



**UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY  
REGION 8**

2014 SEP -4 PM 2: 12

EPA REGION VIII  
HEARING CLERK

\_\_\_\_\_  
IN THE MATTER OF: )  
)  
)  
GlaxoSmithKline Vaccines, NA )  
553 Old Corvallis Road )  
Hamilton, Montana 59840 )  
)  
Respondent )  
\_\_\_\_\_ )

**COMBINED COMPLAINT AND  
CONSENT AGREEMENT**

**DOCKET NO.: CAA-08-2014-0009**

Complainant, United States Environmental Protection Agency, Region 8 (the EPA or Complainant), and Respondent, GlaxoSmithKline Vaccines, NA (Respondent) (together, the Parties), hereby consent and agree as follows:

1. This Combined Complaint and Consent Agreement (CCCA) is entered into by the Parties pursuant to sections 113(a)(3)(A) and 113(d) of the Clean Air Act (CAA), 42 U.S.C. §§ 7413(a)(3)(A) and 7413(d), for alleged violations of the implementing regulations associated with the "Prevention of Accidental Releases" requirements of section 112(r) of the CAA, 42 U.S.C. § 7412(r). This proceeding is subject to EPA's *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties and the Revocation or Suspension of Permits* (Rules of Practice), 40 C.F.R. part 22.
2. The undersigned EPA official has been properly delegated the authority to enter into this CCCA.
3. 40 C.F.R. § 22.13(b) provides that where the Parties agree to settle one or more causes of action before the filing of a complaint, an administrative action may be commenced and concluded simultaneously by the issuance of a CCCA.
4. The Parties agree that the settling of this action and refraining from the adjudication of any issue of fact or law, with regard to the issues herein, is in their interest and in the public interest.
5. Respondent consents to the terms of this CCCA, including the assessment of the civil penalty specified below.

## JURISDICTION AND WAIVER OF RIGHT TO HEARING

6. Respondent admits the jurisdictional allegations in this CCCA and neither admits nor denies all remaining allegations, terms and conditions contained herein.

7. Respondent waives any and all claims for relief, and otherwise available rights to judicial or administrative review or other remedies which the Respondent may have, with respect to any issue of fact or law or any terms and conditions set forth in this CCCA, including any right of judicial review under the Administrative Procedure Act, 5 U.S.C. §§ 701-708.

## STATUTORY AND REGULATORY FRAMEWORK

8. Section 112(r)(7) of the CAA, 42 U.S.C. § 7412(r)(7), authorizes the Administrator to promulgate regulations regarding the prevention and detection of accidental releases of designated chemicals. Section 112(r)(7)(B) of the CAA, 42 U.S.C. § 7412(r)(7)(B), requires the Administrator to promulgate regulations requiring the owners or operators of stationary sources where a regulated substance is present above a threshold quantity to prepare a risk management plan (RMP) to prevent or minimize risks of accidental releases of those designated substances. The regulations, promulgated by the EPA pursuant to CAA § 112(r)(7), are set forth in 40 C.F.R. part 68.

9. Under 40 C.F.R. § 68.3, the following definitions apply:

- a. "Stationary source" means "any buildings, structures, equipment, installations or substance emitting stationary activities which belong to the same industrial group which are located on one or more contiguous properties, which are under the control of the same person (or persons under common control) and from which an accidental release may occur."
- b. "Regulated substance" means "any substance (listed pursuant to section 112(r)(3) of the Clean Air Act) in 40 C.F.R. § 68.130." Threshold quantities for the regulated substances are included in 40 C.F.R. § 68.130.

10. Section 302(e) of the CAA, 42 U.S.C. § 7602(e), defines the term "person" to include in relevant part, an individual, corporation, or partnership.

11. Respondent is a corporation, and therefore a person, and thus subject to regulation under section 112 of the CAA, 42 U.S.C. § 7412.

12. Respondent is the owner and/or operator of the pharmaceutical manufacturing and Research & Development facility, a stationary source, which is located at 553 Old Corvallis Road, Hamilton, Montana (Facility).

13. The Facility uses, handles, and/or stores more than a threshold quantity of chloroform (CAS #: 67-66-3), a regulated substance.

14. Pursuant to section 112(r)(7) of the CAA, 42 U.S.C. § 7412(r)(7), the Respondent is required to prepare and implement a RMP to detect and prevent or minimize accidental releases of such substances.

15. 40 C.F.R. § 68.12 provides that the owner or operator of a stationary source subject to 40 C.F.R. part 68 shall submit a single RMP as provided in §§ 68.150 to 68.185.

16. 40 C.F.R. § 68.150 provides that the owner shall submit the first RMP no later than the date on which a regulated substance is first present above a threshold quantity in a process.

#### SPECIFIC ALLEGATIONS

17. In a letter dated January 30, 2014, the EPA contacted the Facility to determine Respondent's compliance with the CAA § 112(r)(7). Based on subsequent communications with the Facility, the EPA alleges the Facility is in violation of the CAA § 112(r)(7). The alleged violation is described in paragraph 18 below.

18. The facility exceeded a threshold quantity of chloroform (CAS #: 67-66-3) on February 17, 2010, in a process. The Facility did not submit the required RMP until April 14, 2014. Therefore, the Facility was in violation of the CAA § 112(r)(7), and 40 C.F.R. §§ 68.12 and 68.150, from February 17, 2010, until April 14, 2014.

#### PENALTY

19. Section 113(d)(1)(B) of the Act, 42 U.S.C. § 7413(d)(1)(B), and 40 C.F.R. part 19 authorize the assessment of a civil penalty of up to \$37,500 per day of violation for each violation of the

implementing regulations associated with the "Prevention of Accidental Releases" requirements of 42 U.S.C. § 7412(r). To determine the amount of the civil penalty to be assessed pursuant to section 113(e)(1) of the Act, 42 U.S.C. § 7413(e)(1), the EPA took into account, in addition to such other factors as justice may require, the size of the business, the economic impact of the penalty on the business, the violator's full compliance history and good faith efforts to comply, the duration of the violations as established by any credible evidence (including evidence other than the applicable test method), payment by the violator of penalties previously assessed for the same violations, the economic benefit of noncompliance, and the seriousness of the violations.

20. Respondent consents and agrees to pay a civil penalty in the amount of **one hundred seventy-two thousand nine hundred dollars (\$172,900)**.

21. Attachment A (Collection Information) to this CCCA, provides terms for payment including the assessment of fees and interest charges for late payments.

22. The violation alleged in paragraph 18 has been corrected.

23. Once the Respondent receives a copy of the Final Order and pays in full the penalty assessment described above, the EPA agrees not to take any further civil administrative penalty action against the Respondent for the violation alleged in this CCCA.

#### OTHER TERMS

24. This CCCA contains all terms of the settlement agreed to by the Parties.

25. This CCCA, upon incorporation into a final order, applies to and is binding upon the EPA, Respondent, and Respondent's successors or assigns.

26. Nothing in the CCCA shall relieve Respondent of the duty to comply with the CAA and its implementing regulations.

27. Failure of Respondent to comply with any terms of this CCCA shall constitute a breach and may result in referral of the matter to the U.S. Department of Justice for enforcement of this agreement and such other relief as may be appropriate.

28. Any change in ownership or corporate status of Respondent, including, but not limited to, any transfer of assets or real or personal property, shall not alter Respondent's responsibilities under this agreement.

29. Nothing in the CCCA shall be construed as a waiver by the United States of its authority to seek costs or any appropriate civil penalty associated with any action instituted in the appropriate U.S. District Court as a result of Respondent's failure to perform pursuant to the terms of this CCCA.

30. The undersigned representative of Respondent certifies that he or she is fully authorized to enter into and legally bind Respondent to the terms and conditions of the CCCA.

31. The Parties agree to submit this CCCA to the Regional Judicial Officer, with a request that it be incorporated into a final order.

32. Each Party shall bear its own costs and attorney fees in connection with this administrative matter.


33. Respondent agrees that the penalty shall never be claimed as a federal or other tax deduction or credit.

34. This CCCA, upon incorporation into a final order by the Regional Judicial Officer and full satisfaction by the Parties, shall be a complete and full civil settlement of the EPA's civil penalty claims against Respondent for the specific violation alleged in this CCCA.

UNITED STATES ENVIRONMENTAL PROTECTION  
AGENCY, REGION 8,  
Office of Enforcement, Compliance and  
Environmental Justice

Complainant


Date: September 4, 2014

By:   
Suzanne J. Bohan  
Acting Assistant Regional Administrator  
Office of Enforcement, Compliance  
and Environmental Justice

GlaxoSmithKline Vaccines, NA

Respondent

Date: 21 Aug 2014

By:   
Hamilton Site Director  
Title



## **COLLECTION INFORMATION**

Payment shall be due on or before 30 calendar days after the date of the Final Order issued by the Regional Judicial Officer who adopts this agreement. If the due date falls on a weekend or legal Federal holiday, then the due date is the next business day. Payments must be received by 11:00 a.m. Eastern Standard Time to be considered as received that day.

In the event payment is not received by the specified due date, interest accrues from the date of the Final Order, not the due date, at a rate established by the Secretary of the Treasury pursuant to 31 U.S.C. § 3717, and will continue to accrue until payment in full is received. (That is, on the 1st late day, 30 days of interest accrues.)

In addition, a handling charge of fifteen dollars (\$15) shall be assessed the 61st day from the date of the Final Order, and each subsequent thirty-day period that the debt, or any portion thereof, remains unpaid. In addition, a six percent (6%) per annum penalty shall be assessed on any unpaid principal amount if payment is not received within 90 days of the due date (that is, the 121st day from the date the Final Order is signed). Payments are first applied to handling charges, 6% penalty interest, and late interest; then any balance is applied to the outstanding principal amount.

The payment shall be made by remitting a cashier's or certified check, including the name and docket number of this case, for the amount, payable to "Treasurer, United States of America," (or be paid by one of the other methods listed below) and sent as follows:

### **CHECK PAYMENTS:**

U.S. Environmental Protection Agency  
Fines and Penalties  
Cincinnati Finance Center  
PO Box 979077  
St. Louis, MO 63197-9000

### **WIRE TRANSFERS:**

Wire transfers should be directed to the Federal Reserve Bank of New York

Federal Reserve Bank of New York  
ABA = 021030004  
Account = 68010727  
SWIFT address = FRNYUS33  
33 Liberty Street  
New York NY 10045  
Field Tag 4200 of the Fedwire message should read " D 68010727 Environmental  
Protection Agency "



**OVERNIGHT MAIL (Federal Express, Airborne, or other commercial carrier):**

US Bank  
Cincinnati Finance Center Box 979077  
1005 Convention Plaza  
Mail Station SL-MO-C2GL  
St. Louis, MO 63101

Contact: Natalie Pearson  
314-418-4087

**ACH (also known as REX or remittance express):**

Automated Clearinghouse (ACH) for receiving US currency  
PNC Bank  
808 17th Street, NW  
Washington, DC 20074  
Contact -- Jesse White 301-887-6548  
ABA = 051036706  
Transaction Code 22 - checking  
Environmental Protection Agency  
Account 310006  
CTX Format  
(Include name and docket number)

**ON LINE PAYMENT:**

There is now an On Line Payment Option, available through the Dept. of Treasury.  
This payment option can be accessed from the information below:

WWW.PAY.GOV  
Enter sfo 1.1 in the "Search Public Forms" field

Open form and complete required fields then click "Submit Data".

**AUTOMATED CLEARINGHOUSE**

Automated clearinghouse payments can be made through the US Treasury using the following information:

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, MD 20737

US Treasury Contact Information:  
Randolph Maxwell: 202-874-3420  
Remittance Express (REX): 1-866-234-5681