

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8**

October 8, 2020
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IN THE MATTER OF:

Tolmar, Inc.,

Respondent

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Docket No. CWA-08-2021-0001

**ADMINISTRATIVE ORDER ON
CONSENT**

Received by

EPA Region VIII

Hearing Clerk

INTRODUCTION

1. This Administrative Order on Consent (Consent Order) is entered into voluntarily by the U.S. Environmental Protection Agency (EPA) and Tolmar, Inc. (Tolmar or Respondent) to carry out the goals of section 101(a) of the Clean Water Act (CWA), 33 U.S.C. § 1251(a) to “restore and maintain the chemical, physical, and biological integrity of the Nation’s waters.”
2. This Consent Order is issued under the authority of section 309(a) of the CWA, 33 U.S.C. § 1319(a).
3. The Findings of Fact and of Violation (Findings) in paragraphs 14 through 39, below, are made solely by the EPA. In signing this Consent Order, Respondent neither admits nor denies the Findings. Without any admission of liability, Respondent consents to the issuance of this Consent Order and agrees to abide by all of its conditions. Respondent waives any and all remedies, claims for relief, and otherwise available rights to judicial or administrative review Respondent may have with respect to any issue of fact or law set forth in this Consent Order, including any right of judicial review of this Consent Order under the Administrative Procedure Act, 5 U.S.C. §§ 701-706. Respondent further agrees not to challenge the jurisdiction of the EPA or any of the Findings in any proceeding to enforce this Consent Order or in any action under this Consent Order.

STATUTORY AND REGULATORY BACKGROUND

4. The CWA prohibits any discharge of pollutants from a point source into navigable waters, except in compliance with certain other provisions of the CWA. 33 U.S.C. §§ 1311(a), 1362(6), 1362(7), 1362(12), and 1362(14).
5. Section 402 of the CWA, 33 U.S.C. § 1342, allows discharges of pollutants to navigable waters as authorized by National Pollutant Discharge Elimination System (NPDES) permits. The EPA, and states with NPDES programs approved by the EPA, may issue NPDES permits that authorize discharges of pollutants into waters of the United States, subject to conditions and limitations set forth in such permits. 33 U.S.C. § 1342.

6. Among the types of dischargers that can receive NPDES permits authorizing pollutants to be discharged into navigable waters are publicly owned treatment works, or POTWs. The term “POTW” encompasses a treatment works itself and a municipality with jurisdiction over discharges to and from such a treatment works. 40 C.F.R. § 403.3(q).
7. Section 307 of the CWA, 33 U.S.C. § 1317, directed the EPA to promulgate regulations establishing pretreatment standards for introducing pollutants into POTWs. The EPA has promulgated regulations at 40 C.F.R. part 403 (General Pretreatment Regulations) and at 40 C.F.R. parts 405 through 471 (Categorical Pretreatment Standards). These regulations are designed to regulate the introduction of pollutants into POTWs that are determined not to be susceptible to treatment by such treatment works or that could interfere with the operation of such treatment works.
8. Non-domestic sources that introduce pollutants into POTWs are known as Industrial Users or IUs, as defined in 40 C.F.R. § 403.3(j).
9. The introduction of pollutants from an IU to a POTW is known as an “Indirect Discharge” or a “Discharge,” as defined in 40 C.F.R. § 403.3(i). Unless otherwise stated, any reference in this Consent Order to a “discharge” shall refer to the introduction of pollutants to a POTW, as distinguished from the POTW’s discharge of pollutants to navigable waters.
10. According to 40 C.F.R. § 403.3(v), the term Significant Industrial User, also referenced as SIU, includes, with exceptions not relevant here (and provided in 40 C.F.R. §§ 403.3(v)(2) and 403.3(v)(3)):
 - i. any IU subject to the Categorical Pretreatment Standards; and
 - ii. any other IU that:
 - discharges an average of at least 25,000 gallons per day of process wastewater (excluding sanitary, non-contact cooling and boiler blowdown water) to a POTW;
 - contributes a process wastestream that makes up five or more percent of the average dry weather hydraulic or organic capacity of the POTW’s treatment plant; or
 - is designated by the relevant Control Authority (defined in 40 C.F.R. § 403.3(f)) as an SIU on the basis of having a reasonable potential for adversely affecting the POTW’s operation or for violating any Pretreatment Standard or requirement (in accordance with 40 C.F.R. § 403.8(f)(6)). (The terms Pretreatment Standard and Pretreatment requirement are defined in 40 C.F.R. §§ 403.3(l) and 403.3(t).)
11. The EPA has established Categorical Pretreatment Standards for quantities or concentrations of pollutants or pollutant properties which may be discharged to a POTW by existing or new industrial users in specific industrial subcategories, pursuant to 40 C.F.R. § 403.6.
12. One industrial category for which the EPA has established Categorical Pretreatment Standards is the Pharmaceutical Manufacturing Point Source Category. See 40 C.F.R. part 439 - Pharmaceutical Manufacturing Point Source Category.

13. Under the EPA's General Pretreatment Regulations, IUs subject to Categorical Pretreatment Standards are required to sample, analyze, and submit periodic reports of the nature and concentration of discharged pollutants subject to the relevant Categorical Pretreatment Standards and to provide notifications and conduct repeat analyses in the event of violations. 40 C.F.R. § 403.12.

FINDINGS

14. Respondent is a for-profit corporation incorporated under the laws of the State of Delaware.
15. As a corporation, Respondent is a "person" as defined by section 502(5) of the CWA, 33 U.S.C. § 1362(5) and 40 C.F.R. § 122.2.
16. At all times relevant to this Consent Order, Respondent has owned and operated a pharmaceutical manufacturing facility (Facility) located at 1201 Cornerstone Drive, Windsor, Colorado.
17. The Facility manufactures dermatological and injectable products by mixing, compounding, and formulating operations.
18. The Facility discharges industrial process wastewater containing pollutants, as defined by section 502(6) of the CWA, 33 U.S.C. § 1362(6), to a POTW owned and operated by the Town of Windsor (Windsor POTW).
19. To date, the State of Colorado has not obtained EPA approval of its authority to administer the pretreatment component of the NPDES program. Accordingly, the EPA administers the pretreatment component of the NPDES program in Colorado.
20. The EPA has not required the Town of Windsor to develop an EPA-approved pretreatment program in accordance with 40 C.F.R. § 403.8(a). Therefore, the EPA is the pretreatment Control Authority, as defined in 40 C.F.R. § 403.3(f), for IUs that discharge to the Windsor POTW.
21. The Windsor POTW treats domestic and industrial wastewater and meets the definition of a POTW under 40 C.F.R. § 403.3(q). Its address is 30502 Highway 257, Windsor, Colorado 80550.
22. The Windsor POTW discharges into the Cache La Poudre River, which is considered a "navigable water," as defined by section 502(7) of the CWA, 33 U.S.C. § 1362(7).
23. The Windsor POTW is a "point source" that "discharges" "pollutants," as these terms are defined by section 502, subsections (14), (12), and (6) of the CWA, 33 U.S.C. § 1362, subsections (14), (12), and (6), respectively.
24. The Facility is subject to the Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category at 40 C.F.R. part 439 and to the General Pretreatment Regulations.
25. Subpart D of the Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category at 40 C.F.R. part 439 was promulgated on September 21, 1998 (63 Fed. Reg. 50388-50437), following a May 2, 1995 proposal (60 Fed. Reg. 21592).

26. The Facility was constructed in 2014, and pharmaceutical operations began at the Facility in that year. The Facility first discharged process wastewater regulated by the Pharmaceutical Manufacturing Point Source Category Pretreatment Standards in March 2019. Therefore, for purposes of subpart D of the Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category at 40 C.F.R. part 439, the Facility is a “new source” as defined in 40 C.F.R. § 403.3(m)(1) and is subject to 40 C.F.R. § 439.47.
27. As an IU that discharges wastewater regulated by 40 C.F.R. part 439, Respondent is an SIU.
28. As an IU subject to a Categorical Pretreatment Standard, Respondent is required to submit semi-annual reports to the EPA indicating the nature and concentration of pollutants limited by 40 C.F.R. part 439. 40 C.F.R. § 403.12(e).
29. The Colorado Department of Public Health and Environment (CDPHE) has required Respondent to report its discharges of acetone semi-annually to the EPA, CDPHE and the Town of Windsor.
30. As an IU subject to the General Pretreatment Regulations, Respondent is required to notify the EPA and to conduct repeat sampling in the event any sampling it performs indicates a violation of a Pretreatment Standard. 40 C.F.R. § 403.12(g)(2).
31. The EPA conducted an inspection of the Facility on December 13, 2019.
32. On January 16, 2020, the EPA transmitted a report of its December 13, 2019 inspection to Respondent. On February 22, 2020, Respondent provided a response to the EPA inspection report.
33. Respondent has advised the EPA that on May 28, 2020, the Facility temporarily stopped discharging its wastewater to the Windsor POTW.

Violation of Monthly Average Acetone Limitation

34. For discharges of acetone to the POTW, the Respondent is subject to an average monthly limit of 8.2 milligrams per liter (mg/l) for discharges from the Facility. 40 C.F.R. § 439.47.
35. As documented during the EPA inspection referenced above, and as indicated in reports Respondent submitted to the EPA and CDPHE, Respondent violated the acetone average monthly effluent limit of 40 C.F.R. § 439.47 for discharges from the Facility during the following months:
 - March 2019 (8.7 mg/l result for sample taken on March 27, 2019 - this was the only reported acetone sample for the first quarter of 2019);
 - June 2019 (17 mg/l result for sample taken on June 17, 2019 - this was the only reported acetone sample for the second quarter of 2019);
 - September 2019 (12.3 mg/l result for sample taken on September 19, 2019 - this was the only reported acetone sample for the third quarter of 2019);

- February 2020 (11.5 mg/l result for sample taken on February 10, 2020 - this was the only reported acetone sample for the month of February 2020); and
- March 2020 (10.5 mg/l result for sample taken on March 9, 2020 - this was the only reported acetone sample for the month of March 2020).

Violation of Notification Requirement

36. If any sampling performed by Respondent indicates a violation of a Pretreatment Standard, Respondent is required to notify the EPA within 24 hours of becoming aware of the violation. 40 C.F.R. § 403.12(g)(2).
37. Respondent failed to notify the EPA within 24 hours of becoming aware of the monthly average acetone violations indicated by samples taken on March 27, 2019, June 17, 2019, and September 19, 2019, in violation of 40 C.F.R. § 403.12(g)(2).

Violation of Repeat Sampling and Analysis Requirement

38. If sampling performed by Respondent indicates a violation, Respondent is required, within 30 days after becoming aware of the violation, to repeat the sampling and analysis and to submit the results of the repeat analysis to the EPA. 40 C.F.R. § 403.12(g)(2).
39. Respondent failed to resample or provide results of resampling to the EPA within 30 days of becoming aware of the results of samples taken on March 27, 2019, June 17, 2019 and September 19, 2019, in violation of 40 C.F.R. § 403.12(g)(2).

ORDER FOR COMPLIANCE

Based on the foregoing Findings, the EPA orders, and Respondent agrees, as follows:

40. For each month during which Respondent discharges to the Windsor POTW, Respondent shall sample its discharge for acetone.
41. For each instance in which Respondent becomes aware of acetone concentration in Respondent's discharge exceeding 8.2 mg/l, Respondent shall (a) within 24 hours notify the EPA of the sample result, and (b) within 30 days submit analytical results of re-sampling to the EPA. These notifications and submissions shall be provided as required by paragraph 43, below.
42. Within 30 days of the effective date of this Consent Order (see paragraph 53, below), Respondent shall submit to the EPA a comprehensive written plan and schedule for achieving compliance with the monthly average acetone limitation cited above. The EPA may accept the compliance schedule as written or require modifications.
 - a. The compliance plan shall describe in detail the specific actions to be taken or work to be completed.

- b. The compliance schedule shall include proposed sequential milestones for completing the proposed actions/work. All such actions/work shall be completed as expeditiously as possible, with a final compliance date of no later than April 30, 2021, subject to any extensions, as provided for in paragraph 45 of this Consent Order.
- c. Upon acceptance by the EPA, the compliance schedule will be incorporated by reference into this Consent Order. Any non-compliance with the compliance schedule shall be deemed a failure to comply with this Consent Order and shall be subject to EPA enforcement. If implementation of the plan fails to achieve compliance, the EPA may order further steps.
- d. Respondent shall submit quarterly reports to the EPA describing the actions Respondent has taken to comply with the terms of this Consent Order. These reports should include, at a minimum, a detailed update on the progress of the compliance plan, including a description of activities completed, milestones met during the reporting period, potential setbacks, new information which may result in changes to the compliance plan or schedule, and those activities scheduled for the next reporting period. The quarterly reports shall also describe the disposal method and include a copy of the manifest(s) for any wastewater disposed offsite during the quarter. The first report is due October 15, 2020, and shall cover the time period from July 1, 2020 through September 30, 2020. Subsequent reports are due on January 15, 2021 (covering October 1, 2020 – December 31, 2020), April 15, 2021 (covering January 1, 2021 – March 31, 2021), July 15, 2021 (covering April 1, 2021 – June 30, 2021), and so forth on the fifteenth day of the month following the end of the quarter until termination of the Consent Order by EPA (see paragraph 42 below).
- e. Within 30 days after completion of the final scheduled corrective action, Respondent shall submit a written certification to EPA that it has completed all actions included in the compliance schedule.

43. All submittals to the EPA required by this Consent Order shall be provided via U.S. mail and e-mail to:

Emilio Llamozas
Environmental Engineer
Enforcement and Compliance Assurance Division
U.S. EPA Region 8 (8ENF-W-NW)
1595 Wynkoop Street
Denver, Colorado 80202
Llamozas.emilio@epa.gov
303-312-6407

44. All submittals required by this Consent Order shall include the following certification statement, signed and dated by either a principal executive officer or duly authorized representative of Respondent:

I hereby 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 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 or imprisonment for knowing violations.

45. At the EPA's sole discretion, the EPA may extend deadlines required by this Consent Order with written notice to Respondent, without further formal amendment of this Consent Order. All other modifications to this Consent Order may be made only by written agreement of the parties.
46. Upon completion of all requirements of this Consent Order, Respondent may submit a request for termination to the EPA, together with all necessary supporting documentation. Upon request from Respondent, EPA will confer with Respondent within 60 days of receiving Respondent's request to terminate. If the EPA finds it is appropriate to terminate this Consent Order, the EPA may do so unilaterally.
47. The provisions of this Consent Order are severable. If any provision of this Consent Order is determined to be unenforceable, the remaining provisions shall remain in full force and effect.
48. The Consent Order shall apply to and be binding upon Respondent, its agents, successors, and assigns, and upon all persons, contractors, and consultants acting under or on behalf of Respondent in matters related to compliance with this Consent Order. No change in the ownership or operation of the Facility shall alter its responsibilities under this Consent Order unless the EPA, Respondent, and the transferee agree in writing to allow the transferee to assume such responsibilities. A copy of this Consent Order shall be provided to any successors prior to such transfer. Additionally, 30 calendar days prior to such transfer, Respondent shall notify the EPA at the address specified in paragraph 43, above.
49. Respondent shall provide a copy of this Consent Order to all contractors, subcontractors, laboratories and consultants retained to perform or monitor any portion of the work called for by this Consent Order, on or before the date of such retention, and shall condition all such contracts on compliance with the terms of this Consent Order.
50. Compliance with this Consent Order shall not relieve Respondent of its obligations to comply with any applicable federal, state, or local requirements.
51. This Consent Order does not constitute a waiver or a modification of any requirements of the CWA, or its implementing regulations, all of which remain in full force and effect. The EPA retains the right to seek any and all remedies available under section 309 of the CWA, 33 U.S.C. § 1319, or any other authority, for any violation cited in this Consent Order.
52. This Consent Order does not constitute a waiver or election by the EPA to forego any civil or criminal action to seek penalties, fines, or other relief as it may deem appropriate. Section 309(d) of the CWA, 33 U.S.C. § 1319(d), authorizes the assessment of civil penalties of up to \$55,800 (as adjusted for inflation by 40 C.F.R. part 19) per day for each violation. Section 309(c) of the CWA, 33 U.S.C. § 1319(c), authorizes fines and imprisonment for willful or negligent violations.
53. This Consent Order shall be effective on the date it is filed with the Office of the Regional Hearing Clerk for EPA Region 8.

54. Respondent may assert a business confidentiality claim pursuant to 40 C.F.R. § 2.203(b) with respect to part or all of any information submitted to the EPA pursuant to this Order. The EPA shall disclose information covered by a business confidentiality claim only to the extent permitted by, and by means of the procedures set forth at, 40 C.F.R. part 2, subpart B.
55. The EPA and Respondent consent to service of the Consent Order by e-mail at the following valid e-mail addresses: livingston.peggy@epa.gov (for Complainant), and generalcounsel@tolmar.com (for Respondent).
56. The undersigned representative of Respondent certifies s/he has the legal authority to bind Respondent to the terms and conditions of this Consent Order.

**UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY REGION 8**

COLLEEN RATHBONE

Digitally signed by COLLEEN
RATHBONE
Date: 2020.10.08 12:59:53 -06'00'

Date: _____


By: _____

Colleen Rathbone, Chief
Water Enforcement Branch
Enforcement and Compliance Assurance Division

**TOLMAR, INC.
Respondent**

Date: 9/29/2020

By: _____


Brian D. Lewandowski
Vice President General Counsel