



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

SEP 28 2015

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL # 7009 1680 0000 7648 7962
RETURN RECEIPT REQUESTED

Scott N. Fein, Esq.
Whiteman Osterman & Hanna LLP
One Commerce Plaza
Albany, NY 12260

Re: Commence and Conclude Consent Agreement and Final Order
Actavis, Inc.
Docket No.: **RCRA-05-2015-0018**

Dear Mr. Fein:

Enclosed please find a copy of a signed fully-executed Commence and Conclude Consent Agreement and Final Order (CC/CAFO) in resolution of the above case. The original was filed on September 28, 2015, with the Regional Hearing Clerk (RHC).

Please have your client pay the civil penalty in the amount of \$30,800 in the manner prescribed in paragraphs 54 and 55 of the CC/CAFO, and reference all checks with the docket number RCRA-05-2015-0018. The payment is due within 30 calendar days of the effective date of the CC/CAFO. Also, enclosed is a *Notice of Securities and Exchange Commission Registrant's Duty to Disclose Environmental Legal Proceedings*. Thank you for your cooperation in resolving this matter.

Sincerely,

A handwritten signature in cursive script that reads "Gary J. Victorine".

Gary J. Victorine, Chief
RCRA Branch

Enclosures

cc: Todd Marvel, Illinois Environmental Protection Agency; marvel.todd@illinois.gov
(w/CAFO)

HEAR/)
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY)
RECEIVED REGION 5)

In the Matter of:

Actavis, Inc.)
605 Tri-State Parkway)
Gurnee, Illinois 60031-5277)
U.S. EPA ID No. ILR000136762)

Respondent.)

Docket No. RCRA-05-2015-0018

Proceeding to Commence and Conclude)
an Action to Assess a Civil Penalty)
Under Section 3008(a) of the Resource)
Conservation and Recovery Act,)
42 U.S.C. § 6928(a))

Consent Agreement and Final Order

Preliminary Statement

1. This is an administrative action commenced and concluded under Section 3008(a) of the Solid Waste Disposal Act, as amended, also known as the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6928(a), and Sections 22.13(b) and 22.18(b)(2) and (3) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation/Termination or Suspension of Permits (Consolidated Rules) as codified at 40 C.F.R. Part 22.

2. The Complainant is the Director of the Land and Chemicals Division, United States Environmental Protection Agency (U.S. EPA), Region 5.

3. U.S. EPA provided notice of commencement of this action to the State of Illinois pursuant to Section 3008(a)(2) of RCRA, 42 U.S.C. § 6928(a)(2).

4. Respondent is Actavis, Inc., a corporation doing business in the State of Illinois.

5. Where the parties agree to settle one or more causes of action before the filing of a complaint, the administrative action may be commenced and concluded simultaneously by the issuance of a consent agreement and final order (CAFO). 40 C.F.R. § 22.13(b).

6. The parties agree that settling this action without the filing of a complaint or the adjudication of any issue of fact or law is in their interest and in the public interest.

7. Respondent consents to the assessment of the civil penalty specified in this CAFO, and to the terms of this CAFO.

Jurisdiction and Waiver of Right to Hearing

8. Jurisdiction for this action is conferred upon U.S. EPA by Sections 3006 and 3008 of RCRA, 42 U.S.C. §§ 6926 and 6928.

9. Respondent admits the jurisdictional allegations in this CAFO and neither admits nor denies the factual allegations in this CAFO.

10. Respondent waives its right to request a hearing as provided at 40 C.F.R. § 22.15(c), any right to contest the allegations in this CAFO, and its right to appeal this CAFO.

11. Respondent certifies that it is complying fully with RCRA, 42 U.S.C. §§ 6901 – 6992k, and the regulations at 40 C.F.R. Parts 260 - 279.

Statutory and Regulatory Background

12. U.S. EPA has promulgated regulations, codified at 40 C.F.R. Parts 260 through 279, governing generators and transporters of hazardous waste and facilities that treat, store, and dispose of hazardous waste, pursuant to Sections 3001 – 3007, among others, of RCRA, 42 U.S.C. §§ 6921 – 6927, and 6934.

13. Pursuant to Section 3006 of RCRA, 42 U.S.C. § 6926, the Administrator of U.S. EPA may authorize a state to administer the RCRA hazardous waste program in lieu of the federal program when the Administrator finds that the state program meets certain conditions. Any violation of regulations promulgated pursuant to Subtitle C (Sections 3001-3023 of RCRA, 42 U.S.C. §§ 6921-6939e) or any state provision authorized pursuant to Section 3006 of RCRA

constitutes a violation of RCRA, subject to the assessment of civil penalties and issuance of compliance orders as provided in Section 3008 of RCRA, 42 U.S.C. § 6928.

14. Pursuant to Section 3006(b) of RCRA, 42 U.S.C. § 6926(b), the Administrator of U.S. EPA granted the State of Illinois final authorization to administer a state hazardous waste program in lieu of the federal government's base RCRA program effective January 31, 1986. 51 Fed. Reg. 3778 (January 31, 1986). Under Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), U.S. EPA may issue an order assessing a civil penalty for any past or current violation, requiring compliance immediately or within a specified period of time, or both.

15. Under Section 3008(a) of RCRA, 42 U.S.C. § 6928(a), U.S. EPA may issue an order assessing a civil penalty for any past or current violation, requiring compliance immediately or within a specified period of time, or both. The Administrator of U.S. EPA may assess a civil penalty of up to \$25,000 per day for each violation of Subtitle C of RCRA according to Section 3008 of RCRA, 42 U.S.C. § 6928. The Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701 note (1996), required U.S. EPA to adjust its penalties for inflation on a periodic basis. Pursuant to the Civil Monetary Penalty Inflation Adjustment Rule, published at 40 C.F.R. Part 19, U.S. EPA may assess a civil penalty of up to \$37,500 per day for each violation of Subtitle C of RCRA that occurred after January 12, 2009.

EPA's Factual Allegations and Alleged Violations

16. Respondent was and is a "person" as defined by 35 IAC § 720.110, 40 C.F.R. § 260.10, and Section 1004(15) of RCRA, 42 U.S.C. § 6903(15).

17. Respondent is the “owner” or “operator,” as those terms are defined under 35 IAC § 720.110 and 40 C.F.R. § 260.10, of a facility located at 605 Tri-State Parkway, Gurnee, Illinois (facility).

18. On July 30, 2012, the Illinois Environmental Protection Agency (IEPA) conducted a Compliance Evaluation Inspection (Inspection) of the facility.

19. The facility consists of land and structures, other appurtenances, and improvements on the land used for storing hazardous waste.

20. At the time of the Inspection, Respondent warehoused, accumulated, stored in containers, or otherwise handled expired, damaged, or off-specification smoking cessation pharmaceutical products in the form of nicotine chewing gum and nicotine patches.

21. EPA alleges that nicotine chewing gum and off-specification nicotine patches are wastes and solid wastes as defined at 35 IAC §§ 720.110 and 721.102 [40 C.F.R. §§ 261.10 and 261.2], and Section 1004(27) of RCRA, 42 U.S.C. § 6903(27).

22. Under 35 IAC §§ 720.110 and 721.103(a)(2)(B) [40 C.F.R. §§ 261.10 and 261.3(a)(2)(ii)], a solid waste is a hazardous waste if it is listed in Subpart D of 35 IAC § 721 [40 C.F.R. § 261, Subpart D]. Nicotine is a listed hazardous waste under 35 IAC § 721.133 [40 C.F.R. § 261.33], and is assigned EPA Hazardous Waste Number P075.

23. P075 wastes are acute hazardous wastes under 35 IAC § 721.133(e) [40 C.F.R. § 261.33(e)].

24. Respondent’s holding of P075 in containers constituted “storage,” as that term is defined under 35 IAC § 720.110 [40 C.F.R. § 260.10], and Section 1004(33) of RCRA, 42 U.S.C. § 6903(33).

25. Respondent is a “generator,” as that term is defined in 35 IAC § 720.110 [40 C.F.R. § 260.10].

26. Respondent produced more than 1 kilogram (2.205 pounds) of acute hazardous waste during certain calendar months of its operation, prior to the Inspection, and was a Large Quantity Generator (LQG) under 35 IAC § 721.105(e) [40 C.F.R. § 261.5(e)].

27. Respondent is subject to the regulations promulgated pursuant to Subtitle C of RCRA, 42 U.S.C. §§ 6921 - 6939e, or the analogous Illinois regulations as part of the applicable state hazardous waste management program for the State of Illinois, or both.

28. At all times relevant to this CAFO, the State of Illinois has not issued a permit to Respondent to treat, store, or dispose of hazardous waste at the facility.

29. At all times relevant to this CAFO, Respondent did not have interim status for the treatment, storage, or disposal of hazardous waste at the facility.

COUNT I

Storage of Hazardous Waste without a Permit or Interim Status

30. Complainant incorporates Paragraphs 1 through 29 of this CAFO as though set forth in this paragraph.

31. Pursuant to 35 IAC § 703.121(a) [40 C.F.R. Part 270], and 3005(a) of RCRA, 42 U.S.C. § 6925(a), the treatment, storage, or disposal of hazardous waste by any person who has not applied for or received a permit is prohibited.

32. Pursuant to 35 IAC § 722.134(a) [40 C.F.R. § 262.34(a)], a generator of hazardous waste may accumulate hazardous waste on-site for 90 days or less without having a permit or interim status, provided that the generator complies with all applicable conditions, including the requirements of 35 IAC § 725.116 [40 C.F.R. § 265.16].

33. 35 IAC 725.116(a) [40 C.F.R. § 265.16(a)] requires the generator to provide hazardous waste training to facility personnel who must successfully complete a program of classroom instruction or on-the-job training that teaches them to perform their duties in a way that ensures the facility's compliance with hazardous waste regulations.

34. At the time of the Inspection, Respondent had not provided any hazardous waste training for employees.

35. At the time of the Inspection, Respondent had not applied or received a permit for treatment, storage, or disposal of hazardous waste, and did not have interim status.

36. Respondent failed to satisfy all of the conditions for maintaining its exemption from the requirement that it have an operating permit or interim status.

37. Respondent's storage of hazardous waste without a permit or interim status violated 35 IAC § 703.121(a) [40 C.F.R. Part 270], and Section 3005 of RCRA, 42 U.S.C. § 6925(a).

COUNT II

Failure to Designate a Receiving Facility Permitted to Handle Hazardous Waste

38. Complainant incorporates Paragraphs 1 through 29 of this CAFO as though set forth in this paragraph.

39. 35 IAC § 722.120(b) [40 C.F.R. § 262.20(b)] requires a generator of hazardous waste to designate on any manifest a designated receiving facility that is permitted to handle the waste described on the manifest.

40. Prior to the Inspection, Respondent shipped off-specification nicotine chewing gum to a solid waste disposal facility, Covanta Indianapolis, Inc. (Covanta), 2320 South Harding Street, Indianapolis, Indiana 46221 (EPA Identification Number IND980882365), for treatment

or disposal, without characterizing the P075 waste as hazardous waste or acute hazardous waste on the manifests.

41. The Covanta facility is not permitted to receive or handle hazardous waste for treatment, storage, or disposal.

42. In the manifests used to ship P075 acute hazardous waste to Covanta for treatment or disposal, Respondent failed to designate a receiving facility that was permitted to handle hazardous waste.

43. Respondent's failure to designate a receiving facility permitted to handle hazardous waste on manifests accompanying shipments of P075 acute nicotine hazardous waste violated 35 IAC § 722.120(b) [40 C.F.R. § 262.20(b)].

COUNT III

Failure to Make a Hazardous Waste Determination

44. Complainant incorporates Paragraphs 1 through 29 of this CAFO as though set forth in this paragraph.

45. 35 IAC § 722.111 [40 C.F.R. § 262.11] requires a person who generates a solid waste to determine if that waste is a hazardous waste, including determining whether the waste is listed as a hazardous waste under Subpart D of 35 IAC § 721 [40 C.F.R. § 261].

46. Nicotine is listed as EPA Hazardous Waste Number P075 under Subpart D of 35 IAC § 721 [40 C.F.R. § 261].

47. At the time of the Inspection, Respondent had not made appropriate hazardous waste determinations for off-specification nicotine chewing gum generated or handled by Respondent.

48. Respondent's failure to make appropriate hazardous waste determinations for off-specification nicotine chewing gum generated or handled by Respondent violated 35 IAC § 722.111 [40 C.F.R. § 262.11].

COUNT IV

Failure to Submit Annual Reports

49. Complainant incorporates Paragraphs 1 through 29 of this CAFO as though set forth in this paragraph.

50. 35 IAC § 722.141(a) [40 C.F.R. § 262.41(a)] requires a generator that ships any hazardous waste off-site to a treatment, storage or disposal facility within the United States to prepare and submit an annual report to the State of Illinois by March 1 for the preceding calendar year.

51. At the time of the Inspection, Respondent had not timely submitted annual reports to the State of Illinois for shipments of P075 acute hazardous waste nicotine chewing gum for treatment or disposal to the Covanta facility.

52. Respondent's failure to timely submit annual reports to the State of Illinois violated 35 IAC § 722.141(a) [40 C.F.R. § 262.41(a)].

Civil Penalty

53. Pursuant to Section 3008(a)(3) of RCRA, 42 U.S.C. § 6928(a)(3), Complainant determined that an appropriate civil penalty to settle this action is \$30,800. In determining the penalty amount, Complainant took into account the seriousness of the violations and any good faith efforts to comply with the applicable requirements. Complainant also considered U.S. EPA's RCRA Civil Penalty Policy, dated June 23, 2003.

54. Within 30 days after the effective date of this CAFO, Respondent must pay a \$30,800 civil penalty for the RCRA violations by sending a cashier's or certified check, payable to the "Treasurer, United States of America," to:

For checks sent by regular U.S. Postal Service mail:

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

For checks sent by express mail:

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

The check must state the case title and the docket number of this CAFO.

55. A transmittal letter stating Respondent's name, the case title and the case docket number must accompany the payment. Respondent must send a copy of the check and transmittal letter to:

Regional Hearing Clerk (E-19J)
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Robert Smith (LR-8J)
RCRA Branch
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

Kevin Chow (C-14J)
Office of Regional Counsel
U.S. EPA, Region 5
77 West Jackson Blvd.
Chicago, IL 60604

56. This civil penalty is not deductible for federal tax purposes.

57. If Respondent does not timely pay the civil penalty, U.S. EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties, and the United States enforcement expenses for the collection action. The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

U.S. EPA may bring an action to collect any unpaid portion of the penalty with interest, handling charges, nonpayment penalties, and the United States enforcement expenses for the collection action. The validity, amount, and appropriateness of the civil penalty are not reviewable in a collection action.

58. Pursuant to 31 C.F.R. § 901.9, Respondent must pay the following on any amount overdue under this CAFO. Interest will accrue on any amount overdue from the date payment was due at a rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717(a)(1). Respondent must pay a \$15 handling charge each month that any portion of the penalty is more than 30 days past due. In addition, Respondent must pay a 6 percent per year penalty on any principal amount 90 days past due.

General Provisions

59. This CAFO resolves only Respondent's liability for federal civil penalties for the violations and facts alleged in the CAFO.

60. This CAFO does not affect the right of U.S. EPA or the United States to pursue appropriate injunctive or other equitable relief or criminal sanctions for any violations of law.

61. This CAFO does not affect Respondent's responsibility to comply with RCRA and other applicable federal, state, local laws or permits.

62. This CAFO is a "final order" for purposes of 40 C.F.R. § 22.31, U.S. EPA's RCRA Civil Penalty Policy, and U.S. EPA's Hazardous Waste Civil Enforcement Response Policy (December 2003).

63. The terms of this CAFO bind Respondent, its successors, and assigns.

64. Each person signing this agreement certifies that he or she has the authority to sign for the party whom he or she represents and to bind that party to its terms.

65. Each party agrees to bear its own costs and attorney's fees in this action.

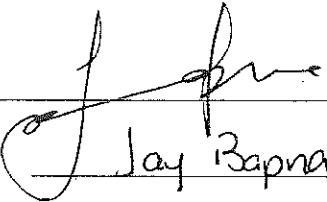
66. This CAFO constitutes the entire agreement between the parties.

67. Consistent with the "Standing Order Authorizing E-Mail Service of Order and Other Documents Issued by the Regional Administrator or Regional Judicial Officer Under the Consolidated Rules," dated March 27, 2015, the parties consent to service of this CAFO by e-mail at the following valid e-mail addresses: chow.kevin@epa.gov (for Complainant), and sfein@woh.com (for Respondent). The parties waive their right to service by the methods specified in 40 C.F.R. § 22.6.

**Consent Agreement and Final Order
In the Matter of: Actavis, Inc.**

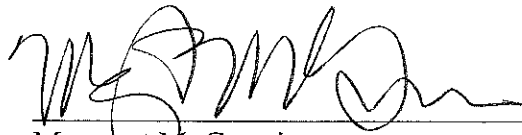
Actavis, Inc., Respondent

Sept. 15, 2015
Date


By: Jay Zapna
Title: Sr. Vice President Global
Actavis, Inc. Engineering and EHS

United States Environmental Protection Agency, Complainant

9/22/2015
Date

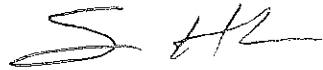

Margaret M. Guerriero
Director
Land and Chemicals Division

In the Matter of:
Actavis, Inc.
Docket No. RCRA-05-2015-0018

Final Order

This Consent Agreement and Final Order, as agreed to by the parties, shall become effective immediately upon filing with the Regional Hearing Clerk. This Final Order concludes this proceeding pursuant to 40 C.F.R. §§ 22.18 and 22.31. IT IS SO ORDERED.

23 September 2015
Date



Susan Hedman
Regional Administrator
United States Environmental Protection Agency
Region 5

Consent Agreement and Final Order
In the Matter of: Actavis, Inc.
Docket Number: RCRA-05-2015-0018

CERTIFICATE OF SERVICE

I hereby certify that I served a true and correct copy of the foregoing *Consent Agreement and Final Order*, which was filed on September 28, 2015, in the following manner to the addressees:

Copy by E-Mail and
Certified Mail
Return-Receipt Requested,
to Attorney for Respondent:

Scott N. Fein, Esq.
Whiteman Osterman & Hanna LLP
One Commerce Plaza
Albany, NY 12260
sfein@woh.com

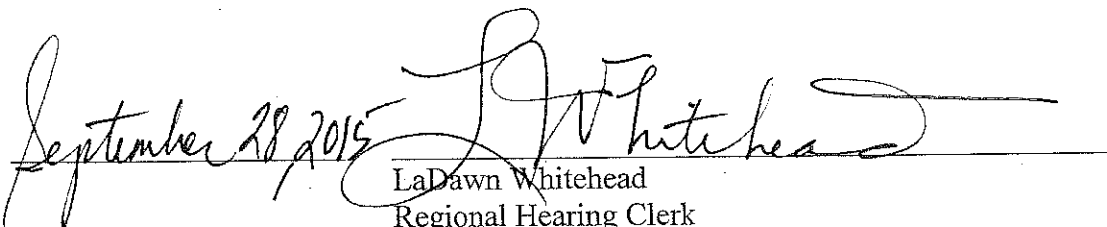
Copy by E-mail to
Attorney for Complainant:

Kevin Chow
chow.kevin@epa.gov

Copy by E-mail to
Regional Judicial Officer:

Ann Coyle
coyle.ann@epa.gov

Dated: September 28, 2015



LaDawn Whitehead
Regional Hearing Clerk

U.S. Environmental Protection Agency, Region 5

CERTIFIED MAIL RECEIPT NUMBER(S): _____

7011 1150 0000 2640 4529

NOTICE OF SECURITIES AND EXCHANGE COMMISSION REGISTRANTS' DUTY TO DISCLOSE ENVIRONMENTAL LEGAL PROCEEDINGS

Securities and Exchange Commission regulations require companies registered with the SEC (e.g., publicly traded companies) to disclose, on at least a quarterly basis, the existence of certain administrative or judicial proceedings taken against them arising under Federal, State or local provisions that have the primary purpose of protecting the environment. Instruction 5 to Item 103 of the SEC's Regulation S-K (17 CFR 229.103) requires disclosure of these environmental legal proceedings. For those SEC registrants that use the SEC's "small business issuer" reporting system, Instructions 1-4 to Item 103 of the SEC's Regulation S-B (17 CFR 228.103) requires disclosure of these environmental legal proceedings.

If you are an SEC registrant, you have a duty to disclose the existence of pending or known to be contemplated environmental legal proceedings that meet any of the following criteria (17 CFR 229.103(5)(A)-(C)):

- A. Such proceeding is material to the business or financial condition of the registrant;
- B. Such proceeding involves primarily a claim for damages, or involves potential monetary sanctions, capital expenditures, deferred charges or charges to income and the amount involved, exclusive of interest and costs, exceeds 10 percent of the current assets of the registrant and its subsidiaries on a consolidated basis; or
- C. A governmental authority is a party to such proceeding and such proceeding involves potential monetary sanctions, unless the registrant reasonably believes that such proceeding will result in no monetary sanctions, or in monetary sanctions, exclusive of interest and costs, of less than \$100,000; provided, however, that such proceedings which are similar in nature may be grouped and described generically.

Specific information regarding the environmental legal proceedings that must be disclosed is set forth in Item 103 of Regulation S-K or, for registrants using the "small business issuer" reporting system, Item 103(a)-(b) of Regulation S-B. If disclosure is required, it must briefly describe the proceeding, "including the name of the court or agency in which the proceedings are pending, the date instituted, the principal parties thereto, a description of the factual basis alleged to underlie the proceedings and the relief sought."

You have been identified as a party to an environmental legal proceeding to which the United States government is, or was, a party. If you are an SEC registrant, this environmental legal proceeding may trigger, or may already have triggered, the disclosure obligation under the SEC regulations described above.

This notice is being provided to inform you of SEC registrants' duty to disclose any relevant environmental legal proceedings to the SEC. This notice does not create, modify or interpret any existing legal obligations, it is not intended to be an exhaustive description of the legally applicable requirements and it is not a substitute for regulations published in the Code of Federal Regulations. This notice has been issued to you for information purposes only. No determination of the applicability of this reporting requirement to your company has been made by any governmental entity. You should seek competent counsel in determining the applicability of these and other SEC requirements to the environmental legal proceeding at issue, as well as any other proceedings known to be contemplated by governmental authorities.

If you have any questions about the SEC's environmental disclosure requirements, please contact the SEC Office of the Special Senior Counsel for Disclosure Operations at (202) 942-1888.