hereof, upon the seriousness of the alleged violations, and Respondent’s good faith efforts to comply with the applicable regulations, it is ordered that Respondent be assessed a civil penalty of **ninety-four thousand and 00/100 dollars (\$94,000.00)**.



42. The penalty shall be paid within thirty (30) calendar days of the effective date of this CAFO and made payable to Treasurer, United States of America.

43. The following are Respondent's options for transmitting the penalties:

Checks sent via U.S. Postal Mail (including certified mail) or U.S. Postal Service Express Mail should be remitted to:

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

Checks sent via Overnight Mail (non-U.S. Postal Service) should be remitted to:

U.S. Bank  
Government Lockbox 979077  
U.S. EPA Fines and Penalties  
1005 Convention Plaza  
SL-MO-C2-GL  
St. Louis, MO 63101  
314-418-1028

Wire Transfers should be remitted to:

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

The case name and docket number (**In the Matter of Professional Compounding Centers of America, Inc., Docket No. RCRA-06-2017-0936**) shall be documented on or within your chosen method of payment to ensure proper credit.

44. The Respondent shall send a simultaneous notice of such payment to the following:

Lorena S. Vaughn  
Regional Hearing Clerk (6RC-D)  
U.S. EPA, Region 6  
1445 Ross Avenue  
Dallas, TX 75202-2733

U.S. Environmental Protection Agency  
Compliance Assurance and Enforcement Division  
Waste Enforcement Branch  
Waste Compliance II Section (6EN-H2)  
1445 Ross Avenue  
Dallas, TX 75202-2733  
Attn: Debra Pandak

Your adherence to this request will ensure proper credit is given when penalties are received by EPA.

45. Pursuant to 31 U.S.C. § 3717 and 40 C.F.R. § 1311, unless otherwise prohibited by law, EPA will assess interest and late payment penalties on outstanding debts owed to the United States and a charge to cover the cost of processing and handling a delinquent claim. Interest on the civil penalty assessed in this CAFO will begin to accrue on the effective date of the CAFO and will be recovered by EPA on any amount of the civil penalty that is not paid within thirty (30) calendar days of the civil penalty's due date and 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). Moreover, the costs of the Agency's administrative handling of overdue debts will be charged and assessed monthly throughout the period the debt is overdue. 40 C.F.R. § 13.11(b). EPA will also assess a \$15.00 administrative handling charge for administrative costs on unpaid penalties for the thirty (30) day period after the payment is due and an additional \$15.00 for each subsequent thirty (30) day period the penalty remains unpaid. In addition, a penalty charge of up to six percent per year will be assessed monthly on any portion of the debt that remains delinquent more than ninety (90)

days. 40 C.F.R. § 13.11(b). Should a penalty charge on the debt be required, it shall accrue from the first day payment is delinquent. 40 C.F.R. § 901.9(d). Other penalties for failure to make a payment may also apply.

**B. Costs**

46. Each party shall bear its own costs and attorney's fees. Furthermore, Respondent specifically waives its right to seek reimbursement of its costs and attorney's fees under the Equal Access to Justice Act (5 U.S.C. § 504), as amended by the Small Business Regulatory Enforcement Fairness Act (P.L. 04-121), and any regulations promulgated pursuant to those Acts.

**C. Termination and Satisfaction**

47. When Respondent believes that it has complied with all the requirements of this CAFO, including compliance with the Compliance Order and payment of the civil penalty, Respondent shall also certify this in writing and in accordance with the certification language set forth in Section IV (Compliance Order), Paragraph 39. Unless the EPA, Region 6 objects in writing within sixty (60) days of EPA's receipt of Respondent's certification, then this CAFO is terminated on the basis of Respondent's certification.

**D. Effective Date of Settlement**

48. This CAFO shall become effective upon filing with the Regional Hearing Clerk.

**THE UNDERSIGNED PARTIES CONSENT TO THE ENTRY OF THIS  
CONSENT AGREEMENT AND FINAL ORDER:**


FOR THE RESPONDENT:

Date: 7-27-17

  
\_\_\_\_\_  
L. David Sparks  
Director  
Professional Compounding Centers of  
America, Inc.

FOR THE COMPLAINANT:

Date: 7/27/17

  
\_\_\_\_\_  
Cheryl T. Seager  
Director  
Compliance Assurance and Enforcement  
Division  
U.S. EPA Region 6

**FINAL ORDER**

Pursuant to the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, 40 C.F.R. Part 22, the foregoing CAFO is hereby ratified. This Final Order shall not in any case affect the right of EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law. This Final Order shall resolve only those causes of action alleged herein. Nothing in this Final Order shall be construed to waive, extinguish or otherwise affect Respondent's (or its officers, agents, servants, employees, successors, or assigns) obligation to comply with all applicable federal, state, and local statutes and regulations, including the regulations that were the subject of this action. Respondent is ordered to comply with the terms of settlement and the civil penalty payment instructions as set forth in the CAFO. Pursuant to 40 C.F.R. § 22.31(b), this Final Order shall become effective upon filing with the Regional Hearing Clerk.

Date: 8/9/17



Regional Judicial Officer

Thomas Rucki

**CERTIFICATE OF SERVICE**

I hereby certify that on the 9<sup>th</sup> day of August, 2017, the original of the foregoing Consent Agreement and Final Order was hand delivered to the Regional Hearing Clerk, U.S. EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, and that a true and correct copy of the CAFO was sent to the following by the method below:

**VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED:** 7007302000015228496

L. David Sparks  
Director  
Professional Compounding Centers of America, Inc.  
9901 South Wilcrest Drive  
Houston, Texas, 77099

*for* Sandra Hardy  
Ms. Lori Jackson  
Paralegal