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

June 14, 2007

In Reply Refer To: WTR-7

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

Re: May 21, 2007 Clean Water Act Inspection

Dear Mr. Baffi:

Enclosed is the June 14, 2007 report for our inspection of the BioMarin Pharmaceutical facility in Novato. Please submit a short response to the Summary of Findings in Section 3.0 of this report to EPA, with copies to the Novato Sanitary District and the Regional Water Quality Control Board, by **August 31, 2007**. The violations we discovered cause BioMarin to be liable for enforcement actions, including an Administrative Order to establish an enforceable schedule for long-term correction of the pH violations.

The main findings of this report are summarized below:

1. On numerous occasions for at least the past few years, this facility has violated one of the national prohibitions and local permit limits for pH, because many of its wastewaters discharged untreated to the sewers.
2. This facility has also violated a permit condition which states that the pH values which are outside the required range of pH values shall not exceed 7 hours and 26 minutes in any calendar month. EPA determined that the facility was out of compliance with this permit condition during the month of January 2006.
3. As soon as possible, the facility must implement a more effective solution to control the pH of its wastewater discharge.

We would like to thank you and your staff for your helpfulness and courtesy during the inspection. We remain available to you and Novato Sanitary District to assist in any way. If you have any questions, please call Anna Yen at (415) 972-3976 or e-mail her at yen.anna@epa.gov.

Sincerely,
<**Original signed by**>
Ken Greenberg
Chief, CWA Compliance Office

Enclosure

cc: Linda Candelaria, Novato Sanitary District, enclosure by e-mail
Michael Chee, RWQCB-San Francisco Bay, enclosure by e-mail

U.S. Environmental Protection Agency
Region 9
Clean Water Act Compliance Office

NPDES Compliance Evaluation Inspection Report

Industrial User:	BioMarin Pharmaceutical, Inc.
Industrial User Address:	46 Galli Drive, Novato, CA 94949 – manufacturing facility address (105 Digital Drive, Novato, CA 94949 – official address)
Inspection Date:	May 21, 2007
EPA Region 9 Inspectors:	Greg Arthur, Environmental Engineer Anna Yen, Environmental Engineer Water Division, CWA Compliance Office
Novato Sanitary District (NSD) Inspectors:	Linda Candelaria, Laboratory Supervisor Kristin Kerr, EOA, Inc. – Consultant for NSD
Facility Contacts During Inspection:	Robert Baffi, Sr. Vice President, Technical Operations R. Andrew Ramelmeier, Vice President, Manufacturing & Process Development James Kroyer, Director, Facilities Michael Kraus, EHS Manager

Report Prepared by Anna Yen on June 14, 2007.

1.0 Scope and Purpose

During a pretreatment compliance audit (PCA) of Novato Sanitary District ("NSD" or "the District") by Tetra Tech, EPA learned that NSD had issued numerous notices of violation for pH violations to the BioMarin Pharmaceutical (BioMarin) facility in Novato. The main purpose of the inspection on May 21, 2007 was to investigate the circumstances surrounding the many pH violations and whether further enforcement action was warranted.

1.1 General and Process Description

BioMarin was founded in March 1997, with this Novato facility becoming operational in January 2000. BioMarin specializes in producing enzymes, which are used to treat serious diseases and medical conditions, including genetic diseases. The production of enzyme products generally consists of media preparation in bioreactors, cold-room storage, ultrafiltration, purification, and final filtration.

BioMarin consists of several buildings in Novato. The building at its official address of 105 Digital Drive, along with several other of BioMarin's buildings along Digital Drive, are office buildings only. The only building that houses manufacturing/production is located at 46 Galli Drive, which is just off Digital Drive and not too far from BioMarin's office buildings. EPA inspected the building at 46 Galli Drive only.

The inspection started with a presentation given by BioMarin in a conference room of the building. BioMarin then guided the inspectors through the pretreatment areas (the batch treatment system and the continuous treatment system), the control manhole, the pH chart, and pH logbook. BioMarin did not bring the EPA inspectors or the NSD inspectors into the clean room or laboratory areas.

1.2 Facility Wastewater Sources

BioMarin generates manufacturing process wastewater streams from both a fermentation process and a purification process. In addition, other process wastewaters and non-process wastewaters include the following:

- Ion exchange brine
- Reverse osmosis (RO) reject stream
- Boiler blowdown
- Cooling tower blowdown
- Pump seal water
- Water discharge from lab sinks
- Cleaning/sanitizing of floors, walls, ceilings
- Domestic wastewater (restrooms)

Only the manufacturing process wastewater is treated. Pretreatment occurs in one of two on-site pH adjustment systems before discharging to a 4-inch main line located beneath the building which leads to the District's sewer system. Other wastewater streams, as listed above, all flow untreated into the 4-inch main. The domestic wastewater enters the 4-inch main downstream of the other wastewater streams.

BioMarin stated that, in the evenings, the wastewater flow is low and is primarily domestic wastewater, wastewater from floor drains due to janitorial staff cleaning the floors/walls/ceilings, and possibly some RO reject. During the day or evening, another wastewater source could be tank clean-in-place (CIP) systems from which the wastewater also undergoes pretreatment in one of the pH adjustment systems.

BioMarin stated that floor drains were only in the manufacturing area of the building. In order to maintain certain certifications that BioMarin has, it must meet strict criteria regarding microbiological controls. As a result, BioMarin sanitizes the floors on a daily basis and the walls and ceilings on a weekly basis. BioMarin stated that the janitorial staff have been informed that they must neutralize any cleaning agents used and test the wastewater solution before allowing it down the drain. BioMarin has recently even included this requirement in the contract with the janitorial company. However, problems with release of low pH solutions to the floor drains persist.

1.3 Facility Process pH Adjustment Systems

BioMarin provides two on-site pH adjustment systems for process wastewater streams, one being a batch system, the other a continuous system. All components of the pH adjustment systems were connected by hard piping. No flexible hosing was noted. The pH adjustment systems consist of adding either sodium hydroxide or sulfuric acid to the process wastewater using metering pumps and an automatic process control system for the pH level. The batch pH adjustment system involves the following steps:

- Process flow enters a 250-gallon flow equalization tank.
- The pH is adjusted automatically by dosing with either sodium hydroxide or sulfuric acid.
- Discharge of the tank contents occurs in batches.

The continuous pH adjustment system involves the following steps:

- Process flow enters a 1000-gallon equalization tank equipped with a mixer.
- Process wastewater is pre-neutralized by addition of sodium hydroxide or sulfuric acid, as appropriate.
- The contents are pumped to the pH adjustment tank which contains baffles in it to create a tortuous path for the flow, with the intent of resulting in well-mixed contents.
- The pH is adjusted automatically by dosing with either sodium hydroxide or sulfuric acid.
- Discharge of the tank contents occurs continuously.

Each of the pH adjustment systems has an alarm system, but only the batch system has an automatic shutoff.

1.4 Wastewater Discharge

The 4-inch main discharge line runs beneath the building, carrying a mixture of treated and untreated wastewater, industrial and domestic, to the District's sewer system.

Wastewater from this facility will discharge to the Ignacio Wastewater Treatment Plant. NSD owns and operates this wastewater treatment plant under an NDPES permit (No. CA0037958).

2.0 Federal Categorical Standards

The facility is subject to Part 439 – "Pharmaceutical Manufacturing Point Source Category" – of the federal categorical pretreatment standards and is, therefore, a Categorical Industrial User (CIU) as well as a Significant Industrial User (SIU). Specifically, it must comply with the requirements of 40 CFR 439.17 and 40 CFR 439.27, Pretreatment Standards for New Sources. The facility's discharge permit issued by NSD contains these requirements.

2.1 Federal Prohibition Against Dilution as a Substitute for Treatment

The federal pretreatment standards, specifically 40 CFR 403.6(d), prohibit dilution as a substitute for treatment of process wastewater. NSD has determined alternate discharge limits using the Combined Wastestream Formula, as explained in 40 CFR 403.6(e):

> Where process effluent is mixed prior to treatment with wastewaters other than those generated by the regulated process, fixed alternative discharge limits may be derived by the Control Authority or by the Industrial User with the written concurrence of the Control Authority.

The facility's discharge permit issued by NSD includes these alternative discharge limits. These limits apply to this facility's wastewater discharge rather than those specified in the categorical standards 40 CFR 439.17 and 40 CFR 439.27.

2.2 National Prohibition Against pHs Below 5.0 Standard Units

The facility's discharge permit issued by NSD includes a permit condition that states that the facility shall maintain the pH within the range of pH 5.5 to pH 10.5 standard units. Consistent with one of the federal specific prohibitions found at 40 CFR 403.5(b)(2), the facility's discharge permit also states: "No individual excursion shall be less than pH 5 at any time."

The federal specific prohibition at 40 CFR 403.5(b)(2) states:

> In addition, the following pollutants shall not be introduced into a POTW:…Pollutants which will cause corrosive structural damage to the POTW, but in no case Discharges with pH lower than 5.0, unless the works is specifically designed to accommodate such Discharges;

During the pretreatment compliance audit (PCA) conducted by Tetra Tech on May 2, 2007, EPA learned that this facility has violated the above permit condition on numerous occasions. Based on the pH logs included in the quarterly reports that BioMarin submits to NSD, EPA counted a total of 15 such violations in 2005, a total of 23 in 2006, and already a total of 6 in the first quarter of 2007. In addition, several of the violations have been serious, such as a pH level of 1.1, occurring as recently as March 8, 2007.

For almost all occurrences, NSD has issued BioMarin a notice of violation for each of these violations. BioMarin has consistently reported violations of this permit condition in its quarterly reports and includes a root cause analysis and corrective action for each occurrence of such violation. However, despite implementation of its corrective actions, BioMarin continues to violate this permit condition, and NSD has not escalated enforcement action yet.

2.3 Compliance with Local Permit Conditions

The facility's discharge permit also includes the following pH-related condition:

> The total time during which the pH values are outside the required range of pH values shall not exceed 7 hours and 26 minutes in any calendar month.

EPA performed a spot check on the facility's pH logs included in its quarterly reports submitted to NSD. Based on the quarterly report for the period of January 1, 2006 through March 31, 2006, EPA determined that the facility was out of compliance with the above permit condition during the month of January 2006. EPA calculated a total of 672 minutes, or approximately 11.2 hours, that the facility had pH values outside the required range. However, on the cover letter of this quarterly report, BioMarin states the contrary:

> In addition, the total time, during which the pH values were outside the required range of pH values, did not exceed the 7 hours and 26 minutes time limitation in any calendar month.

EPA did not see any documentation of NSD having identified or acted on this violation.

2.4 Monitoring Data for pH

The facility's permit requires that the facility monitor for pH continuously with a chart recorder at a control manhole just outside the front entrance of the building. NSD is to obtain grab samples at the control manhole; the permit does not specify the frequency.

The facility's permit also requires that the facility include a report of pH compliance in each of its quarterly compliance reports that it must submit to NSD. The pH compliance report must include pH excursion information: "the reasons for the pH excursion, the length of the excursion, what was done to correct the excursion, and steps taken to prevent further problems."

BioMarin has complied with the above monitoring and reporting requirements. BioMarin also maintains pH alarm logs on which staff have been instructed to record pH excursions when the alarm has been activated. The logs include information such as date and time of the alarm, pH measurement, and cause of the excursion. BioMarin includes these logs in its quarterly compliance reports. EPA reviewed the pH compliance reports for 2005, 2006, and the first quarter of 2007. See Sections 2.2 and 2.3 for details.

2.5 More Effective Corrective Action for Controlling pH

BioMarin stated that it has plans underway to expand the facility. It expects to complete the expansion early next year. During this construction, it will add utilities to prepare for another buildout. However, though BioMarin explained that it was working on a solution, BioMarin seemed to express some uncertainty as to whether it would be able to construct a solution to its pH problem during this construction period. BioMarin stated that it has considered various options to separate the process wastewater from domestic wastewater. One option BioMarin brought to the attention of the inspectors was that the 4-inch main could be severed at a point that domestic wastewater would be routed elsewhere. The facility would also make modifications to ensure that all process wastewaters would be treated before discharge to the District's sewer system. However, BioMarin stated that various obstacles have prevented this approach from being implemented, such as preventing particulate matter from getting into the processing areas, etc.

Based on BioMarin's compliance reports, many of the pH violations have occurred because of human error. Consequently, many of the corrective actions that BioMarin has implemented and stated in its pH compliance reports have involved training of its maintenance staff and cleaning crew. However, it is apparent by the facility's recurring pH violations that these types of corrective actions are not enough to solve the problem.

During this inspection, the EPA inspectors determined that, because of the low flows at night and because a great majority of the excursions occur for relatively short periods of time, an appropriately-sized equalization tank should be adequate to allow the facility to control pH levels more consistently. In addition, in response to one of BioMarin's perceived obstacles, the EPA inspectors stated that new piping does not necessarily need to be located belowground. The EPA inspectors emphasized the importance of BioMarin implementing a permanent solution to control its pH levels on a consistent basis. The EPA inspectors also stressed that implementation of a solution is readily achievable and should not be delayed any further.

A few weeks after the inspection, EPA received an e-mail from the company which provided more clarity to its plans for implementing a long-term solution to correct the pH problems. BioMarin plans to implement a project in two phases. Phase 1 will consist of severing the 4-inch main from the domestic line, then rerouting and connecting the 4-inch main to a new two-chamber equalization tank. Wastewater from the second chamber will feed to a sampling sump before discharging to the District's sewer system. BioMarin has scheduled this work during its annual plant shutdown in December 2007/January 2008, with a goal of completing the work at the end of January 2008. Phase 2 will involve design and construction of a new neutralization system so that out-of-range pH discharge could be diverted to this system for pretreatment. However, this new neutralization system would be part of a new manufacturing facility, the design of which, at this time, has not been finalized and approved yet. Therefore, BioMarin did not provide a time frame for completion of Phase 2.

3.0 Summary of Findings

1. On numerous occasions for at least the past few years, this facility has violated the federal specific prohibition found at 40 CFR 403.5(b)(2) and a permit condition which states that the pH cannot be less than 5 at any time.
2. This facility has also violated a permit condition which states that the pH values which are outside the required range of pH values shall not exceed 7 hours and 26 minutes in any calendar month. EPA determined that the facility was out of compliance with this permit condition during the month of January 2006.
3. Despite a total of 23 pH violations in 2006 and already a total of 6 in the first quarter of 2007, one of these being a pH level of 1.1, NSD has not escalated enforcement action beyond issuance of notices of violation.
4. As soon as possible, the facility must implement a more effective solution to control the pH of its wastewater discharge.