



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street
San Francisco, CA 94105-3901

July 16, 2007

Certified Mail 7000 0520 0025 3713 4102

RETURN RECEIPT REQUESTED

In Reply Refer To: CWA-309(a)-07-019

Robert Baffi, Sr. Vice President, Technical Operations
BioMarin Pharmaceutical, Inc.
105 Digital Drive
Novato, California 94949

Dear Mr. Baffi:

As a result of a routine pretreatment audit of Novato Sanitary District on May 2, 2007, and our follow-up May 21, 2007 inspection of the BioMarin Pharmaceutical facility at 46 Galli Drive in Novato, we discovered recurring pH violations. In our inspection report for the May 21, 2007 inspection (dated June 14, 2007), we summarized the violations that occurred over the period from 2005 through the first quarter of 2007 and concluded that the facility must implement a more effective solution to control the pH of its wastewater discharge.

The enclosed Administrative Order ("Order") requires BioMarin Pharmaceutical to achieve consistent compliance with its permit limits for pH. This order also requires self-monitoring for one year. Once BioMarin Pharmaceutical completes installation and startup of its proposed system for pH control, the latter portion of the self-monitoring reports will provide a means for BioMarin Pharmaceutical to demonstrate consistent compliance.

KEY DATES	ADMINISTRATIVE ORDER CWA-309(a)-07-019	
	Item No.	Requirement
9/28/07	1	Submit preliminary engineering plan.
Upon commencement of construction	2	Submit notice of construction.
8/1/07	4-7	Begin one year of self-monitoring under this Order.
1/31/08	3	Complete installation and startup of proposed system for pH control.
7/31/08		End self-monitoring under this Order.
* * *		Self-monitoring reports are due on the 28 th day of each month for the samples collected during the previous month.

The enclosed Order and the findings that constitute the basis behind the Order are issued pursuant to Sections 308(a) and 309(a)(3), (a)(4) and (a)(5)(A) of the Clean Water Act (“the Act”) as amended [33 U.S.C. § 1318(a) and 1319(a)(3), (a)(4), and (a)(5)(A)]. Any violation of the terms of this Order or pretreatment standards could subject BioMarin Pharmaceutical to a civil action for appropriate relief pursuant to Section 309(b) of the Act [33 U.S.C. § 1319(b)] and/or penalties under Section 309(d) of the Act [33 U.S.C. § 1319(d)] of up to \$31,500 per day of violation. In addition, under Section 309(g) of the Act [33 U.S.C. § 1319(g)], any violation of the pretreatment standards could also subject BioMarin Pharmaceutical to an administrative penalty action of up to \$12,000 per day of violation not to exceed \$157,000. Sections 309(c)(1), (c)(2), and (c)(4) of the Act [33 U.S.C. § 1319(c)(1), (c)(2), and (c)(4)], also provide penalties for negligent violations, knowing violations and knowingly making false statements.

If you have any questions regarding this matter, please contact Anna Yen of my staff at (415) 972-3976 or at yen.anna@epa.gov.

Sincerely,
<Original
signed by>

Alexis Strauss
Director, Water Division

Enclosure

cc: Linda Candelaria, Novato Sanitary District
Michael Chee, RWQCB-San Francisco Bay

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION 9

In the Matter of)	
)	
BioMarin Pharmaceutical, Inc.)	FINDING OF VIOLATION
Novato, California)	
)	AND ORDER
Proceedings under Section 308(a) and 309(a)(3),)	
(a)(4) and (a)(5)(A) of the Clean Water Act, as)	Docket No. CWA-309(a)-07-019
amended, 33 U.S.C. Section 1318(a) and)	
1319(a)(3), (a)(4) and (a)(5)(A))	

STATUTORY AUTHORITY

The following Finding of Violation and Order (Docket No. CWA-309(a)-07-019) (hereinafter “the Order”) is issued under the authority vested in the Administrator of the U.S. Environmental Protection Agency (“EPA”) pursuant to Sections 308(a) and 309(a)(3), (a)(4), and (a)(5)(A) of the Clean Water Act [33 U.S.C. § 1318(a) and 1319(a)(3), (a)(4), and (a)(5)(A)] (hereinafter “the Act”). This authority has been delegated by the Administrator and the Regional Administrator of EPA Region 9 to the Director of the Water Division of EPA Region 9.

FINDING OF VIOLATION

The Director of the Water Division of EPA Region 9 finds that BioMarin Pharmaceutical, Inc., (“BioMarin”) in Novato, California, is in violation of Section 307(d) of the Act [33 U.S.C. § 1317(d)]. This Finding is made on the basis of the following facts:

1. Section 307(d) of the Act [33 U.S.C. § 1317(d)] prohibits any owner or operator of any source from introducing pollutants into publicly owned treatment works (“POTWs”) in violation of any effluent standard or prohibition or pretreatment standard promulgated under Section 307 of the Act:

2. Under Section 307(b) of the Act [33 U.S.C. § 1317(b)], EPA promulgated the following general pretreatment regulations:
 - a. The national pretreatment standards in 40 CFR 403.5(b)(2) for all industrial dischargers into POTWs nationwide, which prohibit the introduction of pollutants that will cause corrosive structural damage to the POTW, and in no case have a pH below 5.0 s.u.;
 - b. The national pretreatment standards in 40 CFR 403.5(d) for all industrial dischargers into NSD's domestic sewer system and wastewater treatment plant, which defines local limits developed in accordance with the 40 CFR 403.5(c) to be Pretreatment Standards for the purposes of Section 307(d) of the Act [33 U.S.C. § 1317(d)];
 - c. The definitions in 40 CFR 403.3 of the following terms:
 - i. The term, Interference, means a discharge which, alone or in conjunction with discharges from other sources, both inhibits or disrupts the POTW's treatment process, operations, sludge processes, or sludge use or disposal, and therefore causes a violation of any requirement of the POTW's NPDES permit;
 - ii. The term, Pass-Through, means a discharge which exits the POTW into waters of the United States at levels, alone or in conjunction with other sources, and therefore causes a violation of any requirement of the POTW's NPDES permit;
 - iii. The term, Pretreatment Standards, means any regulation containing pollutant discharge limits promulgated by EPA in accordance with Section

307 (b) and (c) of the Act, [33 U.S.C. § 1317(b) and (c)], including the specific prohibitions and local limits established pursuant to 40 CFR 403.5(b) and (d).

3. BioMarin is a corporation and therefore a person within the meaning of Section 502(5) of the Act, [33 U.S.C. § 1362(5)]. BioMarin is a domestic and non-domestic wastewater source in Novato, California. BioMarin introduces pollutants within the meaning of Section 502(6) of the Act [33 U.S.C. § 1362(6)], into the Novato Sanitary District (NSD) domestic sewer system and wastewater treatment plant, which is a POTW within the meaning of Section 307(b) and the pretreatment regulation in 40 CFR 403.3(q). BioMarin is therefore subject to the provision of the Act, [33 U.S.C. § 1251 et seq., including Section 307, 33 U.S.C. § 1317].
4. On May 21, 2007, EPA inspectors and representatives of Novato Sanitary District conducted a compliance evaluation inspection of BioMarin:
 - a. Facility Description: BioMarin owns and operates a pharmaceutical manufacturing facility at 46 Galli Drive in Novato, California:
 - i. The pharmaceutical manufacturing facility generates for discharge to the sewers, manufacturing process wastewater, clean-in-place washdown, ion exchange brine, reverse osmosis reject water, boiler blowdown, cooling tower blowdown, pump seal water, water discharge from lab sinks, washwater from regular sanitizing of floors/walls/ceilings, and domestic wastewater.

- b. Wastewater Discharges to the Sewer: BioMarin discharges both process-related wastewaters and domestic wastewater into the domestic sewers which feed into NSD’s Ignacio wastewater treatment plant for discharge into the San Pablo Bay:
- i. Process-related wastewaters and non-process wastewaters, including domestic wastewater, all collect in one 4-inch main and discharge through one sewer connection into the NSD sewers under NSD permit No. 014;
 - ii. Only the manufacturing process wastewater streams are treated; however, untreated wastewater, both industrial and domestic, subsequently combine with the manufacturing process wastewater streams in the 4-inch main before eventually discharging to the NSD sewers;
 - iii. Treatment of the manufacturing process wastewater streams consists of on-site pH adjustment systems;
 - iv. The discharges of wastewater to the sewers are continuously monitored for pH at one compliance sampling point, which is a control manhole just outside the front entrance of the building, herein referred to as the “designated control manhole” or “compliance sampling point.”
- c. Pretreatment Standards: The following pH-related national prohibition and local limits apply to the discharges to the NSD sewers from BioMarin:

Regulated Parameter	Nat’l Prohibition	Local Limits	
		Required Range	Time Constraints in Permit
pH	Not less than 5.0 s.u. at any time	5.5 to 10.5 s.u.	1) The total time during which pH values are outside the required range of pH values shall not exceed 7 hours and 26 minutes in any calendar

			month. 2) No individual excursion from the range of pH values shall exceed 60 minutes.
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- d. Inspection Report: The report for the May 21, 2007 inspection was prepared and issued on June 14, 2007.
5. BioMarin violated Section 307(d) of the Act [33 U.S.C. § 1317(d)] in that:
- a. Based on BioMarin’s submitted compliance reports to NSD as required by its discharge permit, from January 2005 through March 2007, the discharges from BioMarin through the designated control manhole to the NSD sewers did not comply with the pH-related national prohibition on at least 44 occasions resulting in 38 days of violation, with the following breakdown:
- i. Calendar year 2005: 15 violation events (14 days)
- ii. Calendar year 2006: 23 violation events (18 days)
- iii. First quarter of calendar year 2007: 6 violation events (6 days)
- b. Based on BioMarin’s submitted compliance reports to NSD as required by its discharge permit, the discharges from BioMarin through the designated control manhole to the NSD sewers did not comply with local limits for pH on at least 1 occasion for the month of January 2006.
- A summary table of the violations in items 5a. and b. are included in Appendix A of this Order.*
6. The inspection report issued on June 14, 2007 of the May 21, 2007 EPA inspection of BioMarin is by reference made part of this Order.

ADMINISTRATIVE ORDER

Taking these Findings into consideration and considering the potential environmental and human health effects of the violations and all good faith efforts to comply, EPA has determined that compliance in accordance with the following requirements is reasonable. Pursuant to Section 308(a) and 309(a)(3), (a)(4) and (a)(5)(A) of the Act [33 U.S.C. § 1318(a) and 1319(a)(3), (a)(4) and (a)(5)(A)], IT IS HEREBY ORDERED that BioMarin comply with the following requirements:

pH Control

1. By **SEPTEMBER 28, 2007**, BioMarin shall submit a preliminary engineering plan of the steps to be taken in order to consistently comply with the national prohibition and local permit limits for pH. This preliminary engineering plan shall include:
 - a. The design of the proposed system, including existing components, modifications to existing components, and new components, that will be installed and operated to achieve consistent compliance with pH limits.
 - i. Components include, but are not limited to, equipment, piping, monitoring, instrumentation and telemetry.
 - ii. The design of the proposed system shall include severing of the domestic wastewater line(s) from the 4-inch main that currently leads to the designated control manhole, resulting in a 4-inch main that conveys non-domestic wastewater only.
 - iii. Submittal of the design of the proposed system shall include the following:

- (a.) A written explanation of the resulting design and operation of the proposed system, including the stages of pH control, the reagents in use, and the conceptual theory behind the pH control;
 - (b.) A schematic of the proposed system, with all components labeled;
 - (c.) If the proposed system does not include a new pH adjustment system, the rationale for how the proposed system will achieve consistent compliance with the applicable pH limits without a new pH adjustment system. Include a description of how the proposed system will handle situations when the pH probe just upstream of the designated control manhole indicates that the wastewater is out of compliance with applicable pH limits.
- b. A schedule of construction which results in completion of installation and startup of the entire proposed system no later than January 31, 2008.
2. BioMarin shall submit a notice of construction upon commencement of construction of the proposed system, postmarked within 10 days of such date.
3. By **JANUARY 31, 2008**, BioMarin shall complete installation and startup of the new system to consistently comply with the applicable pH limitations, as required by item 1 of this Order, and submit a notice of completion.

Self-Monitoring Requirements

4. From **AUGUST 1, 2007 THROUGH JULY 31, 2008**, BioMarin shall self-monitor the wastewater discharges to the sewers at the designated control manhole, as follows:

- a. **ONCE EVERY MONTH**, BioMarin shall summarize the continuous pH meter strip charts to reflect the following:
- i. The number of minutes each day in which the pH is below 2.0;
 - ii. The number of minutes each day in which the pH is below 5.0;
 - iii. The number of minutes each day in which the pH is below 5.5;
 - iv. The number of minutes each day in which the pH is above 10.5.
- b. BioMarin shall record the summary information required in item 4a for each month.
5. BioMarin shall provide calibration of the continuous pH meter as necessary to achieve the listed detection limits indicated below:

Parameters	Sampling Protocols	Required Detection Limits
pH	continuous meter	0.1 s.u.

6. The sewer sampling of the discharges required in item 4 of this Order shall be representative of the overall discharge to the NSD sewers at the compliance sampling point, unless EPA approves a new sample point or points.

Submittals

7. By the **TWENTY-EIGHTH (28th) DAY OF EACH MONTH**, BioMarin shall submit all self-monitoring results for the previous month. The first monthly report is due on September 28, 2007 for the August 2007 self-monitoring. The 12th-and-last monthly report is due on August 28, 2008 for the July 2008 self-monitoring.

8. All reports submitted pursuant to this Order shall be signed by a principal executive officer of BioMarin and shall include the following statement:

I 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 who manage the system, or those persons directly responsible for gathering the information, I certify that the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I certify that all wastewater samples analyzed and reported herein are representative of the ordinary process wastewater flow from this facility. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

9. All submittals shall be mailed to the following addresses:

U.S. ENVIRONMENTAL PROTECTION AGENCY
75 Hawthorne Street
San Francisco, California 94105
Attn: Anna Yen (WTR-7)

REGIONAL WATER QUALITY CONTROL BOARD
1515 Clay Street, Suite 1400
Oakland, California 94612
Attn: Michael Chee

NOVATO SANITARY DISTRICT
500 Davidson Street
Novato, California 94945
Attn: Linda Candelaria

General Provisions

10. This Order is not and shall not be interpreted to be a National Pollutant Discharge Elimination System permit under Section 402 of the Act, [33 U.S.C. § 1342], nor a local industrial user permit under 40 CFR 403.8(f)(1)(iii). In addition, this letter shall not in any way extinguish, waive, satisfy, or otherwise affect BioMarin's obligation to comply

with the Act or its regulations, as well as any other Federal, State or local law, including the sewer use ordinance for the Novato Sanitary District.

11. The request for information included in this Order is not subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act because it is not a “collection of information” within the meaning of 44 U.S.C. § 3502(3) and 5 CFR 1320.5(c) because it is directed to fewer than ten persons. Furthermore, it is exempt from OMB review under the Paperwork Reduction Act because it is an administrative action against a specific entity [44 U.S.C. § 3518(c)(1)(B) and 5 CFR 1320.4(a)(2)].
12. EPA has promulgated regulations to protect the confidentiality of the business information it receives. These regulations are set forth in 40 CFR Part 2, Subpart B and in the Federal Register at 41 F.R. 36902 (9/1/1976) and 43 F.R. 40000 (9/8/1978). A claim of business confidentiality may be asserted in the manner specified by 40 CFR 2.203(b) for part or all of the information requested. EPA will disclose business information covered by such a claim only as authorized under 40 CFR Part 2, Subpart B. If no claim accompanies the business information at the time EPA receives it, EPA may make it available to the public without further notice. BioMarin may not withhold from EPA any information on the grounds that it is confidential.
13. This Order takes effect upon signature.

16 July 2007
Date

<Original signed by>
Alexis Strauss
Director
Water Division

Appendix A
Violations of Local Limits and National Prohibitions

BioMarin, Novato pH Violations from July 2005 through March 2007				
Monitoring * Date	Type	National Prohibition or Local Permit Limit	Violation	Days of Violation
3/8/07	cont	pH not < 5.0 at any time	< 5.0	1
2/28/07	cont	pH not < 5.0 at any time	< 5.0	1
2/23/07	cont	pH not < 5.0 at any time	< 5.0	1
2/21/07	cont	pH not < 5.0 at any time	< 5.0	1
2/16/07	cont	pH not < 5.0 at any time	< 5.0	1
2/4/07	cont	pH not < 5.0 at any time	< 5.0	1
12/17/06	cont	pH not < 5.0 at any time	< 5.0	1
12/14/06	cont	pH not < 5.0 at any time	< 5.0	1
9/19/06	cont	pH not < 5.0 at any time	< 5.0	1
9/1/06	cont	pH not < 5.0 at any time	< 5.0	1
8/24/06	cont	pH not < 5.0 at any time	< 5.0	1
7/13/06	cont	pH not < 5.0 at any time	< 5.0	1
5/23/06	cont	pH not < 5.0 at any time	< 5.0	1
4/30/06	cont	pH not < 5.0 at any time	< 5.0	1
3/2/06	cont	pH not < 5.0 at any time	< 5.0	1
2/27/06	cont	pH not < 5.0 at any time	< 5.0	1
2/26/06	cont	pH not < 5.0 at any time	< 5.0	1
2/23/06	cont	pH not < 5.0 at any time	< 5.0	1
2/21/06	cont	pH not < 5.0 at any time	< 5.0	1
2/12/06	cont	pH not < 5.0 at any time	< 5.0	1
1/25/06	cont	pH not < 5.0 at any time	< 5.0	1
1/17/06	cont	pH not < 5.0 at any time	< 5.0	1
1/15/06	cont	pH not < 5.0 at any time	< 5.0	1
1/12/06	cont	pH not < 5.0 at any time	< 5.0	1
Jan 2006	cont	pH not < 5.5 or not >10.5 for >446 min/calendar mo.	672	31
12/30/05	cont	pH not < 5.0 at any time	< 5.0	1
12/2/05	cont	pH not < 5.0 at any time	< 5.0	1
12/1/05	cont	pH not < 5.0 at any time	< 5.0	1
11/15/05	cont	pH not < 5.0 at any time	< 5.0	1
11/8/05	cont	pH not < 5.0 at any time	< 5.0	1
10/28/05	cont	pH not < 5.0 at any time	< 5.0	1
10/27/05	cont	pH not < 5.0 at any time	< 5.0	1
10/25/05	cont	pH not < 5.0 at any time	< 5.0	1
10/7/05	cont	pH not < 5.0 at any time	< 5.0	1
8/27/05	cont	pH not < 5.0 at any time	< 5.0	1

8/26/05	cont	pH not < 5.0 at any time	< 5.0	1
8/19/05	cont	pH not < 5.0 at any time	< 5.0	1
8/11/05	cont	pH not < 5.0 at any time	< 5.0	1
7/20/05	cont	pH not < 5.0 at any time	< 5.0	1
* From self-monitoring as required by BioMarin's Non-Domestic Discharge Permit No. 014.			Totals	69