



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 4  
ATLANTA FEDERAL CENTER  
61 FORSYTH STREET  
ATLANTA, GEORGIA 30303-8960

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

AUG 04 2015

Kate Inman  
General Counsel  
OPKO Health, Inc.  
4400 Biscayne Blvd.  
Miami, FL 33137

RE: OPKO Lab, LLC  
EPA ID Number: TNR 000 025 668  
Consent Agreement and Final Order, Docket No. RCRA-04-2015-4005(b)

Dear Ms. Inman:

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 the 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.

If you have any questions, please contact John Goodwin at 404-562-8488, or by email at Goodwin.John@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "CÉSAR A. ZAPATA".

César A. Zapata  
Chief, Enforcement and Compliance Branch  
Resource Conservation and Restoration Division

Enclosure

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 4**

IN THE MATTER OF: )  
 )  
OPKO Lab, LLC )  
1450 Elm Hill Pike )  
Nashville, Tennessee 37211 )  
 )  
 )  
EPA ID No.: TNR 000 025 668 )  
Respondent )  
\_\_\_\_\_ )  
 )

DOCKET NO.: RCRA-04-2015-4005(b)

Proceeding Under Section 3008(a) of the  
Resource Conservation and Recovery Act,  
42 U.S.C. § 6928(a)

RECEIVED  
RCRA-04-2015-4005(b)  
MAY 14 2015 11:57 AM  
EPA REGION 4

**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 Tennessee Hazardous Waste Management Act of 1977 (THWMA), Tennessee Code Annotated (Tenn. Code Ann.) §§ 68-212-101 *et seq.* [Subtitle C of RCRA, 42 U.S.C. §§ 6921-6939f], and the regulations promulgated pursuant thereto and set forth at Chapter 0400-12-01 of the Rules and Regulations of the State of Tennessee (Tenn. Comp. R. & Regs.) [Title 40 of the Code of Federal Regulations (C.F.R.), Parts 260 through 270, and 273]. This action seeks the imposition of civil penalties pursuant to Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), for violations of Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], and Tenn. Comp. R. & Regs. Chapter 0400-12-01 [40 C.F.R. Parts 260 through 270, and 273].
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, Enforcement and Compliance Branch, Resource Conservation and Restoration 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 OPKO Lab, LLC, a limited liability company incorporated under the laws of Florida, doing business in the state of Tennessee at 1450 Elm Hill Pike, Nashville, Tennessee (the Facility).

## III. PRELIMINARY STATEMENTS

6. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), the State of Tennessee (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 Tenn. Code Ann. §§ 68-212-101 *et seq.* and Tenn. Comp. R. & Regs. Chapter 0400-12-01.
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. Tennessee 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. Section 68-212-107(d) of the THWMA, Tenn. Code Ann. § 68-212-107(d) [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 Tenn. Comp. R. & Regs. 0400-12-01-.03 [40 C.F.R. Part 262].
12. Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [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 Tenn. Comp. R. & Regs. 0400-12-01-.06 (permitted) and 0400-12-01-.05 (interim status) [40 C.F.R. Parts 264 (permitted) and 265 (interim status)].

13. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(b)1 [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 Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(c)1 [40 C.F.R. § 261.3], a solid waste is a “hazardous waste” if it meets any of the criteria set forth in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(c)1(ii) [40 C.F.R. § 261.3(a)(2)] and is not otherwise excluded from regulation as a hazardous waste by Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(d)2 [40 C.F.R. § 261.4(b)].
15. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(c)1(ii)(I) and 0400-12-01-.02(3)(a) [40 C.F.R. §§ 261.3(a)(2)(i) and 261.20], solid wastes that exhibit any of the characteristics identified in Tenn. Comp. R. & Regs. 0400-12-01-.02(3)(b)-(e) [40 C.F.R. §§ 261.21-24] are characteristic hazardous waste and are provided with the EPA Hazardous Waste Numbers D001 through D0043.
16. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(3)(a) and (b) [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.
17. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(c)1(ii)(IV)II & Tenn. Comp. R. & Regs. 0400-12-01-.02(4)(b) [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 Tenn. Comp. R. & Regs. 0400-12-01-.02(4) [40 C.F.R. Part 261, Subpart D].
18. Xylene is a listed hazardous waste in Tenn. Comp. R. & Regs. 0400-12-01-.02(4) [40 C.F.R. Part 261, Subpart D] at Tenn. Comp. R. & Regs. 0400-12-01-.02(4)(b)(1) [40 C.F.R. § 261.31(a)] and is identified with the EPA Hazardous Waste Number F003.
19. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [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 Tenn. Comp. R. & Regs. 0400-12-01-.02 [40 C.F.R. Part 261], or whose act first causes a hazardous waste to become subject to regulation.
20. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10], a “small quantity generator” (SQG) means a generator who generates less than 1000 kilograms of hazardous waste in a calendar month.
21. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [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.”
22. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10], a “person” includes a corporation.
23. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [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.”

24. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11], a person who generates a solid waste, as defined in Tenn. Comp. R. & Regs. 0400-12-01-.02(1)(b)1 [40 C.F.R. § 261.2], must determine if that waste is a hazardous waste following the methods articulated in Tenn. Comp. R. & Regs. 0400-12-01-.03(1)(b) [40 C.F.R. § 262.11].
25. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)5 [40 C.F.R. § 262.34(c)(1)], 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, without a permit or without having interim status, as required by Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], and without complying with Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)2 [40 C.F.R. § 262.34(a)], provided that the generator complies with the satellite accumulation area conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)5(i)(I)-(II) [40 C.F.R. § 262.34(c)(1)(i)-(ii)] (hereinafter referred to as the “SAA Permit Exemption”).
26. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)5(i)(I) [40 C.F.R. § 262.34(c)(1)(i)], which incorporates Tenn. Comp. R. & Regs. 0400-12-01-.05(9)(d)1 [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.
27. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6 [40 C.F.R. § 262.34(d)], a SQG may accumulate hazardous waste on-site for 180 days or less without a permit or without having interim status, as required by Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [Section 3005 of RCRA, 42 U.S.C. § 6925], provided that the generator complies with the conditions listed in Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(i)-(vii) [40 C.F.R. § 262.34(d)(1)-(5)] (hereinafter referred to as the “SQG Permit Exemption”).
28. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6 [40 C.F.R. § 262.34(d)(4)], which incorporates Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(iv) [40 C.F.R. § 262.34(a)(2)], and is a condition of the SQG Permit Exemption, a generator is required to ensure that the date upon which each period accumulation begins is clearly marked and visible for inspection on each container.
29. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(ii) [40 C.F.R. § 262.34(d)(2)], which incorporates Tenn. Comp. R. & Regs. 0400-12-01-.05(9)(e) [40 C.F.R. § 265.174], and is a condition of the SQG 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.
30. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.03(5)(c)2 [40 C.F.R. § 262.42(b)], a generator of greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month who does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the waste was accepted by the initial transporter must submit a legible copy of the manifest, with some indication that the generator has not received confirmation of delivery, to the Commissioner (known as an “exception report”).

31. Pursuant to the Tennessee Hazardous Waste Reduction Act of 1990, T.C.A. 68-212-304(a)(1) all small quantity generators are required to prepare a hazardous waste reduction plan and maintain a current copy of the plan at the facility.
32. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(1)(b) [40 C.F.R. § 273.9] a “small quantity handler of universal waste” (SQHUW) is defined as a universal waste handler who does not accumulate 5,000 kilograms or more of universal wastes at any time. “Universal waste” means any of the hazardous wastes listed in Tenn. Comp. R. & Regs. 0400-12-01-.12(1)(a) [40 C.F.R. § 273.1], including hazardous waste lamps.
33. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(f)1 [40 C.F.R. § 273.15(a) and (b)] a SQHUW may accumulate universal waste for no longer than one year and must be able to demonstrate the length of time that the universal waste has been accumulated from the date that it became a waste or was received.
34. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(e)5 [40 C.F.R. § 273.14(e)], a SQHUW must specifically mark or label each lamp or container of lamps with phrases such as: “Universal Waste-Lamps(s)” or “Waste Lamp(s)” or “Used Lamp(s).”
35. Pursuant to Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(d)4(i)(I) [40 C.F.R. § 273.13(d)], a SQHUW must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage, and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions.

#### **IV. EPA ALLEGATIONS AND DETERMINATIONS**

36. Respondent is a “person” as defined in Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10].
37. Respondent is the “owner” and “operator” of a “facility” located in Davidson County, Tennessee, as those terms are defined in Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) [40 C.F.R. § 260.10].
38. Respondent is a “generator” of “hazardous waste” as those terms are defined in Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) and 0400-12-01-.02(1)(c)1 [40 C.F.R. §§ 260.10 and 261.3].
39. Respondent is a “small quantity generator” (SQG) of hazardous waste and a “small quantity handler of universal waste” (SQHUW) as those terms are defined in Tenn. Comp. R. & Regs. 0400-12-01-.01(2)(a) and 0400-12-01-.12(1)(b) [40 C.F.R. §§ 260.10 and 273.9].
40. Respondent is limited liability company that provides anatomic, molecular, and clinical pathology services.
41. On December 10, 2013, the EPA and the Tennessee Department of Environment and Conservation (TDEC) conducted a compliance evaluation inspection (CEI) at Respondent’s facility. The findings of the CEI were documented in a Report mailed to Respondent, dated January 5, 2014.

42. At the time of the CEI, the EPA and TDEC observed that Respondent had failed to date seven drums of hazardous waste (D001 & F003) placed in storage.
43. The EPA therefore alleges that Respondent violated Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [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 SQG Permit Exemption set forth in Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6 [40 C.F.R. § 262.34(d)(4)], by not complying with the dating requirements of Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(iv) [40 C.F.R. § 262.34(a)(2)].
44. At the time of the CEI, the EPA and TDEC observed that Respondent had failed to close seven drums of accumulated hazardous waste (D001 & F003) placed in storage.
45. The EPA therefore alleges that Respondent violated Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [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 SQG Permit Exemption set forth in Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(ii) [40 C.F.R. § 262.34(d)(2)], by not closing the container of accumulated hazardous waste as required in Tenn. Comp. R. & Regs. 0400-12-01-.05(9)(d)1 [40 C.F.R. § 262.173(a)]
46. At the time of the CEI, the EPA and TDEC observed that Respondent had failed to close two satellite accumulation area containers of hazardous waste (D001 & F003).
47. The EPA therefore alleges that Respondent violated Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [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 Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)5(i)(I) [40 C.F.R. § 262.34(c)(1)(i)], by not complying with the container management requirements of Tenn. Comp. R. & Regs. 0400-12-01-.05(9)(d)1 [40 C.F.R. § 265.173(a)].
48. At the time of the CEI, Respondent had not documented approximately 48 weeks of container inspections prior to the date of the CEI.
49. The EPA therefore alleges that Respondent violated Section 68-212-108 of the THWMA, Tenn. Code Ann. § 68-212-108 [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 SQG Permit Exemption set forth in Tenn. Comp. R. & Regs. 0400-12-01-.03(4)(e)6(ii) [40 C.F.R. § 262.34(d)(2)], by not complying with the inspection requirements of Tenn. Comp. R. & Regs. 0400-12-01-.05(9)(e) [40 C.F.R. § 265.174].
50. At the time of the CEI, Respondent had not filed an exception report for hazardous waste manifests that were missing the final copies signed by the destination facility.
51. The EPA therefore alleges that the Respondent violated Tenn. Comp. R. & Regs. 0400-12-01-.03(5)(c)2 [40 C.F.R. § 262.42(b)] by failing to file an exception report.

52. At the time of the CEI, Respondent had not developed a hazardous waste reduction plan for the Facility.
53. The EPA therefore alleges that the Respondent violated the Tennessee Hazardous Waste Reduction Act of 1990, T.C.A. 68-212-304(a)(1), by failing to develop a hazardous waste reduction plan for the Facility.
54. At the time of the CEI, Respondent had not marked a box of universal waste lamps (used microscope lights) located in the Universal Waste Storage Area with the accumulation start date, or with one of the following phrases: "Universal Waste-Lamp(s)," or "Waste Lamp(s)," or "Used Lamps."
55. The EPA therefore alleges that Respondent violated Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(e)5 [40 C.F.R. §§ 273.14(e)] and 0400-12-01-.12(2)(f)1 [40 C.F.R. § 273.15(a) and (c)] by failing to mark the universal waste container with the appropriate labeling information.
56. At the time of the CEI, Respondent had not placed a universal waste lamp located in the Universal Waste Storage Area inside an appropriate storage container.
57. The EPA therefore alleges that Respondent violated Tenn. Comp. R. & Regs. 0400-12-01-.12(2)(d)4(i)(I) [40 C.F.R. § 273.13(d)] by failing to manage spent lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment.

## V. TERMS OF AGREEMENT

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

58. 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.
59. Respondent neither admits nor denies the factual allegations and determinations set out in this CA/FO.
60. Respondent waives any right to contest the allegations and its right to appeal the proposed Final Order accompanying the Consent Agreement.
61. 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.*
62. 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.



63. 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.
64. 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.
65. Respondent, by signing this CA/FO, certifies that Respondent is currently in compliance with RCRA and the authorized State hazardous waste program.
66. The parties agree that compliance with the terms of this CA/FO shall resolve the violations alleged and the facts stipulated to in this CA/FO.
67. Each party will pay its own costs and attorneys' fees.

#### **VI. PAYMENT OF CIVIL PENALTY**

68. Respondent consents to the payment of a civil penalty in the amount of SEVENTEEN THOUSAND SEVEN HUNDRED DOLLARS (\$17,700.00), which is to be paid within thirty (30) calendar days of the effective date of this CA/FO.
69. Payment 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. EPA 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

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

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

And to:

John C. Goodwin  
Enforcement and Compliance Branch  
Resource Conservation and Restoration Division  
U.S. EPA - Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8909

71. 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. This non-payment is in addition to charges which accrue or may accrue under subparagraphs (a) and (b).

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

## **VII. PARTIES BOUND**

- 73. 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.
- 74. 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.
- 75. 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.

## **VIII. RESERVATION OF RIGHTS**

- 76. 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.
- 77. 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.
- 78. 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.

## **IX. OTHER APPLICABLE LAWS**

79. 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.

## **X. SERVICE OF DOCUMENTS**

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

Roberto Busó  
Associate Regional Counsel  
Office of RCRA, OPA and UST Legal Support  
U.S. Environmental Protection Agency, Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960  
(404) 562-9685

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

Kate Inman  
General Counsel  
OPKO Health, Inc.  
4400 Biscayne Blvd.  
Miami, FL 33137  
(305) 575-4138

## **XI. SEVERABILITY**

82. 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.

## **XII. EFFECTIVE DATE**

83. 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 OPKO Lab, LLC, Docket No. RCRA-04-2015-4005(b):*

**AGREED AND CONSENTED TO:**


**OPKO Lab, LLC**

By: 

Dated: July 2, 2015

Printed Name: Kate Inman  
Position: Secretary

**United States Environmental Protection Agency**

By: 

Dated: JULY 30, 2015

César A. Zapata  
Chief, Enforcement and Compliance Branch  
Resource Conservation and Restoration Division

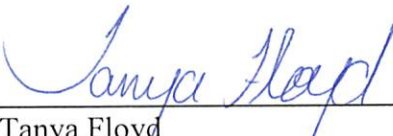
**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 4**

IN THE MATTER OF:	)	DOCKET NO.: RCRA-04-2015-4005(b)
	)	
OPKO Lab, LLC	)	
1450 Elm Hill Pike	)	
Nashville, Tennessee 37211	)	
	)	
	)	Proceeding Under Section 3008(a) of the
	)	Resource Conservation and Recovery Act,
EPA ID No.: TNR 000 025 668	)	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 3<sup>rd</sup> day of August, 2015.

BY:   
Tanya Floyd  
Regional Judicial Officer  
EPA 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 OPKO Lab, LLC, Docket Number: RCRA-04-2015-4005(b), and have served the parties listed below in the manner indicated:

Roberto Busó  
Associate Regional Counsel  
Office of RCRA, OPA and UST Legal Support  
U.S. Environmental Protection Agency, Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960

(Via EPA's electronic mail)

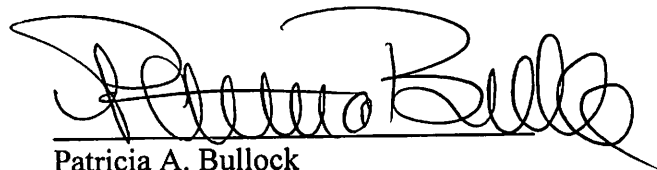
Quantindra Smith  
Enforcement and Compliance Branch  
Resource Conservation and Restoration Division  
U.S. Environmental Protection Agency, Region 4  
61 Forsyth Street, S.W.  
Atlanta, Georgia 30303-8960

(Via EPA's electronic mail)

Kate Inman  
General Counsel  
OPKO Health, Inc.  
4400 Biscayne Blvd.  
Miami, Florida 33137

(Via Certified Mail - Return Receipt  
Requested)

Date: 8-4-15



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