



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

CERTIFIED MAIL RETURN RECEIPT

DEC 17 2019

Mr. CR Valentino
EHS Manager
Patheon API Manufacturing, Inc.
309 Delaware Street
Greenville, South Carolina 29605

SUBJ: Patheon API Manufacturing, Inc., EPA ID SCR000004168
Consent Agreement and Final Order, Docket No.: RCRA-04-2019-4001(b)

Dear Mr. Valentino:

Enclosed, please find a copy of the executed Consent Agreement and Final Order (CA/FO) as filed with the Regional Hearing Clerk in the above-referenced matter. Please note that payment of the civil penalty is due within thirty (30) days of the effective date of the CA/FO, which is the date the CA/FO is filed with the Regional Hearing Clerk. A copy of the penalty payment must be mailed to the Regional Hearing Clerk and to the Program Staff, as referenced in the CA/FO. The timing of all other obligations required by the CA/FO also begins on the effective date of the CA/FO.

Thank you for your assistance in resolving this matter. If you have any questions, please feel free to contact me at (404) 562-8590 or by email at lamberth.larry@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "Alan A. Annicelli".

for Larry L. Lamberth
Chief, Chemical Safety and Land Enforcement
Branch
Enforcement and Compliance Assurance Division

Enclosures

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4**

IN THE MATTER OF:)	DOCKET NO.: RCRA-04-2019-4001(b)
)	
Patheon API Manufacturing, Inc.)	
309 Delaware Street)	Proceeding Under Section 3008(a) of the
Greenville, South Carolina 29605)	Resource Conservation and Recovery Act,
EPA ID No.: SCR000004168)	42 U.S.C. § 6928(a)
)	
Respondent)	
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REGION 4
U.S. ENVIRONMENTAL PROTECTION AGENCY

CONSENT AGREEMENT

I. NATURE OF THE ACTION

1. This is a civil administrative enforcement action, pursuant to Section 3008(a) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6928(a), ordering compliance with the requirements of the South Carolina Hazardous Waste Management Act (SCHWMA), S.C. Code Ann. § 44-56-10 *et seq.* [Subtitle C of RCRA, 42 U.S.C. §§ 6921-6939g], and the regulations promulgated pursuant thereto and set forth at South Carolina Hazardous Waste Management Regulations (SCHWMR), S.C. Code Ann. Regs. 61-79.260-270, 61-79.273, and 61-107.279 [Title 40 of the Code of Federal Regulations (C.F.R.), Parts 260 through 270, 273, & 279]. This action seeks injunctive relief and the imposition of civil penalties pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), for violations of Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] and SCHWMR, S.C. Code Ann. Regs. 61-79.260 through 270 [40 C.F.R. Parts 260 through 270].
2. The *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits*, which govern this action and are promulgated at 40 C.F.R. Part 22, provide that where the parties agree to settlement of one or more causes of action before the filing of a complaint, a proceeding may be simultaneously commenced and concluded by the issuance of a Consent Agreement and Final Order (CA/FO). 40 C.F.R. §§ 22.13(b) and 22.18(b)(2) and (3).
3. Complainant and Respondent have conferred for the purpose of settlement pursuant to 40 C.F.R. § 22.18 and desire to settle this action. Accordingly, before any testimony has been taken upon the pleadings and without any admission of violation or adjudication of any issue of fact or law and in accordance with 40 C.F.R. § 22.13(b), Complainant and Respondent have agreed to the execution of this CA/FO, and Respondent hereby agrees to comply with the terms of this CA/FO.

II. THE PARTIES

4. Complainant is the Chief, Chemical Safety and Land Enforcement Branch, Enforcement and Compliance Assurance Division, United States Environmental Protection Agency (EPA) Region 4. Complainant is authorized to issue the instant CA/FO pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), and applicable delegations of authority.
5. Respondent is Patheon API Manufacturing, Inc., a corporation organized under the laws of South Carolina. Respondent is the owner and operator of a business that develops and manufactures pharmaceuticals located at 309 Delaware Street, Greenville, South Carolina (the Facility).

III. PRELIMINARY STATEMENTS

6. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), the State of South Carolina (State) has received final authorization to carry out a hazardous waste program in lieu of the federal program set forth in RCRA. The requirements of the authorized State program are found at SCHWMA, S.C. Code Ann. § 44-56-10 *et seq.* and S.C. Code Ann. Regs. 61-79.260-270 and 61-79.273, and SCSWMR, S.C. Code Ann. § 61-107.279.
7. Pursuant to Section 3006(g) of RCRA, 42 U.S.C. § 6926(g), the requirements established by the Hazardous and Solid Waste Amendments of 1984 (HSWA), Pub. L. 98-616, are immediately effective in all states regardless of their authorization status and are implemented by the EPA until a state is granted final authorization with respect to those requirements. South Carolina has received final authorization for certain portions of HSWA, including those recited herein.
8. Although the EPA has granted the State authority to enforce its own hazardous waste program, the EPA retains jurisdiction and authority to initiate an independent enforcement action pursuant to Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2). This authority is exercised by the EPA in the manner set forth in the Memorandum of Agreement between the EPA and the State.
9. As the State's authorized hazardous waste program operates in lieu of the federal RCRA program, the citations for the violations of those authorized provisions alleged herein will be to the authorized State program; however, for ease of reference, the federal citations will follow in brackets.
10. Pursuant to Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2), Complainant has given notice of this action to the State before issuance of this CA/FO.
11. Sections 44-56-30 and 44-56-35 of the SCHWMA, S.C. Code Ann. § 44-56-30 and 44-56-35 [Section 3002(a) of RCRA, 42 U.S.C. § 6922(a)], requires the promulgation of standards applicable to generators of hazardous waste. The implementing regulations for these standards are found at S.C. Code Ann. Regs. 61-79 Part 262 [40 C.F.R. Part 262].
12. Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], sets forth the requirement that a facility treating, storing, or disposing of hazardous waste must have a permit or interim status. The implementing regulations for this requirement are found at S.C. Code Ann. Regs. 61-79 Part 264 (permitted) and S.C. Code Ann. Regs. 61-79 Part 265 (interim status) [40 C.F.R. Parts 264 (permitted) and 265 (interim status)].

13. Pursuant to S.C. Code Ann. Regs. 61-79.261.2 [40 C.F.R. § 261.2], a “solid waste” is any discarded material that is not otherwise excluded from the regulations. A discarded material includes any material that is abandoned by being stored in lieu of being disposed.
14. Pursuant to S.C. Code Ann. Regs. 61-79.261.3 [40 C.F.R. § 261.3], a solid waste is a “hazardous waste” if it meets any of the criteria set forth in S.C. Code Ann. Regs. 61-79.261.3(a)(2) [40 C.F.R. § 261.3(a)(2)] and is not otherwise excluded from regulation as a hazardous waste by S.C. Code Ann. Regs. 61-79.261.4(b) [40 C.F.R. § 261.4(b)].
15. Pursuant to S.C. Code Ann. Regs. 61-79.261.3(a)(2)(i) and 61-79.261.20 [40 C.F.R. §§ 261.3(a)(2)(i) and 261.20], solid wastes that exhibit any of the characteristics identified in S.C. Code Ann. Regs. 61-79.261.21-24 [40 C.F.R. §§ 261.21-24] are characteristic hazardous wastes and are provided with the EPA Hazardous Waste Numbers D001 through D043.

Pursuant to S.C. Code Ann. Regs. 61-79.261.20 and 21 [40 C.F.R. §§ 261.20 and 261.21], a solid waste that exhibits the characteristic of ignitability is a hazardous waste and is identified with the EPA Hazardous Waste Number D001.

Pursuant to S.C. Code Ann. Regs. 61-79.261.20 and 22 [40 C.F.R. §§ 261.20 and 261.22], a solid waste that exhibits the characteristic of corrosivity is a hazardous waste and is identified with the EPA Hazardous Waste Number D002.

Pursuant to S.C. Code Ann. Regs. 61-79.261.20 and 24 [40 C.F.R. §§ 261.20 and 261.24], a solid waste that exhibits the characteristic of toxicity is a hazardous waste and is identified with the EPA Hazardous Waste Number associated with the toxic contaminant causing it to be hazardous. Pursuant to S.C. Code Ann. Regs. 61-79.261.24 [40 C.F.R. § 261.24], a solid waste that exhibits the characteristic of toxicity for Chloroform is identified with the EPA Hazardous Waste Number D022.

16. Pursuant to S.C. Code Ann. Regs. 61-79.261.3(a)(2)(ii) and 61-79.261.30 [40 C.F.R. §§ 261.3(a)(2)(ii) and 261.30], a solid waste is a listed “hazardous waste” if it is listed in S.C. Code Ann. Regs. 61-79 Part 261, Subpart D [40 C.F.R. Part 261, Subpart D].

Listed hazardous wastes include F002, F003, and F005, which are certain spent solvent F-Listed wastes from nonspecific sources identified at S.C. Code Ann. Regs. 61-79.261.31 [40 C.F.R. § 261.31].

17. Pursuant to S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10], a “generator” is defined as “any person, by site, whose act or process produces hazardous waste identified or listed in S.C. Code Ann. Regs. 61-79.261 [40 C.F.R. Part 261], or whose act first causes a hazardous waste to become subject to regulation.”
18. Pursuant to S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10], a “facility” includes “all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste.”

19. Pursuant to S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10], a “person” includes a corporation.
20. Pursuant to S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10], an “owner” is “the person who owns a facility or part of a facility” and an “operator” is “the person responsible for the overall operation of a facility.”
21. Pursuant S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10], “storage” means the holding of a hazardous waste for a temporary period, at the end of which the hazardous waste is treated, disposed of, or stored elsewhere.
22. Pursuant to S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. 260.10] a “tank” is a stationary device designed to contain an accumulation of hazardous waste which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, plastic) which provide structural support.
23. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a) (2018) [40 C.F.R. § 262.34(a) (2016)]¹, a generator of 1,000 kilograms or greater of hazardous waste in a calendar month is a Large Quantity Generator (LQG) and may accumulate hazardous waste on-site for 90 days or less without a permit or without having interim status, as required by Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in S.C. Code Ann. Regs. 61-79.262.34(a)(1) - (4) (2018) [40 C.F.R. § 262.34(a)(1) - (4) (2016)] (hereinafter referred to as the “LQG Permit Exemption”).
24. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a)(1)(i) (2018) [40 C.F.R. § 262.34(a)(1)(i) (2016)], which incorporates S.C. Code Ann. Regs. 61-79.265.174 [40 C.F.R. § 265.174], and is a condition of the LQG Permit Exemption, a generator is required to, at least weekly, inspect areas where containers are stored looking for leaking containers and for deterioration of containers caused by corrosion or other factors.
25. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a)(1)(ii) (2018) [40 C.F.R. § 262.34(a)(1)(ii) (2016)], which incorporates S.C. Code Ann. Regs. 61-79 Part 265, Subpart CC [40 C.F.R. Part 265, Subpart CC], which is a condition of the LQG Permit Exemption, a generator accumulating hazardous waste in tanks must comply with the RCRA Subpart CC Air Emission Standards for Tanks, including, but not limited to, the tank requirements in S.C. Code Ann. Regs. 61-79.265.1085 [40 C.F.R. § 265.1085] and the recordkeeping requirements in S.C. Code Ann. Regs. 61-79.265.1090 [40 C.F.R. § 265.1090].
26. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a)(2) (2018) [40 C.F.R. § 262.34(a)(2) (2016)], which is a condition of the LQG Permit Exemption, a generator is required to ensure that the date upon which each period of accumulation begins is clearly marked and visible on each container.

¹ South Carolina’s newly adopted Generator Improvements Rule (GIR) regulations were effective in South Carolina as of May 24, 2019 but are not authorized by EPA and are not federally enforceable. Regardless, the federal and state inspections at Patheon at issue in this CA/FO occurred prior to the State’s adoption of the GIR. As such, and for ease of reference and consistency with the State’s Inspection Report, this CA/FO will cite to the South Carolina hazardous waste regulations in effect at the time of the State inspection, and the corresponding federal regulations, prior to the amendments by the GIR. The requirements prior to the GIR are noted with their most recent effective date.

27. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a)(4) (2018) [40 C.F.R. § 262.34(a)(4) (2016)], which incorporates S.C. Code Ann. Regs. 61-79.265.35 [40 C.F.R. § 265.35], and is a condition of the LQG Permit Exemption, a generator is required to maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of facility operation in an emergency, unless aisle space is not needed for any of these purposes.
28. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(a)(4) (2018) [40 C.F.R. § 262.34(a)(4) (2016)], which incorporates S.C. Code Ann. Regs. 61-79.265.52(d) [40 C.F.R. § 265.52(d)], and is a condition of the LQG Permit Exemption, a generator is required to have a contingency plan which lists the names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator and keep it up to date.
29. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(c)(1) (2018) [40 C.F.R. § 262.34(c)(1) (2016)], a generator may accumulate as much as 55 gallons of hazardous waste in containers at or near the point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste (Satellite Accumulation Area (SAA)), without a permit or without having interim status, as required by Section § 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with S.C. Code Ann. Regs. 61-79.262.34(a) (2018) [40 C.F.R. § 262.34(a) (2016)], provided that the generator complies with the SAA conditions listed in S.C. Code Ann. Regs. 61-79.262.34(c)(1) (2018) [40 C.F.R. § 262.34(c)(1) (2016)] (hereinafter referred to as the “SAA Permit Exemption”).
30. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(c)(1)(i) (2018) [40 C.F.R. § 262.34(c)(1)(i) (2016)], which incorporates S.C. Code Ann. Regs. 61-79.265.173(a) [40 C.F.R. § 265.173(a)], and is a condition of the SAA Permit Exemption, a generator is required to keep containers of hazardous waste closed when waste is not being added or removed.
31. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(c)(2) (2018) [40 C.F.R. § 262.34(c)(2) (2016)], a generator who accumulates hazardous waste in excess of 55 gallons at or near any point of generation must, with respect to that amount of excess waste, comply with the conditions listed in S.C. Code Ann. Regs. 61-79.262.34(a) (2018) [40 C.F.R. § 262.34(a) (2016)].
32. Pursuant to S.C. Code Ann. Regs. 61-79.262.34(c)(1)(ii) (2018) [40 C.F.R. § 262.34(c)(1)(ii) (2016)], which is a condition of the SAA Permit Exemption, a generator is required to mark satellite accumulation containers either with the words “Hazardous Waste” or with other words that identify the contents of the containers.

IV. EPA ALLEGATIONS AND DETERMINATIONS

33. Respondent is a “person” as defined in S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10].
34. Respondent is the “owner/operator” of a “facility” located at 309 Delaware Street, Greenville, South Carolina, 29605, as those terms are defined in S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10].
35. Respondent is a “generator” of “hazardous waste” as those terms are defined in S.C. Code Ann. Regs. 61-79.260.10 [40 C.F.R. § 260.10] and S.C. Code Ann. Regs. 61-79.261.3 [40 C.F.R.

§ 261.3]. Respondent develops and manufactures pharmaceuticals. Respondent, through its operations, generates D001, D002, and D022 characteristic wastes and F002, F003, and F005 listed hazardous wastes.

36. Respondent, through its operations, generates 1,000 kilograms or greater of hazardous waste in a calendar month. On May 28, 2015, the Respondent submitted a Hazardous Waste Generator Notification (EPA Form 8700-12), which characterized the Respondent as a “large quantity generator” of hazardous waste as this term is described in S.C. Code Ann. Regs. 61-79.262.34(a) (2018) [40 C.F.R. § 262.34(a) (2016)].
37. On September 27, 2017, the EPA and the South Carolina Department of Health and Environmental Control (SCDHEC) conducted a RCRA compliance evaluation inspection (CEI) at Respondent’s facility. The EPA’s findings of the CEI were documented in a report mailed to Respondent, dated March 29, 2018.
38. Respondent stores some of its hazardous waste in “tanks”, as that term is defined in S.C. Code Ann. Regs. 61-79.260 [40 C.F.R. 260.10], prior to shipment off-site. On April 17, 2018, Respondent provided the EPA with a waste characterization profile for the aqueous waste with toluene dated February 2, 2017, and two waste characterization profiles for the aqueous waste with solvents dated May 8, 2018 and August 23, 2018 were provided by Respondent on May 21, 2018 and August 23, 2018, respectively. The profiles were developed by Respondent for treatment services to be provided by Disposal and Recycling Technologies. The profiles state that the aqueous waste with toluene and aqueous waste with solvents, are RCRA hazardous wastes. The volatile organic compounds (VOCs) are greater than 500 parts-per-million by weight (ppm/w), and the wastes are subject to Subpart CC of the regulations.
39. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to consistently conduct weekly inspections of all hazardous wastes in the less-than 90-day hazardous waste storage areas from May 3, 2016 until the date of the inspection.
40. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(a)(1)(i) (2018) [40 C.F.R. § 262.34(a)(1)(i) (2016)], by not complying with the inspection requirements of S.C. Code Ann. Regs. 61-79.265.174 [40 C.F.R. § 265.174].
41. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to comply with the RCRA Subpart CC Air Emission Standards for Tanks. Specifically, the Respondent failed to conduct inspections of the fixed roof and closure devices of tank T-A3610, which was storing hazardous waste for defects that could result in air pollutant emissions. Defects include, but are not limited to, visible cracks, holes, or gaps in the roof sections or between the roof and the tank wall; broken, cracked, or otherwise damaged seals or gaskets on closure devices; and broken or missing hatches, access covers, caps, or other closure devices.
42. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-

79.262.34(a)(1)(ii) (2018) [40 C.F.R. § 262.34(a)(1)(ii) (2016)], by not complying with the Organic Air Emission Standards of S.C. Code Ann. Regs. 61-79 Part 265, Subpart CC [40 C.F.R. Part § 265.1085(c)(4)(i)]

43. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to comply with the RCRA Subpart CC Air Emission Standards for Tanks. Specifically, the Respondent failed to perform an initial inspection of the fixed roof and its closure devices of tank T-A3610 on or before the date that the tank began storing hazardous waste subject to this section.
44. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(a)(1)(ii) (2018) [40 C.F.R. § 262.34(a)(1)(ii) (2016)], by not complying with the Organic Air Emission Standards of S.C. Code Ann. Regs. 61-79 Part 265, Subpart CC [40 C.F.R. Part § 265.1085(c)(4)(ii)]
45. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to comply with the RCRA Subpart CC Air Emission Standards for Tanks. Specifically, the Respondent failed to maintain inspection records for tank T-A3610, which was storing hazardous waste subject to RCRA Subpart CC.
46. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925], by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(a)(1)(ii) (2018) [40 C.F.R. § 262.34(a)(1)(ii) (2016)], by not complying with the Organic Air Emission Standards of S.C. Code Ann. Regs. 61-79 Part 265, Subpart CC [40 C.F.R. Part § 265.1090].
47. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to mark an accumulation start date on one 55-gallon container of hazardous waste located in the less than 90-day hazardous waste storage area adjacent to the tank farm.
48. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption by not complying with the dating requirements of S.C. Code Ann. Regs. 61-79.262.34(a)(2) (2018) [40 C.F.R. § 262.34(a)(2) (2016)].
49. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to maintain aisle space between thirty-two (32) 55-gallon containers of hazardous waste located in the Production Second Floor Accumulation Area.
50. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-

79.262.34(a)(4) (2018) [40 C.F.R. § 262.34(a)(4) (2016)], by not complying with the aisle space requirements of S.C. Code Ann. Regs. 61-79.265.35 [40 C.F.R. § 265.35].

51. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to update its contingency plan, which was dated January 20, 2016, to reflect the appropriate emergency coordinator. The emergency coordinator listed in the contingency plan at the time of the RCRA CEI no longer worked at the facility.
52. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the LQG Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(a)(4) (2018) [40 C.F.R. § 262.34(a)(4) (2016)], by not complying with the contingency plan requirements of S.C. Code Ann. Regs. 61-79.265.52(d) [40 C.F.R. § 265.52(d)], which requires a generator to have a contingency plan, which lists the names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator and keep it up to date.
53. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to keep the following SAA containers of hazardous waste closed when waste was not being added or removed, including:
 - a. One open 55-gallon container of hazardous waste PPE that was in the Production Second Floor Accumulation Area. The container top had a broken latch that prevented the container from closing.
 - b. One open 55-gallon drum of hazardous waste used to collect waste from machine number A3310-FD.
 - c. One open 14-gallon container of “hazardous chromatography waste” located in the QC Lab on the second floor.
 - d. One open three-gallon container of HPLC (HPLC #12) hazardous waste located in the Analytical R&D Lab Room 149.
54. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) and (b) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the SAA Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(c)(1)(i) (2018) [40 C.F.R. § 262.34(c)(1)(i) (2016)], by not complying with the container management requirements of S.C. Code Ann. Regs. 61-79.265.173(a) [40 C.F.R. § 265.173(a)].
55. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had accumulated hazardous waste in amounts in excess of 55-gallons at the point of generation, and with respect to that amount of excess waste, failed to comply within 3 days with S.C. Code Ann. Regs. 61-79.262.34(c)(2) (2018) [40 C.F.R. § 262.34(c)(2) (2016)] for the following containers:
 - a. Two 55-gallon drums of hazardous waste dated 8/2/17 and 9/10/17 located in the Process Technology Building,
 - b. One full 55-gallon drum of hazardous waste dated 8/23/17 located in the Third-Floor Dry Charging area,

- c. Two full 55-gallon drums of hazardous waste dated 9/15/17 and 9/23/17 in the First Floor Production area,
 - d. One full 55-gallon drum of hazardous waste, dated 9/17/17 located across from the Tank Farm, and
 - e. Two full 55-gallon drums of hazardous waste dated 9/16/17 and 9/22/17 located in the Warehouse, staged near shipping and receiving.
56. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the SAA Permit Exemption set forth in S.C. Code Ann. Regs. 61-79.262.34(c)(2) (2018) [40 C.F.R. § 262.34(c)(2) (2016)], by accumulating hazardous waste in excess of the amounts listed in S.C. Code Ann. Regs. 61-79.262.34(c)(1) (2018) [40 C.F.R. § 262.34(c)(1) (2016)] and mismanaging the excess accumulation.
57. During the September 27, 2017 RCRA CEI, the EPA observed that Respondent had failed to label a 55-gallon container used to collect hazardous waste from a process machine that produces filter dryer waste with the words “hazardous waste.”
58. The EPA therefore alleges Respondent violated Section 44-56-60(a)(2) and (b) of the SCHWMA, S.C. Code Ann. § 44-56-60(a)(2) [Section 3005 of RCRA, 42 U.S.C. § 6925] by storing hazardous waste without a permit or interim status, because Respondent failed to meet a condition of the SAA Permit Exemption by not complying with the labeling requirements of S.C. Code Ann. Regs. 61-79.262.34(c)(1)(ii) (2018) [40 C.F.R. § 262.34(c)(1)(ii) (2016)].

V. TERMS OF AGREEMENT

Based on the foregoing Preliminary Statements, Allegations and Determinations, the parties agree to the following:

- 59. For the purposes of this CA/FO, Respondent admits the jurisdictional allegations set out in the above paragraphs pursuant to Section 3008 of RCRA, 42 U.S.C. § 6928.
- 60. Respondent neither admits nor denies the factual allegations and determinations set out in this CA/FO.
- 61. Respondent waives any right to contest the allegations and its right to appeal the proposed Final Order accompanying the Consent Agreement.
- 62. Respondent waives its right to challenge the validity of this CA/FO and the settlement of the matters addressed in this CA/FO based on any issue related to the Paperwork Reduction Act, 44 U.S.C. § 3501 *et seq.*
- 63. Respondent waives any right it may have pursuant to 40 C.F.R. § 22.8 to be present during any discussions with, or to be served with and reply to, any memorandum or communication addressed to EPA officials where the purpose of such discussion, memorandum, or communication is to persuade such official to accept and issue this CA/FO.

64. Respondent waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review that Respondent may have with respect to any issue of fact or law set forth in this CA/FO, including any right of judicial review under Chapter 7 of the Administrative Procedure Act, 5 U.S.C. §§ 701-706.
65. The parties agree that the settlement of this matter is in the public interest and that this CA/FO is consistent with the applicable requirements of RCRA.
66. Respondent waives any right to contest the allegations and its right to appeal the proposed Final Order accompanying the Consent Agreement.
67. Respondent, by signing this CA/FO, certifies that Respondent is currently in compliance with RCRA and the authorized State hazardous waste program.
68. Respondent consents to the issuance of this compliance order.
69. Respondent consents to the conditions specified in this CA/FO.
70. The parties agree that compliance with the terms of this CA/FO shall resolve the violations alleged in this CA/FO.
71. Each party will pay its own costs and attorneys' fees.
72. The terms, conditions, and compliance requirements of this Consent Agreement may not be modified or amended except upon the written agreement of both Parties, and approval of the Regional Judicial Officer.

VI. WORK TO BE PERFORMED

73. By no later than sixty (60) days after the Effective Date of this CA/FO, Respondent shall develop and submit to the EPA, with a copy to the SCDHEC, a document that identifies and/or describes the tanks at the Facility subject to Subpart CC ("CC Tanks Program") and which includes or addresses the following:
 - a. The CC Tanks Program, which must determine:
 - i. applicability of RCRA Subpart CC regulations to specific tanks at the Facility,
 - ii. each type of Air Emission Control(s) associated with each Covered Tank, including whether controls are Tank Level 1 Controls or Tank Level 2 Controls,
 - iii. if Tank Level 1 Controls are associated with a Covered Tank, provide the determination for the maximum organic vapor pressure of the hazardous waste in the tank performed in accordance with the requirements of S.C. Code Ann. Regs. 61-79.265.1084(c) or 61-79.265.1085(c) [40 C.F.R. § 265.1084(c) or § 265.1085(c)];

- iv. if applicable, for each tank not using Air Emission Controls specified in S.C. Code Ann. Regs. 61-79.265.1085 [40 C.F.R. § 265.1085], and in accordance with S.C. Code Ann. Regs. 61-79.265.1080(b)(7) [40 C.F.R. § 265.1080(b)(7)], the Facility must provide the information required pursuant to S.C. Code Ann. Regs. 61-79.265.1090(j) [40 C.F.R. § 265.1090(j)];
 - v. a plan to keep records in accordance with S.C. Code Ann. Regs. 61-79.265.1090 [40 C.F.R. § 265.1090];
 - b. the Facility's written inspection and monitoring plan pursuant to S.C. Code Ann. Regs. 61-79.265.1089(b) [40 C.F.R. § 265.1089(b)];
 - c. a tracking program (e.g., Management of Change) that ensures that new tanks added to the Facility for any reason are integrated into the CC Tanks Program and that tanks that are taken out of service are removed from the CC Tanks Program;
 - d. the roles and responsibilities of all employee and contractor personnel assigned to RCRA, Subpart CC functions at the Facility;
 - e. how the number of personnel dedicated to RCRA, Subpart CC functions is sufficient to satisfy the requirements of the CC Tanks Program; and,
 - f. how the Facility plans to implement this CC Tanks Program.
74. Once developed, Respondent shall review the CC Tanks Program document described herein annually, and update it as necessary on a yearly basis, but no later than January 31 of each calendar year commencing with calendar year 2021.
75. Respondent has also agreed to institute a third-party hazardous waste focused inspection program at the Respondent's Facility and implement the third-party's recommendations. Respondent agrees to retain, at its expense, a qualified third-party inspection team to conduct at least one (1) third-party inspection over the course of one year, documenting the third-party inspection through photographs, film, and written reports. The Respondent will provide the third-party inspection documentation to the SCDHEC and the EPA and remedy and/or correct any deficiencies identified.
- a. Within sixty (60) days of the effective date of this CA/FO, Respondent shall engage a third-party inspection team ("Third-Party Team") and submit the Third-Party Team members' resumes and qualifications to the EPA. The Third-Party Team shall have at least one person with chemistry expertise, one expert in environmental compliance auditing, and one expert in chemical process safety management. One Third-Party Team member may fulfill more than one of these expertise requirements, but the Third-Party Team shall have at least two people for inspection safety reasons.
 - b. To ensure the Third-Party Team's independence from Respondent and promote a thorough third-party inspection:
 - i. No member of the Third-Party Team may have previously performed work for Respondent or for any of Respondent's officers, although Team members who

previously bid on projects but did not receive work from Respondent may participate;

- ii. No member of the Third-Party Team shall be allowed to work for Respondent or for any of Respondent's officers for five (5) years after the third-party inspection is completed;
 - iii. Before the third-party inspection, it is permissible for the Third-Party Team to visit the Facilities for purposes of bidding on Third-Party Inspection Program work and consulting on the Third-Party Team's inspection;
 - iv. Before conducting the third-party inspection, each member of the Third-Party Team shall have read this CA/FO and the CEI Report issued by the EPA, dated March 29, 2018;
 - v. During the third-party inspection, Respondent shall provide the Third-Party Team with unimpeded access to the entirety of the Respondent's Facility on any day that Respondent is operating. Respondent shall also permit the Third-Party Team to take photographs and film its third-party inspections provided the photography/film equipment is confirmed by Respondent to be intrinsically safe;
 - vi. After the third-party inspection, no communication shall occur between Respondent and the Third-Party Team without the SCDHEC and the EPA simultaneously being copied on the communication (except such communications that occur on-site while the third-party inspection is being conducted). Accordingly, all such communication must be transmitted such that the SCDHEC and the EPA may be copied (i.e., USPS mail or e-mail); and
 - vii. Respondent shall not have an opportunity to review or comment on the third-party inspection report or drafts thereof before the Third-Party Team sends them to the SCDHEC, the EPA and Respondent.
- c. The Third-Party Team shall conduct the third-party inspection within eleven (11) months of the effective date of this CA/FO. The purpose of the third-party inspection is to give all parties the opportunity to assess how Respondent manages hazardous waste when Respondent is operating with the highest level of care. Accordingly, the Third-Party Team must give Respondent three (3) days of notice before the third-party inspection. The Third-Party Team shall perform the inspection during normal business hours, Monday through Friday, excluding holidays. The Third-Party Team shall inspect the whole Facility, indoors and outdoors.
- d. Within thirty (30) days after the inspection, the Third-Party Team shall simultaneously submit to the SCDHEC, the EPA and Respondent an inspection report, photographs, and a digital video of the inspection ("Inspection Report"). The Inspection Report shall be organized by room and outdoor area visited, and provide detailed information about any deficiencies found, including proposed manners of correcting any deficiencies identified. Respondent shall not have the opportunity to review any draft or final Inspection Report before such submittal.

- e. Within forty (40) days of receiving the final Inspection Report, Respondent shall remedy and/or correct any RCRA deficiencies identified in the Inspection Report and send a letter to the SCDHEC and the EPA confirming that the deficiencies have been corrected unless the parties agree that another deadline is appropriate.
- f. The Respondent shall keep copies of the final Inspection Report, photographs and digital films for three (3) years.
- g. The Third-Party Team shall notify Respondent if it finds any non-RCRA-related deficiencies of EPA-administered statutes (for example, violations of the Clean Air Act, Clean Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act, or Toxic Substances Control Act), and Respondent shall correct those deficiencies within forty (40) days of receiving the final Inspection Report.
- h. Respondent shall notify the SCDHEC and the EPA immediately by telephone and e-mail if the Third-Party Team discovers any condition at the Respondent's Facilities that could pose an imminent and substantial endangerment to human health or the environment.
- i. Notifications:
 - i. Submissions required by this CA/FO shall be in writing and shall be mailed to the following addresses with a copy also sent by electronic mail:

David Champagne
U.S. Environmental Protection Agency, Region 4
Land, Asbestos and Lead Section
Enforcement and Compliance Assurance Division
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960
champagne.david@epa.gov

And

Robin Duffy
Environmental Health Manager
S.C. Dept. of Health & Environmental Control
2600 Bull Street
Columbia, SC 29201
duffyrs@dhec.sc.gov

- ii. The EPA and/or the State will send all written communications to the following representative(s) for Respondent:

Chuck Valentino, EHS Manager
Patheon API Manufacturing, Inc.
306 Delaware Street
Greenville, SC 29605
chuck.valentino@thermofisher.com

- j. All submissions made by the Respondent or the Third-Party Team to the EPA pursuant to the requirements of this CA/FO shall contain the following certification signed by a responsible corporate officer:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate 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 submissions of false information."

VII. PAYMENT OF CIVIL PENALTY

76. Respondent consents to the payment of a civil penalty in the amount of SEVENTY-TWO THOUSAND SIX HUNDRED DOLLARS (\$72,600), which is to be paid within thirty (30) calendar days of the effective date of this CA/FO.
77. Payment(s) shall be made by cashier's check, certified check, by electronic funds transfer (EFT), or by Automated Clearing House (ACH) (also known as REX or remittance express). If paying by check, the check shall be payable to: **Treasurer, United States of America**, and the Facility name and docket number for this matter shall be referenced on the face of the check. If Respondent sends payment by the U.S. Postal Service, the payment shall be addressed to:

United States Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, Missouri 63197-9000

If Respondent sends payment by non-U.S. Postal express mail delivery, the payment shall be sent to:

U.S. Bank
Government Lockbox 979077
U.S. Environmental Protection Agency, Fines & Penalties
1005 Convention Plaza
SL-MO-C2-GL
St. Louis, Missouri 63101
(314) 425-1818

If paying by EFT, Respondent shall transfer the payment to:

Federal Reserve Bank of New York
ABA: 021030004
Account Number: 68010727
SWIFT address: FRNYUS33
33 Liberty Street
New York, New York 10045
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency"

If paying by ACH, Respondent shall remit payment to:

US Treasury REX / Cashlink ACH Receiver
ABA: 051036706
Account Number: 310006, Environmental Protection Agency
CTX Format Transaction Code 22 – checking
Physical location of US Treasury facility:
5700 Rivertech Court
Riverdale, Maryland 20737
Contact: John Schmid, (202) 874-7026
REX (Remittance Express): 1-866-234-5681

78. Respondent shall submit a copy of the payment to the following individuals:

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960

And to:

David Champagne, Inspector
Land, Asbestos and Lead Section
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960

79. If Respondent fails to remit the civil penalty as agreed to herein, the EPA is required to assess interest and penalties on debts owed to the United States and a charge to cover the costs of processing and handling the delinquent claim. Interest, at the statutory judgment rate provided for in 31 U.S.C. § 3717, will therefore begin to accrue on the civil penalty if not paid within 30 calendar days after the effective date of this Consent Agreement or, if paying in installments, not paid in accordance with the installment schedule provided above. Pursuant to 31 U.S.C. § 3717, Respondent must pay the following amounts on any amount overdue:

- a. Interest. Any unpaid portion of a civil penalty or stipulated penalty must bear interest at the rate established by the Secretary of the Treasury pursuant to

31 U.S.C. § 3717(a)(1). Interest will therefore begin to accrue on a civil penalty or stipulated penalty if it is not paid by the last date required. Interest will be assessed at the rate of the United States Treasury tax and loan rate in accordance with 4 C.F.R. § 102.13(c).

- b. Monthly Handling Charge. Respondent must pay a late payment handling charge of fifteen dollars (\$15.00) on any late payment, with an additional charge of fifteen dollars (\$15.00) for each subsequent thirty (30) calendar-day period over which an unpaid balance remains.
- c. Non-Payment Penalty. On any portion of a civil penalty or a stipulated penalty more than ninety (90) calendar days past due, Respondent must pay a non-payment penalty of six percent (6%) per annum, which will accrue from the date the penalty payment became due and is not paid. 31 U.S.C. § 3717(e)(2). This non-payment penalty is in addition to charges which accrue or may accrue under subparagraphs (a) and (b).

80. Penalties paid pursuant to this CA/FO are not deductible for federal purposes under 26 U.S.C. § 162(f).

VIII. PARTIES BOUND

81. This CA/FO shall be binding on Respondent and its successors and assigns. Respondent shall cause its officers, directors, employees, agents, and all persons, including independent contractors, contractors, and consultants acting under or for Respondent, to comply with the provisions hereof in connection with any activity subject to this CA/FO.
82. No change in ownership, partnership, corporate or legal status relating to the Facility will in any way alter Respondent's obligations and responsibilities under this CA/FO.
83. The undersigned representative of Respondent hereby certifies that she or he is fully authorized to enter into this CA/FO and to execute and legally bind Respondent to it.

IX. RESERVATION OF RIGHTS

84. Notwithstanding any other provision of this CA/FO, an enforcement action may be brought pursuant to Section 7003 of RCRA, 42 U.S.C. § 6973, or other statutory authority, should the EPA find that the handling, storage, treatment, transportation, or disposal of solid waste or hazardous waste at Respondent's Facility may present an imminent and substantial endangerment to human health or the environment.
85. Complainant reserves the right to take enforcement action against Respondent for any future violations of RCRA and the implementing regulations and to enforce the terms and conditions of this CA/FO.
86. Except as expressly provided herein, nothing in this CA/FO shall constitute or be construed as a release from any civil or criminal claim, cause of action, or demand in law or equity for any liability Respondent may have arising out of, or relating in any way to, the storage, transportation, release, or disposal of any hazardous constituents, hazardous substances,

hazardous wastes, pollutants, or contaminants found at, taken to, or taken from Respondent's Facility.

X. OTHER APPLICABLE LAWS

87. All actions required to be taken pursuant to this CA/FO shall be undertaken in accordance with the requirements of all applicable local, state, and Federal laws and regulations. Respondent shall obtain or cause its representatives to obtain all permits and approvals necessary under such laws and regulations.

XI. SERVICE OF DOCUMENTS

88. A copy of any documents that Respondent files in this action shall be sent to the following attorney who represents the EPA in this matter and who is authorized to receive service for the EPA in this proceeding:

Ximena Vasquez
Assistant Regional Counsel
Office of Regional Counsel
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960
(404) 562-9548

89. A copy of any documents that Complainant files in this action shall be sent to the following individuals who represent Respondent in this matter and who are authorized to receive service for Respondent in this proceeding:

Klaus Hilber, Lead Counsel API
Pharma Services
Patheon, part of Thermo Fisher Scientific
Patheon Austria GmbH & Co KG
St.-Peter-Straße 25 | 4020 Linz, Austria
Tel: +43 732 6916 2477 | Mobile: +43 664 314 3774
klaus.hilber@thermofisher.com

Mr. Troy M. Raines Sr.
Director/General Manager
Patheon API Manufacturing, Inc.
309 Delaware Street
Greenville, South Carolina 29605
troy.raines@thermofisher.com

XII. SEVERABILITY

90. It is the intent of the parties that the provisions of this CA/FO are severable. If any provision or authority of this CA/FO or the application of this CA/FO to any party or circumstances is held by any judicial or administrative authority to be invalid or unenforceable, the application of such

provisions to other parties or circumstances and the remainder of the CA/FO shall remain in force and shall not be affected thereby.

XIII. EFFECTIVE DATE

91. The effective date of this CA/FO shall be the date on which the CA/FO is filed with the Regional Hearing Clerk.

In the matter of Patheon API Manufacturing, Inc., Docket No. RCRA-04-2019-4001(b):

AGREED AND CONSENTED TO:

Patheon API Manufacturing, Inc.

By: Troy M. Raines Dated: 5 Dec 2019
Troy M. Raines Sr.
Director/General Manager

United States Environmental Protection Agency

By: Alan A. Annicella Dated: 12/05/2019
for Larry L. Lamberth, Chief
Chemical Safety and Land Enforcement Branch
Enforcement and Compliance Assurance Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4

IN THE MATTER OF:) DOCKET NO.: RCRA-04-2019-4001(b)
)
Patheon API Manufacturing, Inc.)
309 Delaware Street) Proceeding Under Section 3008(a) of the
Greenville, South Carolina 29605) Resource Conservation and Recovery Act.
EPA ID No.: SCR000004168) 42 U.S.C. § 6928(a)
)
Respondent)
_____)

FINAL ORDER

The foregoing Consent Agreement is hereby approved, ratified and incorporated by reference into this Final Order in accordance with the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits*, 40 C.F.R. Part 22. The Respondent is hereby ORDERED to comply with all of the terms of the foregoing Consent Agreement effective immediately upon filing of this Consent Agreement and Final Order with the Regional Hearing Clerk. This Order disposes of this matter pursuant to 40 C.F.R. §§ 22.18 and 22.31.

BEING AGREED, IT IS SO ORDERED this 16th day of December 2019.

BY: Tanya Floyd
Tanya Floyd
Regional Judicial Officer
U.S. Environmental Protection Agency, Region 4

CERTIFICATE OF SERVICE

I hereby certify that I have this day filed the original and a true and correct copy of the foregoing Consent Agreement and the attached Final Order (CA/FO), in the Matter of Patheon API Manufacturing, Inc., Docket Number: RCRA-04-2019-4001(b), and have served the parties listed below in the manner indicated:

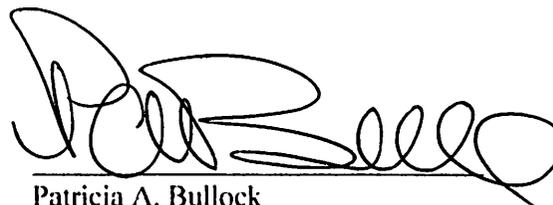
David Champagne (Via EPA's electronic mail)
Physical Scientist
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960

Ximena Vasquez (Via EPA's electronic mail)
Assistant Regional Counsel
Office of Regional Council
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960

Quantindra Smith (Via EPA's electronic mail)
Targeting, Data & Measures Office
Enforcement and Compliance Assurance Division
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960

Mr. Troy M. Raines Sr. (Via Certified Mail - Return Receipt Requested)
Director/General Manager
Patheon API Manufacturing, Inc.
309 Delaware Street
Greenville, South Carolina 29605

Date: 12-17-19



Patricia A. Bullock
Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 4
61 Forsyth Street, S.W.
Atlanta, Georgia 30303-8960
(404) 562-9511