COMMONWEALTH of VIRGINIA

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VIRGINIA WASTE MANAGEMENT BOARD ENFORCEMENT ACTION - ORDER BY CONSENT ISSUED TO WILLIAMSON DRUG COMPANY, INCORPORATED FOR EXTENDED CARE ASSOCIATES EPA ID No. VAR000519439

SECTION A: Purpose

This is a Consent Order issued under the authority of Va. Code § 10.1-1455, between the Virginia Waste Management Board, and Williamson Drug Company, Incorporated, regarding the Extended Care Associates facility, for the purpose of resolving certain violations of the Virginia Waste Management Act and the applicable regulations.

SECTION B: Definitions

Unless the context clearly indicates otherwise, the following words and terms have the meaning assigned to them below:

1. "Board" means the Virginia Waste Management Board, a permanent citizens' board of the Commonwealth of Virginia, as described in Va. Code §§ 10.1-1184 and -1401.

2. "BRRO" means the Blue Ridge Regional Office of DEQ, located in Lynchburg, Virginia.

3. "CESQG" means a conditionally exempt small quantity generator of hazardous waste, a generator of less than 100 kilograms of hazardous waste in a month and meeting the other restrictions of 40 CFR § 261.5 and 9 VAC 20-80-120(A).

4. "CFR" means the Code of Federal Regulations, as incorporated into the Regulations.

5. "Department" or "DEQ" means the Department of Environmental Quality, an agency of the Commonwealth of Virginia, as described in Va. Code § 10.1-1183.

6. "Director" means the Director of the Department of Environmental Quality, as described in Va. Code § 10.1-1185.

7. "Facility" or "Site" means the Extended Care Associates Facility located at 105 Bradley Drive in Lynchburg, Virginia.

8. "Generator" means person who is a hazardous waste generator, as defined by 40 CFR § 260.10.

9. "Hazardous Waste" means any solid waste meeting the definition and criteria provided in 40 CFR § 261.3.

10. "LQG" means large quantity generator, a hazardous waste generator that generates 1000 kilograms (2200 pounds) or greater of hazardous waste in a calendar month and meets other restrictions. *See* 40 CFR § 262.34(a)-(b) and (g)-(l).

11. "Notice of Violation" or "NOV" means a type of Notice of Alleged Violation under Va. Code § 10.1-1455.

12. "Order" means this document, also known as a "Consent Order" or "Order by Consent."

13. "Regulations" or "VHWMR" means the Virginia Hazardous Waste Management Regulations, 9 VAC 20-60-12 *et seq*. Sections 20-60-14, -124, -260 through -266, -268, -270, -273, and -279 of the VHWMR incorporate by reference corresponding parts and sections of the federal Code of Federal Regulations (CFR), with the effected date as stated in 9 VAC 20-60-18, and with independent requirements, changes, and exceptions as noted. In this Order, when reference is made to a part or section of the CFR, unless otherwise specified, it means that part or section of the CFR as incorporated by the corresponding section of the VHWMR. Citations to independent Virginia requirements are made directly to the VHWMR.

14. "Solid Waste" means any discarded material meeting the definition provided in 40 CFR § 261.2.

15. "SQG" means a small quantity generator, a hazardous waste generator that generates greater than 100 kilograms but less than 1000 kilograms of hazardous waste in a calendar month and meets other restrictions. *See* 40 CFR § 262.34(d)-(f).

16. "Va. Code" means the Code of Virginia (1950), as amended.

17. "VAC" means the Virginia Administrative Code.

18. "Virginia Waste Management Act" means Chapter 14 (§ 10.1-1400 *et seq.*) of Title 10.1 of the Va. Code. Article 4 (Va. Code §§ 10.1-1426 through 10.1-1429) of the Virginia Waste Management Act addresses Hazardous Waste Management.

19. "Warning Letter" or "WL" means a type of Notice of Alleged Violation under Va. Code § 10.1-1455.

20. "WDCI" means Williamson Drug Company, Incorporated, a corporation authorized to do business in Virginia and its affiliates, partners, and subsidiaries. WDCI is a "person" within the meaning of Va. Code § 10.1-1400.

SECTION C: Findings of Fact and Conclusions of Law

1. WDCI owns and operates the Facility in Lynchburg, Virginia. The Facility provides medications to extended health care facilities. Operations at the Facility are subject to the Virginia Waste Management Act and the Regulations.

2. WDCI d/b/a Extended Care Associates submitted a RCRA Subtitle C Site Identification Form (received November 2, 2010) that gave notice of regulated waste activity at the Facility as a SQG of hazardous waste. WDCI d/b/a Extended Care Associates was issued EPA ID No. VAR000519239 for the Facility.

3. At the Facility, WDCI generates pharmaceuticals that are discontinued, expired, or refused by the extended health care facilities, which are a solid waste. The pharmaceuticals are also a hazardous waste with P-Listed and U-Listed waste codes (P001, P042, P046, P075 and P081). This hazardous waste is accumulated in a large cardboard box and a small container at the Facility after its generation.

4. On November 26, 2012, Department staff inspected the Facility for compliance with the requirements of the Virginia Waste Management Act and the Regulations. Based on the inspection and follow-up information, Department staff made the following observations.

5. WDCI has been operating the Facility at this location since 1999. The Facility notified EPA that it was a SQG of hazardous waste on November 2, 2010. Between 1999 and 2010, WDCI disposed of its P-listed pharmaceutical waste through Stericycle, a contracted regulated medical waste transportation, treatment, and disposal company. WDCI did not correctly identify the pharmaceutical waste stream as a hazardous waste. WDCI was disposing of its spent fluorescent lamps as solid waste. 40 CFR § 262.11 requires that a generator of solid waste, as defined in 40 CFR § 261.2, must determine if that waste is a hazardous waste using either analytical testing or generator knowledge.

6. WDCI calculates monthly generation rates were by averaging the quantities of P-listed hazardous waste shipped (obtained from the manifests) over the time between shipments. Based on this methodology, WDCI appears to have become a LQG in April 2011 and has maintained this generator status to date by generating greater than 2.2 lbs. of P-listed

waste each month (4lbs – 75 lbs/month, 75 lbs. on September 6, 2012). WDCI did not notify DEQ in writing of this change in generator status in April 2011. 9 VAC 20-60-315(D) requires anyone who becomes a LQG shall notify the Department in writing immediately of this change in status and document the change in the operational record. WDCI submitted to the DEQ the notification of the change in generator status to a LQG on March 14, 2013.

7. WDCI has not notified the DEQ of the location of its 90-day hazardous waste accumulation area. 9 VAC 20-60-262(B)(4) requires a generator to notify the Department and document in the operating record that he intends to accumulate hazardous waste in accordance with 40 CFR § 262.34 prior to or immediately upon establishment of each accumulation area. WDCI submitted a map of the layout of the Facility which was marked with the location of the <90-day accumulation area on April 29, 2013.

8. There were five off-site shipments (06/07/2012, 03/01/2012, 12/02/2011, 11/03/2011and 10/06/2011) of hazardous waste for which the manifests were not complete with the signature of the disposal facility representative. 40 CFR § 262.40(a) requires that a generator must keep a signed copy from the designated facility which received the waste of record for at least three years from the date the waste was accepted by the initial transporter. WDCI obtained signed copies of the five manifests from the disposal facility and submitted them to the DEQ via e-mail on November 28, 2012.

9. As a LQG for the year 2011, WDCI was subject to the annual fee for LQGs. WDCI was not assessed the fee and has not paid this fee for 2011 because DEQ was not notified that WDCI was a LQG. 9 VAC 20-60-1283(E) requires that anyone who is a LQG at any time during the year shall be assessed the full annual fee amount no matter how short the period the facility is operated or how briefly the generator is a large quantity generator. The DEQ invoiced WDCI for the 2011 annual fee and the DEQ received the 2011 annual fee from WDCI on June 3, 2013.

10. As a LQG for the year 2011, WDCI was required to submit a RCRA Biennial Hazardous Waste Report to EPA by March 1, 2012. WDCI did not submit this report. 40 CFR § 262.41 requires that a generator who ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States must prepare and submit a single copy of a Biennial Report to the Regional Administrator by March 1 of each even numbered year. WDCI submitted the 2011 biennial report electronically on May 10, 2013 as evidenced by the Declaration of Electronic Filing submitted to DEQ on May 10, 2013.

11. On January 14, 2012, based on the inspection and follow-up information, the Department issued Notice of Violation No. NOV-12-12-BRRO-L-001 to Extended Care Associates for alleged violations of 40 CFR § 262.11, 40 CFR § 261.2, 9 VAC 20-60-315(D), 9 VAC 20-60-262(B)(4), 40 CFR § 262.40(a), 9 VAC 20-60-1283(E), and 40 CFR § 262.41, as described in paragraphs C(5) through C(10), above.

12. On January 24, 2013, WDCI submitted a written response to the NOV which consisted of an e-mail acknowledging receipt of the NOV. The e-mail did not contain any information regarding the violations alleged in the NOV.

13. Based on the results of the November 26, 2012 inspection, the Board concludes that WDCI has violated 40 CFR § 262.11, 40 CFR § 261.2, 9 VAC 20-60-315(D), 9 VAC 20-60-262(B)(4), 40 CFR § 262.40(a), 9 VAC 20-60-1283(E), and 40 CFR § 262.41, as described in paragraphs C(5) through C(10), above.

14. WDCI has submitted documentation that verifies that the violations described in paragraphs C(5) through C(10), above, have been corrected.

SECTION D: Agreement and Order

Accordingly, by virtue of the authority granted it in Va. Code § 10.1-1455, the Board orders WDCI, and WDCI agrees to pay a civil charge of $20,230 within 30 days of the effective date of the Order in settlement of the violations cited in this Order.

Payment shall be made by check, certified check, money order or cashier's check payable to the "Treasurer of Virginia," and delivered to:

Receipts Control
Department of Environmental Quality
Post Office Box 1104
Richmond, Virginia 23218

WDCI shall include its Federal Employer Identification Number (FEIN) 54-0590067 with the civil charge payment and shall indicate that the payment is being made in accordance with the requirements of this Order for deposit into the Virginia Environmental Emergency Response Fund (VEERF).

SECTION E: Administrative Provisions

1. The Board may modify, rewrite, or amend this Order with the consent of WDCI for good cause shown by WDCI, or on its own motion pursuant to the Administrative Process Act, Va. Code § 2.2-4000 *et seq.*, after notice and opportunity to be heard.

2. This Order addresses and resolves only those violations specifically identified in Section C of this Order. This Order shall not preclude the Board or the Director from taking any action authorized by law, including but not limited to: (1) taking any action authorized by law regarding any additional, subsequent, or subsequently discovered violations; (2) seeking subsequent remediation of the facility; or (3) taking subsequent action to enforce the Order.

3. For purposes of this Order and subsequent actions with respect to this Order only, WDCI admits to the jurisdictional allegations, and agrees not to contest, but does not admit, the findings of fact and conclusions of law in this Order.

4. WDCI consents to venue in the Circuit Court of the City of Richmond for any civil action taken to enforce the terms of this Order.

5. WDCI declares it has received fair and due process under the Administrative Process Act and the Virginia Waste Management Act and it waives the right to any hearing or other administrative proceeding authorized or required by law or regulation, and to any judicial review of any issue of fact or law contained herein. Nothing herein shall be construed as a waiver of the right to any administrative proceeding for, or to judicial review of, any action taken by the Board to modify, rewrite, amend, or enforce this Order.

6. Failure by WDCI to comply with any of the terms of this Order shall constitute a violation of an order of the Board. Nothing herein shall waive the initiation of appropriate enforcement actions or the issuance of additional orders as appropriate by the Board or the Director as a result of such violations. Nothing herein shall affect appropriate enforcement actions by any other federal, state, or local regulatory authority.

7. If any provision of this Order is found to be unenforceable for any reason, the remainder of the Order shall remain in full force and effect.

8. WDCI shall be responsible for failure to comply with any of the terms and conditions of this Order unless compliance is made impossible by earthquake, flood, other acts of God, war, strike, or such other unforeseeable circumstances beyond its control and not due to a lack of good faith or diligence on its part. WDCI shall demonstrate that such circumstances were beyond its control and not due to a lack of good faith or diligence on its part. WDCI shall notify the DEQ Regional Director verbally within 24 hours and in writing within three business days when circumstances are anticipated to occur, are occurring, or have occurred that may delay compliance or cause noncompliance with any requirement of the Order. Such notice shall set forth:

   a. the reasons for the delay or noncompliance;

   b. the projected duration of any such delay or noncompliance;

   c. the measures taken and to be taken to prevent or minimize such delay or noncompliance; and

   d. the timetable by which such measures will be implemented and the date full compliance will be achieved.

   Failure to so notify the Regional Director verbally within 24 hours and in writing within three business days, of learning of any condition above, which the parties intend to assert will

result in the impossibility of compliance, shall constitute a waiver of any claim to inability to comply with a requirement of this Order.

9. This Order is binding on the parties hereto and any successors in interest, designees and assigns, jointly and severally.

10. This Order shall become effective upon execution by both the Director or his designee and WDCI. Nevertheless, WDCI agrees to be bound by any compliance date which precedes the effective date of this Order.

11. This Order shall continue in effect until:

    a. The Director or his designee terminates the Order after WDCI has completed all of the requirements of the Order;

    b. WDCI petitions the Director or his designee to terminate the Order after it has completed all of the requirements of the Order and the Director or his designee approves the termination of the Order; or

    c. the Director or Board terminates the Order in his or its sole discretion upon 30 days' written notice to WDCI.

    Termination of this Order, or any obligation imposed in this Order, shall not operate to relieve WDCI from its obligation to comply with any statute, regulation, permit condition, other order, certificate, certification, standard, or requirement otherwise applicable.

12. Any plans, reports, schedules or specifications attached hereto or submitted by WDCI and approved by the Department pursuant to this Order are incorporated into this Order. Any non-compliance with such approved documents shall be considered a violation of this Order.

13. The undersigned representative of WDCI certifies that he or she is a responsible official authorized to enter into the terms and conditions of this Order and to execute and legally bind WDCI to this document. Any documents to be submitted pursuant to this Order shall also be submitted by a responsible official of WDCI.

14. This Order constitutes the entire agreement and understanding of the parties concerning settlement of the violations identified in Section C of this Order, and there are no representations, warranties, covenants, terms or conditions agreed upon between the parties other than those expressed in this Order.

15. By its signature below, WDCI voluntarily agrees to the issuance of this Order.

And it is so ORDERED this 15th day of August, 2013

Robert J. Weld, Regional Director
Department of Environmental Quality

Williamson Drug Company, Incorporated voluntarily agrees to the issuance of this Order.

Date: 7/2/13 By: _____, President
Elizabeth A. Haley
Williamson Drug Company, Incorporated

State of Ohio
City/County of Hamilton

The foregoing document was signed and acknowledged before me this 2 day of July, 2013, by Elizabeth A. Haley who is President of Williamson Drug Company, Incorporated on behalf of the corporation.

Kara Hardy
Notary Public

n/a
Registration No.

NOTARIAL SEAL STATE OF OHIO

Kara Hardy, Attorney At Law
NOTARY PUBLIC - STATE OF OHIO
My commission has no expiration date
Sec. 147.03 R.C.

My commission expires: n/a

Notary seal: