PART I Page 1 of 37 Pages Permit No. PR0026695

NPDES PERMIT NO. PR0026695

AUTHORIZATION TO DISCHARGE UNDER THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

In compliance with the provisions of the Clean Water Act, as amended, 33 U.S.C. §1251 et. seq. (the "Act"),

Amgen Manufacturing Limited (AML) P.O. Box 4060 Juncos, Puerto Rico 00777

hereinafter referred to as "the permittee" is authorized to discharge from the following facility:

AML Wastewater Treatment Plant State Road PR-31, Km 24.6 Juncos, Puerto Rico 00777

to receiving water

Gurabo River

in accordance with effluent limitations, monitoring requirements and other conditions set forth in Parts I and II hereof. All references to Title 40 of the Code of Federal Regulations are to regulations that are in effect on the effective date of this permit, including all amendments thereto published in the Federal Register. Unless otherwise specified herein, all terms are defined as provided in the applicable regulations under Title 40 of the Code of Federal Regulations.

This permit modification shall become effective on May 1, 2012. This permit and the authorization to discharge shall expire at midnight, November 30, 2016.

Signed this 14 day of March, 2012

ohn Filippelli, Director

Division of Environmental Planning and Protection U.S. Environmental Protection Agency Region II

PART I Modified Page 6 of 37 Pages Permit No. PR0026695

Notes:

To comply with the monitoring requirements specified above, samples shall be taken at the sampling point of discharge serial number 001.

All flow measurements shall achieve accuracy within the range of plus or minus 10%.

- α Waste Load Allocation (WLA) was performed in order to develop the water quality based effluent limitation.
- γ See Special Conditions 5 and 6.
- φ See Special Condition 9.
- δ See Special Condition 10.
- Φ The permittee shall implement a monitoring program using the analytical method approved by EPA with the lowest possible detection level, in accordance with Rule 1306.2(C) of the PRWQSR, as amended, until the completion of twelve (12) sampling events, after which they will be conducted annually. The sampling events cannot be more often than one event per month. The monitoring program shall commence not later than thirty (30) days after the EQB's written approval of the Quality Assurance Project Plan (QAPP). The QAPP must be submitted for evaluation and approval of EQB not later than December 31, 2011. The results of the monitoring program shall be submitted to EQB and EPA Region 2 no later than sixty (60) days of completion of the monitoring program. Based on the evaluation of the results obtained, EQB will determine if an effluent limitation is necessary for this parameter. In such case, the WQC will be reopened to include the applicable effluent limitation.
- λ The permittee shall implement a monitoring program using the analytical method approved by EPA with the lowest possible detection level, in accordance with Rule 1306.2 (C) of the PRWQSR, as amended, until the completion of twelve (12) sampling events, after which they will be conducted annually. The sampling events cannot be more often than one event per month. The monitoring program shall commence not later than thirty (30) days after the EQB's written approval of the QAPP. The QAPP must be submitted for evaluation and approval of EQB not later than December 31, 2011. The results of the monitoring program shall be submitted to EQB and EPA Region 2 not later than sixty (60) days of completion of the monitoring program. Based on the evaluation of the results obtained, EQB will determine if more frequent monitoring is necessary for this parameter. In such case, the WQC will be reopened to revise the monitoring frequency for such parameter, if considered necessary.
- 1, 2, 3, 4 and 5 see endnotes to the special conditions.

PART I Modified Page 7 of 37 Pages Permit No. PR0026695

TABLE A-2 WASTE LOAD ALLOCATION (WLA) MONITORING REQUIREMENTS

The EQB has performed a WLA pursuant to Article 10 of the PRWQSR. During the period beginning on EDCD + 60 days and lasting through one year, after which the monitoring shall be conducted annually, the permittee shall perform ambient monitoring at the immediate vicinity¹ of the discharge station and the background² monitoring station as specified below. The sampling events cannot be more often than one event per month. Within thirty (30) days of completion of the one year monitoring program, the permittee shall submit a report to EQB and EPA containing the ambient monitoring results obtained as well as the monthly monitoring results obtained during the same period at the sampling point for discharge 001 for the below parameters. Based on the evaluation of the results obtained, EQB shall determine if the current limitations established shall remain as is or if it is necessary to reopen the WQC to modify (increase or decrease) the effluent limitations for the following parameters:

Receiving Water Name and Classification: Rio Gurabo, SD.

Parameter	Monitoring Requirements	
	Measurement Frequency	Sample Type
Hardness ³ (as CaCO ₃) (mg/l)	Monthly	Grab
Copper (Cu) $(\mu g/l)^{2,3,4}$	Monthly	Grab
Lead (Pb) $(\mu g/l)^{2,3,4}$	Monthly	Grab
Temperature °F (°C) ^{2,3,4}	Monthly	Grab
Phosphorous, Total (P) $(mg/l)^{2,3,4}$	Monthly	Grab

Notes_

1 The immediate vicinity of the discharge station shall be located one hundred forty three (143) meters downstream from discharge 001.

2 The background sampling station shall be located five (5) meters upstream from discharge 001.

3 Monitoring is only required at the background sampling station.

For 2, 3 and 4, see endnotes to the Special Conditions.

EPA Note: The Effective Date of the Commencement of Discharge (EDCD) shall be the date upon which the permittee begins planned, continuous discharge to the Gurabo River. The permittee shall notify both EPA and EQB in writing of the intent to commence planned, continuous discharge fourteen (14) days prior to the EDCD, at the addresses listed in Part I.C. In the event that the QAPPs are approved by the EQB prior to the EDCD, the monitoring programs shall commence not later than thirty (30) days after the EDCD. The EDCD does not apply to short-term discharges that are the result of emergency circumstances or contingency actions.

PART II Modified Page 31 of 37 Pages Permit No. PR0026695

- (3) The alteration or addition results in a significant change in the permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan.
- b. Anticipated noncompliance. The permittee shall give advance notice to the Director of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.
- c. Transfers. This permit is not transferable to any person except after notice to the Director. The Director may require modification or revocation and reissuance of the permit to change the name of the permittee and incorporate such other requirements as may be necessary under the Clean Water Act. (See 40 C.F.R. §122.61; in some cases, modification or revocation and reissuance is mandatory.)
- d. Monitoring reports. Monitoring results shall be reported at the intervals specified in Part I of this permit.
 - (1) Monitoring results shall be reported on a Discharge Monitoring Report (DMR) or forms provided or specified by the Director for reporting results of monitoring of sludge use or disposal practices.
 - (2) If the permittee monitors any pollutant more frequently than required by the permit using test procedures approved under 40 C.F.R. 136, or another method required for an industry-specific waste stream under 40 C.F.R. subchapters N or O, the results of such monitoring shall be included in the calculation and reporting of the data submitted in the DMR or sludge reporting form specified by the Director.
 - (3) Calculations for all limitations which require averaging of measurements shall utilize an arithmetic mean unless otherwise specified by the Director in the permit.
- e. Compliance Schedules. Reports of compliance or noncompliance with, or any progress reports on, interim and final requirements contained in any compliance schedule of this permit shall be submitted no later than 14 days following each schedule date.
- f. Twenty-four hour reporting.
- (1) The permittee shall report any noncompliance which may endanger health or the