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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 8

SEP 26 2013
EPA REGION VIII
HEARING CLERK

IN THE MATTER OF:) Docket No. CWA-08-2013-0035
)
Corixa Corporation) ADMINISTRATIVE ORDER ON
553 Old Corvallis Road) CONSENT
Hamilton, MT)
)
Respondent.) Proceeding under section 309(a) of the
) Clean Water Act, 33 U.S.C. § 1319(a)

INTRODUCTION

This Administrative Order on Consent (Consent Order) is entered into voluntarily by the U.S. Environmental Protection Agency (EPA) and Corixa Corporation (Corixa) to carry out the goals of the Clean Water Act, as amended, 33 U.S.C. § 1251 et seq. (CWA), to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters."

STATUTORY AUTHORITY

The following findings are made and order issued pursuant to the authority vested in the Administrator of the EPA by section 309(a)(3) of the CWA, 33 U.S.C. § 1319(a)(3), and as further delegated to the undersigned Assistant Regional Administrator of the Office of Enforcement, Compliance and Environmental Justice, EPA Region 8. This Consent Order and the compliance agreed to herein are based on EPA's findings of violation of section 301 of the CWA, 33 U.S.C. § 1311.

PARTIES BOUND

This Consent Order shall apply to and be binding upon the EPA and upon Corixa, its officers, employees, agents, successors, and assigns. The signatories to this Consent Order certify that they are authorized to execute and legally bind the parties they represent to this Consent Order. No change in the ownership or operation of the Facility (defined below) shall

alter Corixa's responsibilities under this Consent Order unless the EPA, Corixa, and the transferee agree in writing to allow the transferee to assume such responsibilities. Additionally, thirty (30) calendar days prior to such transfer, Corixa shall notify the EPA and the Hamilton POTW (defined below) as specified in paragraphs 24 and 25 of the Compliance section of this Consent Order.

STATEMENT OF THE PARTIES

The following findings of fact and violation are made solely by the EPA. In signing this Consent Order, Corixa neither admits nor denies the findings of fact and violation. Corixa states that it was informed by the Hamilton POTW that the Hamilton POTW had the legal authority to allow Corixa to discharge to the Hamilton POTW. As such, and without any admission of liability, Corixa consents to issuance of this Consent Order and agrees to abide by all of the conditions herein. With respect to this Consent Order only, Corixa waives any and all claims for relief Corixa may have with respect to any issue of fact or law set forth in this Consent Order, including, but not limited to, any right of judicial review of this Consent Order under the Administrative Procedures Act, 5 U.S.C. §§ 701-706. Corixa further agrees not to challenge the jurisdiction of the EPA to issue this Consent Order, the findings of fact and violation below, or the Order below, in any proceeding to enforce this Consent Order or in any action under this Consent Order.

FINDINGS OF FACT AND VIOLATION

- 1) Corixa, d/b/a in Montana as GlaxoSmithKline Vaccines (Respondent), is a corporation incorporated under the laws of the State of Delaware.
- 2) Respondent is a corporation and therefore a "person" as defined in section 502(5) of the Act, 33 U.S.C. § 1362(5), and 40 C.F.R. § 122.2.

- 3) Respondent operates the GlaxoSmithKline Vaccines facility in Hamilton, Montana (Facility).
- 4) Respondent discharges process wastewater from the Facility to the City of Hamilton's publicly owned treatment works (Hamilton POTW).
- 5) Section 307(b) of the CWA, 33 U.S.C. § 1342, requires EPA to promulgate regulations for the indirect discharge of certain pollutants to publicly owned treatment works.
- 6) The Hamilton POTW does not have an approved pretreatment program. The State of Montana does not have an approved pretreatment program.
- 7) 40 C.F.R. § 403.8(f)(2)(iv) requires that the EPA receive and analyze self monitoring reports submitted by categorical industrial users of a POTW in accordance with 40 C.F.R. § 403.12.
- 8) EPA sent an information request to the Respondent on February 1, 2012 and received a response on March 13, 2012.
- 9) EPA conducted an inspection at the Facility on August 28, 2012.
- 10) Based on information available to the EPA, EPA has determined that the Facility in Hamilton is a categorical industrial user (CIU) of the Hamilton POTW, and so is regulated under 40 C.F.R. Part 439, Subpart B, Extraction Products.
- 11) 40 C.F.R. § 403.12(b) requires CIUs to submit a baseline report. At the time of the inspection, the Respondent had not submitted a baseline report.
- 12) 40 C.F.R. § 403.12(e) requires periodic compliance reports to be submitted at least twice per year, in June and December. At the time of the inspection, the Respondent had not submitted any periodic monitoring reports.

- 13) 40 C.F.R. § 403.8(f)(2)(vi) includes a requirement that a POTW, or in the case of the Hamilton POTW, the EPA, evaluate whether each CIU needs a plan or other action to control "slug discharges".
- 14) The term "slug discharge" is defined as any non-routine, episodic discharge, including but not limited to an accidental spill or a non-customary batch discharge, which has a reasonable potential to cause "Interference" or "Pass Through", or in any other way violate the POTW's regulations, local limits or permit conditions.
- 15) The results of slug discharge samples shall be available to the "Approval Authority" upon request. Further, CIUs are required to notify the POTW immediately of any changes at its facility affecting potential for a slug discharge.
- 16) When it is determined that a slug control plan is needed, the plan shall contain, at a minimum, the following elements:
 - a) a description of discharge practices, including non-routine batch discharges;
 - b) a description of chemicals stored at the CIU facility;
 - c) procedures for immediately notifying the POTW of slug discharges, including any discharge that would violate a prohibition under 40 C.F.R. § 403.5(b), with procedures for follow-up written notification within five days; and
 - d) if necessary, procedures to prevent adverse impacts from accidental spills, including inspection and maintenance of storage areas, handling and transfer of materials, loading and unloading operations, control of run-off, worker training, building of containment structures or equipment, measures for containing toxic organic pollutants (including solvents), and/or measures and equipment for emergency response."

ORDER

Pursuant to Section 309(a)(5)(A) of the CWA, 33 U.S.C. § 1319(a)(5)(A), the EPA finds that the following compliance measures and schedules are in the best interest of the parties and the affected public.

- 17) Beginning in December 2013, the Respondent shall submit a periodic compliance monitoring report to EPA and the Hamilton POTW each June and December.
- 18) The Respondent shall comply with the discharge limits in the table below. These limits are based on the pretreatment standards for existing sources in 40 C.F.R. Part 439, Subpart B and the combined waste formula in 40 C.F.R. §403.6(e). Where process effluent is mixed prior to treatment with wastewaters other than those generated by the regulated process, 40 C.F.R. § 403.6(e) allows for the calculation of alternative discharge limits. Based on the information submitted in the baseline monitoring report, the Respondent shall comply with the following discharge limits as monitored at the City of Hamilton's pumping station immediately adjacent to the Facility and prior to mixing with wastewater from any domestic or industrial source other than the Facility.

| Regulated Parameter | Alternative Maximum Daily Limit, mg/L | Alternative Average Monthly Limit, mg/L |
|----------------------------|--|--|
| Acetone | 8.06 | 3.19 |
| n-Amyl acetate | 8.06 | 3.19 |
| Ethyl acetate | 8.06 | 3.19 |
| Isopropyl acetate | 8.06 | 3.19 |
| Methylene chloride | 1.17 | 0.27 |

- 19) Alternative Maximum Daily Limit and Alternative Average Monthly Limit are defined in 40 C.F.R. Part 439, Subpart B and 40 C.F.R. § 403.6(e).

- 20) The Respondent shall immediately report to EPA and the Hamilton POTW whenever there is a material or significant change in values used in the calculation to fix alternative limits for the regulated pollutants. When appropriate, the Respondent shall calculate new alternative limits within 30 days and submit them to EPA for approval and provide a courtesy copy to the Hamilton POTW.
- 21) The Respondent shall comply with the prohibitions listed in 40 C.F.R. § 403.5.
- 22) Based on the information available to EPA at this time, EPA has determined that the Facility has a potential for slug discharges and that a plan containing each of the elements in paragraph 16 must be developed and implemented. Within sixty (60) calendar days of receipt of this order, the Respondent shall submit to EPA a slug control plan that meets all requirements of sub-paragraphs 16(a) – (d) above. Within thirty (30) days of receipt of any EPA comments on the slug discharge plan, the Respondent shall incorporate EPA's comments and resubmit the slug discharge plan to EPA. EPA will either approve the slug control plan as submitted or approve it with modifications.
- 23) The Respondent shall comply with all reporting and other relevant requirements in 40 C.F.R. § 403.12, all notices regarding upsets in 40 C.F.R. § 403.16, and notices regarding anticipated and unanticipated bypasses in 40 C.F.R. § 403.17.
- 24) All notices and reports to the EPA required by this Consent Order shall be given to:

Carson Coate, Supervisor, Media Unit
U.S. EPA Region 8 Montana Office
10 W 15 Street Suite 3200
Helena, MT 59626
coate.carson@epa.gov

- 25) All notices and reports to the Hamilton POTW required by this Consent Order shall be given to:

Keith Smith, Public Works Director
City of Hamilton
223 South Second Street
Hamilton, MT 59840

All reports and information required by this Consent Order shall include the following certification statement, signed and dated by either a principal executive officer or other 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.

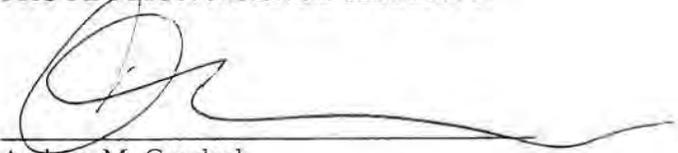
GENERAL PROVISIONS

- 26) Issuance of this Consent Order shall not be deemed an election by the EPA to forego any civil or criminal action to seek civil penalties, fines, or other appropriate relief under the Act for the violations set forth herein.
- 27) Issuance of this Consent Order does not otherwise affect the EPA's ability to enforce or implement the Act.
- 28) Failure to comply with the terms of this Consent Order may result in Respondent's liability for civil penalties for each violation of up to \$37,500 per day under section 309(d) of the Act, 33 U.S.C. § 1319(d), as modified by 40 C.F.R. Part 19. The United States District Court may impose such penalties if the court determines that Respondent has violated the Act and failed to comply with the terms of the Consent Order.

29) This Consent Order shall become effective upon execution by both parties and filing with the EPA Region 8 Hearing Clerk. Should the Hamilton POTW receive approval of its pretreatment program, and should the Hamilton POTW issue an Industrial User Discharge Permit to Respondent (permit), Respondent shall submit the permit to EPA for review. If EPA determines that the permit contains all necessary provisions EPA will terminate this Consent Order as expeditiously as possible thereafter.

**UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY REGION 8**

Date: 9/26/13



Andrew M. Gaydosh
Assistant Regional Administrator
Office of Enforcement, Compliance,
and Environmental Justice

CORIXA CORPORATION

Date: 17 Sept 2013



John Picken
Vice President
Corixa Corporation

