

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 2
290 Broadway
New York, NY 10007-1866

2018 SEP 29 11 7:00
U.S. Environmental Protection Agency
Region 2

IN THE MATTER OF:

Regeneron Pharmaceuticals, Inc.
81 Columbia Turnpike
Rensselaer, NY 12144

Respondent

Proceeding pursuant to Section 309(g) of the
Clean Water Act, 33 U.S.C. § 1319(g)

**CONSENT AGREEMENT AND
FINAL ORDER**

Docket No. CWA-02-2019-3301

I. PRELIMINARY STATEMENT

The Complainant in this proceeding, the Director of the Division of Enforcement and Compliance Assistance, Region 2, United States Environmental Protection Agency ("EPA" or "Complainant"), issued a "Complaint, Findings of Violation, Notice of Proposed Assessment of a Civil Penalty and Notice of Opportunity to Request a Hearing" ("Complaint") to Regeneron Pharmaceuticals, Inc. ("Respondent") on October 29, 2018 ; and

Complainant and Respondent (collectively, "the Parties"), having agreed that settlement of this matter is in the public interest, and that entry of this Consent Agreement and Final Order ("CA/FO" or "Agreement") without further litigation is the most appropriate means of resolving this matter;

NOW, THEREFORE, before the taking of any testimony, upon the pleadings, without adjudication of any issue of fact or law, and upon consent and agreement of the Parties, it is hereby Ordered and Adjudged as follows:

II. PROCEDURAL AND FACTUAL FINDINGS

1. The following Procedural and Factual Findings are made pursuant to the authority vested in the Administrator of the EPA by the Clean Water Act, 33 U.S.C. § 1251 *et. seq.* ("Act"), which authority has been duly delegated to the Regional Administrator of EPA Region 2, and since further re-delegated to the Director, Division of Enforcement and Compliance Assistance, EPA Region 2.
2. EPA is concluding this proceeding for the assessment of a civil penalty, pursuant to Section 309(g) of the Act, 33 U.S.C. § 1319(g), and 40 C.F.R. §§ 22.18(b)(2) and (3) of the "Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits" ("CROP"), which sets forth procedures for conclusion of administrative civil penalty assessment proceedings through issuance of a consent agreement and final order.

3. EPA initiated this proceeding to achieve compliance with the Act pursuant to Section 309(g)(2)(A) of the Act, 33 U.S.C. § 1319(g)(2)(A).
4. The Complaint alleges a violation of Section 308 of the Act for failure to meet the General Pretreatment Regulation's reporting requirements at Respondent's facility located at 81 Columbia Turnpike, Rensselaer, New York where it operates, among other things, pharmaceutical manufacturing operations. Specifically, Respondent is in violation of the requirements at 40 C.F.R. § 403.12(e), which was established pursuant to Section 308(a) of the Act, by failing to submit the required Periodic Reports on Continued Compliance due in December 2017 and June 2018 in a timely manner and by failing to collect and analyze the process wastewater samples during the June 2018 reporting period.
5. This action was public noticed between November 13, 2018 and December 13, 2018. No comments were filed.
6. Respondent has not filed an Answer or requested a hearing pursuant to 40 C.F.R. Part 22.
7. Respondent stipulates that EPA has jurisdiction over the subject matter alleged in the Complaint.
8. Respondent waives any defenses it might have as to jurisdiction and venue, and, without admitting or denying the factual allegations contained in the Complaint, consents to the terms of this CA/FO.
9. Respondent hereby waives its right to a judicial or administrative hearing or appeal on any issue of law or fact set forth in the Complaint.

III. CONSENT AGREEMENT

1. The Paragraphs above are re-alleged and incorporated herein by reference.
2. EPA and Respondent agree that it is in the public interest to resolve the issues alleged in this Consent Agreement without further litigation and the expense and effort that litigation entails.

Based upon the foregoing and pursuant to Section 309(g) of the Act, 33 U.S.C. § 1319(g), and the CROP, it is hereby agreed by and between EPA and Respondent, and Respondent voluntarily and knowingly agrees as follows:

A. SETTLEMENT TERMS

3. For the purpose of this proceeding, Respondent admits the jurisdictional allegations of this CA/FO and neither admits nor denies the factual allegations contained herein.
4. Respondent further waives its right to contest the allegations, at a judicial or administrative hearing, or to appeal this CA/FO.
5. Respondent consents to the payment of the civil penalty in the amount of **Two Thousand and Two Hundred Dollars (\$2,200)**, as stated in the Payment of Civil Penalty Section below.

B. PAYMENT OF CIVIL PENALTY

6. Respondent shall pay a civil penalty in the amount of **Two Thousand and Two Hundred Dollars (\$2,200)** to the “Treasurer of the United States of America.”
7. Payments can be made by debit/credit card, check, or electronically. Electronic payments fall into two categories: wires and Automated Clearinghouse (ACH). Wires are same day and more costly. ACH is the next day or any future scheduled day and is less expensive. Please note that wires and ACH payments must be conducted through the sender's bank. The checks (cashier’s or certified checks only) shall be identified with a notation of the name and docket number of this case, set forth in the caption on the first page of this document. Payment methods are described below:

Type of Payment	Payment Information	
Debit and Credit Card Payments	https://www.pay.gov/paygov/	
Checks from U.S. Banks Finance Center Contacts: Craig Steffen (513-487-2091)	U.S. Postal Service	UPS, Federal Express, or Overnight Mail
	US Environmental Protection Agency Fines and Penalties Cincinnati Finance Center PO Box 979077 St. Louis, MO 63197-9000	U.S. Bank Government Lockbox 979077 US EPA Fines & Penalties 1005 Convention Plaza SL-MO-C2-GL St. Louis, MO 63101 314-418-1028
Checks drawn on foreign banks with no USA branches (any currency)	Cincinnati Finance US EPA, MS-NWD 26 W ML King Drive Cincinnati, OH 45268-0001	
Wire Transfers (any currency) Details on format and content of wire transfer – www.epa.gov/ocfo/finservices/required_info.htm	Federal Reserve Bank of New York ABA: 021030004 Account Number: 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"	
ACH - Automated Clearinghouse for receiving US currency Finance Center Contacts: John Schmid (202-874-7026) REX (Remittance Express) 1-866-234-5681	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	

ON LINE PAYMENT:

There is now an On Line Payment Option, available through the Department of Treasury. This payment option can be accessed from the information below: WWW.PAY.GOV. Enter sfo 1.1 in the search field. Open form and complete required fields.

Respondent shall also send copies of this payment to each of the following:

Doughlas McKenna, Chief
Water Compliance Branch
Division of Enforcement and Compliance Assistance
U.S. EPA, Region 2
290 Broadway, 20th Floor
New York, New York 10007-1866

And

Regional Hearing Clerk
U.S. Environmental Protection Agency, Region 2
290 Broadway, 16th Floor
New York, New York 10007-1866


8. The payment must be received at the above addresses on or before forty-five (45) calendar days after the effective date hereof, set out below (the date by which payment must be received shall hereafter be referred to as the "due date"). The "File Date" is the day on which this CA/FO is filed with the Regional Hearing Clerk.
9. Failure to pay the penalty in full according to the above provisions will result in referral of this matter to the United States Department of Justice or the United States Department of the Treasury for Collection.
10. Further, if the payment is not received on or before the due date, interest will be assessed at the annual rate established by the Secretary of Treasury pursuant to the Debt Collection Act, 31 U.S.C. § 3717, on the overdue amount from the due date through the date of payment. In addition, a late payment handling charge of \$15.00 will be assessed for each 30-day period (or any portion thereof) following the due date in which the balance remains unpaid. A 6% per annum penalty also will be applied on any principal amount not paid within 90 days of the due date.
11. In addition, pursuant to Section 309(g)(9) of the Act, 33 U.S.C. § 1319(g)(9), if payment is not received by the due date, a quarterly nonpayment penalty will be imposed for each calendar quarter during which such nonpayment persists. The quarterly nonpayment penalty is 20% of the aggregate amount of penalties and quarterly nonpayment penalties which are unpaid as of the beginning of such quarter. You also may be required to pay attorneys' fees and costs for collection proceedings in connection with nonpayment.

12. The penalty to be paid is a civil penalty assessed by the EPA and shall not be deductible from Respondent's federal or State of New York taxes.

C. GENERAL PROVISIONS

13. The provisions of this CA/FO shall be binding upon Respondent, its officers, directors, agents, servants, authorized representatives and successors or assigns, including, but not limited to, subsequent purchasers. No transfer of ownership or operation shall relieve Respondent of its obligation to comply with this CA/FO.
14. Except for the specific violations alleged herein, nothing in this agreement shall be construed as prohibiting, altering, or in any way limiting the ability of EPA to seek any other remedies or sanctions available by virtue of Respondent's violation of this agreement or of the statutes and regulations upon which this agreement is based, or for Respondent's violation of any applicable provision of law.
15. This CA/FO shall not relieve Respondent of its obligation to comply with all applicable provisions of federal, state or local law, nor shall it be construed to be a ruling on, or determination of, any issue related to any federal, state or local permit.
16. This CA/FO constitutes a settlement by EPA of all claims for civil penalties pursuant to the Act for the violations by the Respondent alleged herein. Nothing in this CA/FO is intended to, nor shall be construed to, operate in any way to resolve any criminal liability of the Respondent. Compliance with this CA/FO shall not be a defense to any actions subsequently commenced pursuant to Federal laws and regulations administered by EPA, and it is the responsibility of Respondent to comply with such laws and regulations.
17. Each undersigned representative of the Parties to this CA/FO certifies that he or she is fully authorized by the party represented to enter into the terms and conditions of this CA/FO to execute and legally bind that party to it.
18. Each party shall bear its own costs and attorneys' fees in connection with the action resolved by this CA/FO.

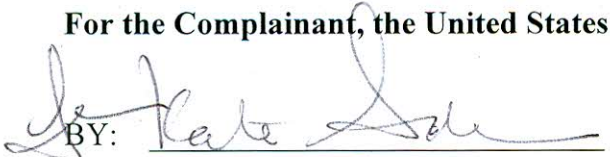
For Respondent: Regeneron Pharmaceuticals, Inc. hereby consents to the issuance of the ORDER and agrees to be bound thereby.

BY: 

DATE: 15 NOVEMBER 2018

~~Mr. Christopher Homicz, Manager of Environmental Health and Safety~~
~~Regeneron Pharmaceuticals, Inc.~~
~~81 Columbia Turnpike~~
~~Rensselaer, NY 12144~~
DANIEL VAN PLEW, EXECUTIVE VICE PRESIDENT & GENERAL MANAGER ICS

For the Complainant, the United States Environmental Protection Agency:

BY: 

DEC 18 2018

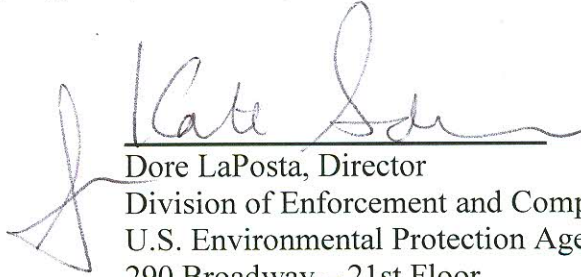
DATE: _____

Dore LaPosta, Director
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency, Region 2
290 Broadway
New York, New York, 10007-1866

IV. FINAL ORDER

The Regional Administrator of the United States Environmental Protection Agency, Region 2, vested by authority delegated by the Administrator of the United States Environmental Protection Agency ("EPA") and having further re-delegated such authority to the Director of the Division of Enforcement and Compliance Assistance, Region 2, EPA, ratifies the foregoing Consent Agreement. The Agreement entered into by the Parties is hereby approved, incorporated herein, and issued as an Order. The effective date of this Order shall be the date of filing with the Regional Hearing Clerk, United States Environmental Protection Agency, Region 2, New York, New York.

DEC 18 2018
DATED: _____

A handwritten signature in blue ink, appearing to read "Kate LaPosta", is written over a horizontal line. To the left of the signature is a large, stylized handwritten mark that resembles a large "D" or a similar symbol.

Dore LaPosta, Director
Division of Enforcement and Compliance Assistance
U.S. Environmental Protection Agency, Region 2
290 Broadway – 21st Floor
New York, New York, 10007-1866

IN THE MATTER OF:
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Rensselaer, NY 12144

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of the Clean Water Act, 33 U.S.C. §
1319(g)

CERTIFICATE OF SERVICE

I certify that the foregoing "Consent Agreement and Final Order" with Regeneron Pharmaceuticals, Inc., was sent on this 19 day of December, 2018, in the following manner to the addressees listed below:

Copy by Hand:

Helen S. Ferrara
Regional Judicial Officer
U.S. Environmental Protection Agency
Region 2
290 Broadway
New York, NY 10007-1866

Original and Copy by Hand:

Karen Maples
Regional Hearing Clerk
U.S. Environmental Protection Agency
Region 2
290 Broadway
New York, NY 10007-1866

Copy by Certified Mail,
Return Receipt Requested:

Daniel Van Plew
Executive Vice President and General Manager
Industrial Operations and Product Supply
Regeneron Pharmaceuticals, Inc.
81 Columbia Turnpike
Rensselaer, NY 12144

Dated: 12/19/18

