

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 6
DALLAS, TX**

IN THE MATTER OF:	§	
	§	
	§	
Boudreaux’s Specialty Compounding Pharmacy	§	Administrative Compliance Order on Consent
	§	USEPA Docket No. RCRA-06-2024-0914
	§	
	§	
RESPONDENT	§	

ADMINISTRATIVE COMPLIANCE ORDER ON CONSENT

I. PRELIMINARY STATEMENT

1. This Administrative Compliance Order on Consent (“ACOC”) is entered into by the United States Environmental Protection Agency, Region 6 (“EPA”) and Respondent, Boudreaux’s Specialty Compounding Pharmacy, (“Boudreaux’s Specialty Compounding Pharmacy” or “Respondent”), and concerns the facility located at 2551 Greenwood Rd Ste 110 Shreveport, TX 71103 (the “Facility”).
2. Notice of this action has been given to the State of Louisiana, under Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2)¹.

¹ On January 24, 1985, the State of Louisiana received final authorization for its base Hazardous Waste Management Program (50 FR 3348). Subsequent revisions have been made to the Louisiana Hazardous Waste Program and authorized by the EPA. Except as otherwise provided, all citations found within this order are to the “EPA-Approved Louisiana Statutory and Regulatory Requirements Applicable to the Hazardous Waste Management Program” dated November 2015, incorporated by reference under 40 C.F.R. § 272. 951(c)(1)(i) effective on December 26, 2018. 83 Fed. Reg. 66143 (December 26, 2018); 40 C.F.R. 272. 951: Louisiana State-Administered Program: Final Authorization. References and citations to the “EPA-Approved Louisiana Statutory and Regulatory Requirements Applicable to the Hazardous Waste Management Program” may vary slightly from the State of Louisiana’s published version. The corresponding C.F.R. citations are also provided.

3. For the purpose of these proceedings, Respondent admits the jurisdictional allegations herein; however, Respondent neither admits nor denies the specific factual allegations and conclusions of law contained in this ACOC. Respondent consents to the issuance of the ACOC solely to avoid the cost, expense, and uncertainty of litigation. This ACOC states a claim upon which relief may be granted.
4. Respondent explicitly waives any right to contest the allegations and its right to appeal the proposed final order contained in this ACOC and waives all defenses which have been raised or could have been raised to the claim set forth in the ACOC.
5. Respondent consents to the issuance of the ACOC hereinafter recited and consents to the specific stated Compliance Order, Section VI, of this ACOC.

II. JURISDICTION

6. This ACOC is issued by the EPA pursuant to Section 3008(a) of the Resource Conservation and Recovery Act ("RCRA"), 42 U.S.C. § 6928(a), as amended by the Hazardous and Solid Waste Amendments of 1984 ("HSWA") and is simultaneously commenced and concluded through the issuance of this ACOC under 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3).
7. Respondent agrees to undertake and complete all actions required by the terms and conditions of this ACOC. In any action by the EPA or the United States to enforce the terms of this ACOC, Respondent agrees not to contest the authority or jurisdiction of the EPA to issue or enforce this ACOC and agrees not to contest the validity of this ACOC or its terms or conditions.

III. STATEMENT OF PURPOSE

8. This ACOC provides for the resolution of EPA Region 6's investigation of Respondent's Facility.
9. In entering into this ACOC, the mutual objectives of EPA, Region 6 and Respondent are to remedy, and/or prevent the potential endangerment to human health and/or the environment from activities involving solid waste and hazardous waste, and to ensure that the injunctive relief that Respondent will complete as described the Section VI, Compliance Order, is protective of human health and/or the environment.

IV. STATUTORY AND REGULATORY BACKGROUND

10. Federal regulation of hazardous waste is primarily based on RCRA, enacted on October 21, 1976, to amend the Solid Waste Disposal Act, and the Hazardous and Solid Waste Amendments ("HSWA") enacted by Congress in 1984 to further amend the Solid Waste Disposal Act. RCRA establishes a "cradle-to-grave" program to be administered by the Administrator of EPA and authorized states for regulating the generation, transportation, treatment, storage, and disposal of hazardous waste. See 42 U.S.C. § 6901 et seq.
11. RCRA's Subchapter III (RCRA §§ 3001-3023, 42 U.S.C. §§ 6921-6940, known as "Subtitle C") required EPA to promulgate regulations establishing performance standards applicable to facilities that generate, transport, treat, store, or dispose of hazardous wastes. Together, RCRA Subtitle C and its implementing regulations, set forth at 40 C.F.R. Parts 260 – 279, comprise EPA's RCRA hazardous waste program.

12. Pursuant to its authority under RCRA, EPA has promulgated regulations at 40 C.F.R. Parts 260 through 272 applicable to generators, transporters, and treatment, storage, and disposal facilities. These regulations generally prohibit treatment, storage, and disposal of hazardous waste without a permit or equivalent "interim status." They prohibit land disposal of certain hazardous wastes and provide detailed requirements governing the activities of those who generate hazardous waste and those who are lawfully permitted to store, treat, and dispose of hazardous waste.
13. Pursuant to 40 C.F.R. § 261.2, a "solid waste" is any discarded material that is not otherwise excluded under 40 C.F.R. § 261.4(a), or that is not excluded by variance. A discarded material is any material which is abandoned, recycled, inherently waste-like, or a military munition. Materials are solid waste, as defined in 40 C.F.R. § 261.2, if they are abandoned by being disposed of, burned or incinerated, or accumulated, stored, or treated (but not recycled) before, or in lieu of, being abandoned by being disposed of, burned, or incinerated.
14. A solid waste is a hazardous waste if it is not excluded from regulation as a hazardous waste under 40 C.F.R. § 261.4(b), and it exhibits any of the characteristics of hazardous waste identified in 40 C.F.R. Part 261, Subpart C or it is listed in C.F.R. Part 261, Subpart D.
15. Characteristic hazardous wastes are assigned "D" codes in 40 C.F.R. Part 261, Subpart C, depending on the specific hazardous characteristic that the waste exhibits.

16. An ignitable hazardous waste has a flash point of less than 60 degrees centigrade (140 degrees Fahrenheit) and is assigned the D001 hazardous waste code pursuant to 40 C.F.R. § 261.21.
17. A corrosive hazardous waste has a pH of less than or equal to 2.0 or greater than or equal to 12.5 and is assigned the D002 hazardous waste code pursuant to 40 C.F.R. § 261.22, and a reactive hazardous waste is assigned the D003 hazardous waste code pursuant to 40 C.F.R. § 261.23.
18. Listed wastes are assigned with "F", "K", "P", and "U" codes in 40 C.F.R. Part 261, Subpart D, depending on the specific waste generated from a non-specific source, a specific source, or discarded commercial chemical products, off-specification species, container residues and spill residues therefrom.
19. 40 C.F.R. Parts 264 and/or 265 applies to owners and operators of facilities that treat, store and/or dispose of hazardous waste.
20. The relevant RCRA statutory and regulatory requirements to this ACOC require that generators of solid waste and hazardous waste must, among other things:
 - A. Determine whether their generated solid wastes are hazardous, pursuant to 40 C.F.R. § 262.11;
 - B. Comply with the statutory notification requirements of Section 3010 of RCRA, 42 U.S.C. § 6930;
 - C. Comply with the manifest requirements, pursuant to 40 C.F.R. § 262.20; and

- D. Determine its generator status by meeting the exemption conditions set forth at 40 C.F.R. § 262.34 or comply with the specific requirements set forth at 40 C.F.R. § 270.10.

V. FINDINGS OF FACT AND CONCLUSIONS OF LAW

21. Respondent is an authorized corporation in the State of Louisiana, authorized in 2015, and is located at 2551 Greenwood Rd Ste 110 Shreveport, TX 71103.
22. Respondent is a "person" within the meaning of Section 1004(15) of RCRA, 42 U.S.C. § 6903(15); and Title 33 of the Louisiana Administrative Code ("LAC") LAC 33:V.109 [40 C.F.R. § 260.10].
23. Respondent's Registered Agent for service in the State of Louisiana is Douglas Boudreaux, located at 2551 Greenwood Rd Ste 110 Shreveport, TX 71103.
24. Boudreaux's Specialty Compounding Pharmacy owns a Facility that is a compounding pharmacy.
25. During the period of August-October 2023, EPA conducted a RCRA investigation and record review ("Investigation") of Boudreaux's Specialty Compounding Pharmacy's performance as a generator of hazardous waste.
26. During the Investigation, EPA discovered that Boudreaux's Specialty Compounding Pharmacy, at a minimum, generated the following waste:
- A. Characteristic of Ignitability: D001 (Ignitability); D002 (Corrosivity); D003 (Reactivity)

- B. Characteristic for multiple toxicity waste: D005 (Barium); D007 (Chromium); D009 (Mercury); D010 (Selenium); D011 (Silver); D013 (Lindane); D022 (Chloroform); D024 (m-Cresol); D026 (Cresol)
- C. P075 (Nicotine, & salts)
- D. U010 (Mitomycin C); U034 (Chloral); U035 (Chlorambucil); U036 (Chlordane, alpha & gamma isomers); U052 (Cresol (Cresylic acid)); U058 (Cyclophosphamide); U059 (Daunomycin); U122 (Formaldehyde); U129 (Lindane); U150 (Melphalan); U188 (Phenol); U197 (p-Benzoquinone); U200 (Reserpine); U201 (Resorcinol); U205 (Selenium sulfide); U206 (Streptozotocin); U237 (Uracil mustard); U248 (Warfarin, & salts, when present at concentrations of 0.3% or less); U240 (2,4-D, salts & esters).
27. The waste streams identified in Paragraph 26 are hazardous waste as defined in LAC 33:V.4901.B. & F, and 4903.E [40 C.F.R. §§ 261.21 and 261.22].
28. The exemptions set forth at LAC 33:V.108.C [40 C.F.R. § 261.5(c)], are not applicable to Boudreaux's Specialty Compounding Pharmacy.
29. From the Investigation, EPA determined that during 2020 Boudreaux's Specialty Compounding Pharmacy may have generated one or more of the hazardous waste streams identified in Paragraph 26 in quantities that exceeded the threshold amount of 100 kilograms of hazardous waste per month, which qualified Boudreaux's Specialty Compounding Pharmacy for the small quantity generator ("SQG") status established under LAC 33: V 1109 [40 C.F.R. Part 262], for the periods that such wastes remained onsite.

30. Boudreaux's Specialty Compounding Pharmacy is a "generator" of "hazardous wastes" at the "facility" identified in Paragraph 1 of this ACOC as those terms are defined in Sections 1004(5) & (6) of RCRA, 42 U.S.C. §§ 6903(5) & (6), and LAC 33:V.109 [40 C.F.R. §§ 260 and 261].
31. As a generator of hazardous waste, Boudreaux's Specialty Compounding Pharmacy is subject to Sections 3002 and 3010 of RCRA, 42 U.S.C. §§ 6922 and 6930, and the regulations set forth at Title 33 of LAC Part V, Chapters 1 through 51, [40 C.F.R. Parts 262 and/or 270].

Claims i. Notification Requirements

32. The allegations in Paragraphs 1-31 are realleged and incorporated herein by reference.
33. 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 characteristic or listed hazardous wastes handled by such person. No identified characteristic or listed hazardous waste subject to this subchapter may be transported, treated, stored, or disposed of unless notification has been given as required by Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).
34. Boudreaux's Specialty Compounding Pharmacy did not file with the Administrator an initial or subsequent notification to accurately state the general description of its hazardous waste activities and its generation and management of hazardous waste during 2020, in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

35. At all times relevant to this ACOC, Respondent failed to comply with its notification requirements in violation of Section 3010(a) of RCRA, 42 U.S.C. § 6930(a).

Claims ii. Failure to Operate within its Stated Generator Status

36. The allegations in Paragraphs 1-31 are realleged and incorporated herein by reference.
37. During the Investigation, EPA determined that Boudreaux's Specialty Compounding Pharmacy either operated as a Conditionally Exempt Small Quantity Generator ("CESQG") and/or considered itself to be a CESQG.
38. Pursuant to LAC 33:V.108 and 40 C.F.R. § 261.5(b), as long as a CESQG generator complies with the applicable requirement under LAC 33:V.108.E, F,G, and J and 40 C.F.R. §§ 261.5 (e), (f), (g) and (j) the generator's hazardous waste is not subject to regulation under LAC 33:V. Chapters 3-37, 41, 43, and 53, except for LAC 33:V .3105, Table 1; 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.
39. On more than one occasion in 2020, Boudreaux's Specialty Compounding Pharmacy exceeded the CESQG status and, for the period such hazardous waste remained onsite, operated as a SQG in violation of one or more of the requirements for SQG under 30 LAC 33:V.1109.E, [40 C.F.R. § 262.34].
40. At all times relevant to this ACOC, Respondent failed to comply with the SQG requirements in violation of LAC 33:V.1109.E [40 C.F.R. Parts 262 and 270].

VI. COMPLIANCE ORDER

41. Pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), Respondent is hereby ordered to take the following actions, and within thirty (30) calendar days of the effective date of the settlement agreement, Respondent shall provide in writing the following:

- A. Respondent shall certify that it has assessed all of its solid waste streams to determine the accurate waste codes and has developed and implemented Standard Operating Procedures ("SOP") to ensure that Boudreaux's Specialty Compounding Pharmacy 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; (c) reporting, transporting, and disposing of hazardous waste; (d) preparing the manifests; and (e) meeting the requirements of the land disposal restrictions;
- B. Respondent shall certify that it has accurately and adequately complied with its RCRA Section 3010 Notification; and
- C. Respondent shall provide, with its certification, a copy of Respondent's SOPs as described in subparagraph A above.

42. In all instances in which this ACOC requires written submission to EPA, the submittal made by Respondent shall be signed by an owner or officer of Boudreaux's Specialty Compounding Pharmacy and shall include the following certification:

"I certify under the penalty of law that this document and all of 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 this ACOC shall be sent to the following:

U.S. EPA, Region 6
Enforcement and Compliance Assurance Division (ECAD-SR)
1201 Elm Street, Suite 500
Dallas, Texas 75270-2102
ATTN: Ashley Pederson

Where possible, notice shall be sent electronically by email to Ashley Pederson, at pederson.ashley@epa.gov.

VII. TERMS OF SETTLEMENT

i. Modification

43. The terms, conditions, and compliance requirements of this ACOC may not be modified or amended except upon the written agreement of both parties, and approved by a Regional Judicial Officer, and such modification or amendment being filed with the Regional Hearing Clerk.

ii. Indemnification

44. Neither EPA nor the United States Government shall be liable for any injuries or damages to person or property resulting from the acts or omissions of Respondent, their officers, directors, employees, agents, receivers, trustees, successors, assigns, or contractors in carrying out the activities required by this ACOC, nor shall EPA or the United States Government be held out as a party to any contract entered into by Respondent in carrying out the activities required by this ACOC.

iii. Record Preservation

45. Respondent shall preserve, during the pendency of this ACOC, all records and documents in its possession or in the possession of its divisions, employees, agents, contractors, or successors, which in any way relate to this ACOC regardless of any document retention policy to the contrary.

iv. Cost

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.

v. Reservation of Rights

47. Notwithstanding any other provisions of this ACOC, EPA retains all of its authority to take, direct, or order any and all actions necessary to protect public health or the environment or to prevent, abate, or minimize an actual or threatened release of hazardous substances, pollutants, or contaminants, or hazardous or solid waste or constituents of such wastes, on, at, or from the Facility, including but not limited to the right to bring enforcement actions under RCRA, CERCLA, and any other applicable statutes or regulations.
48. EPA reserves all of its statutory and regulatory powers, authorities, rights, remedies, both legal and equitable, that may pertain to Respondent's failure to comply with any of the requirements of this ACOC.

49. This ACOC shall not be construed as a covenant not to sue, release, waiver, or limitation of any rights, remedies, powers, claim, and/or authorities, civil or criminal, which EPA has under RCRA, CERCLA, or any other statutory, regulatory, or common law authority of the United States. Further, this ACOC does not resolve Respondent's liability for Federal civil penalties for the violations and facts set forth herein.

vi. Termination and Satisfaction

50. When Respondent believes that it has complied with all the requirements of this ACOC, including compliance with the Compliance Order, Respondent shall so certify in writing and in accordance with the certification language set forth in Section VI (Compliance Order). Unless the EPA, Region 6 objects in writing within sixty (60) days of EPA's receipt of Respondent's certification, then this ACOC is terminated on the basis of Respondent's certification.
51. EPA and Respondent agree to the use of electronic signatures for this matter. EPA and Respondent further agree to electronic service of this Administrative Compliance Order on Consent, pursuant to 40 C.F.R. § 22.6, by email to the following addresses:

Complainant:

Ashley Pederson
pederson.ashley@epa.gov

Respondent:

Paul Strickland
paul@federal-lawyer.com

vii. Effective Date of Settlement


52. This ACOC shall become effective upon filing with the Regional Hearing Clerk.

THE UNDERSIGNED PARTIES CONSENT TO THE ENTRY OF THIS ADMINISTRATIVE COMPLIANCE

ORDER ON CONSENT:

FOR THE RESPONDENT:

Date: 1-7-24



Boudreaux's Specialty Compounding
Pharmacy

FOR THE COMPLAINANT:

Date: January 9, 2023

Cheryl T. Seager
Director
Enforcement and
Compliance Assurance 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 ACOC is hereby ratified. This Final Order shall not in any case affect the right of the EPA or the United States to pursue appropriate civil penalties, injunctive or other equitable relief or criminal sanctions for any violations of law, including those violations alleged herein. 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. The Respondent is ordered to comply with the Compliance Order, Section VI, and the Terms of Settlement, Section VII, as set forth in this ACOC. Pursuant to 40 C.F.R. § 22.31(b) this Final Order shall become effective upon filing with the Regional Hearing Clerk.

Date: _____

Thomas Rucki
Regional Judicial Officer

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing Administrative Compliance Order on Consent was delivered to the Regional Hearing Clerk, U.S. EPA - Region 6, 1201 Elm Street, Suite 500, Dallas, Texas 75270-2102, and that a true and correct copy was sent this day in the following manner to the email addresses:

Copy via Email to Complainant:
pederson.ashley@epa.gov

Copy via Email to Respondent:
paul@federal-lawyer.com

Signed
U.S. EPA Region 6