UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C., 20460

MAR 16 2020

ASSISTANT ADMINISTRATOR
FOR ENFORCEMENT AND
COMPLIANCE ASSURANCE

Wendy Perry
Chemical Sector Representative
Puerto Rico Business Emergency Operation Center
Via Email: wendy_perry@merck.com

Re: February 5, 2020, Request for No Action Assurance for Emergency Generators

Dear Ms. Perry:

This letter is in response to your February 5, 2020 request, on behalf of the Puerto Rico Business Emergency Operations Center, for No Action Assurance (NAA) regarding the operation of emergency generators at certain facilities. Beginning on or about December 28, 2019, and continuing many weeks after, Puerto Rico has experienced multiple earthquakes and aftershocks that have caused extreme damage to its power grid; the largest earthquake to date occurred on January 7, 2020, registering 6.4 on the Richter scale. Among other things, the earthquakes have rendered the Costa Sur power station, a critical baseload station, inoperable. On January 7, 2020, the Governor of Puerto Rico signed an Executive Order declaring a state of emergency throughout Puerto Rico; on January 16, 2020, the President of the United States signed a major disaster declaration for Puerto Rico

On March 13, 2020, the President declared a National Emergency in response to the spread of the novel corona virus (COVID-19) in the United States. The Center for Disease Control and Prevention has recommended that vulnerable groups obtain larger than normal supplies of needed medications and medical supplies. *See* https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html.

The facilities identified in Attachment 1 to this letter are engaged in the production of pharmaceuticals and/or medical supplies, the types of items for which public demand may substantially increase in response to COVID-19 virus concerns. In your February 5, 2020, request and follow-up conversations you reported that some or all of these facilities have experienced problems with the supply or quality of electrical power from the grid. You have reported that these electrical supply issues pose a genuine risk to the ability of these manufacturers to operate.

The U.S. Environmental Protection Agency has determined that issuing a NAA, as detailed below, is in the public interest to ensure production at the identified facilities can continue, given the conditions in Puerto Rico. Through the issuance of this NAA, the EPA is continuing its commitment to address the very difficult circumstances caused by recent earthquakes.

Nothing in this exercise of enforcement discretion relieves any person of the obligation under law, if any, to report emissions from the operation of equipment covered by this action. Pursuant to this NAA, at the facilities listed in Attachment 1, the EPA will not enforce violations by their emergency generators (Covered Generators) during the term of this NAA of:

- Engine operating hour limits established under Puerto Rico's RCAP and incorporated into the facility's Title V permit; and/or
- Engine operating hours limits established under 40 C.F.R. §§ 60.4211(f), 60.4243(d), or 63.6640(f).

This NAA is subject to the following conditions:

1. The emergency generator is used in excess of the otherwise applicable limits only when the operator reasonably believes that grid supplied electricity is, or may be, unsuitable or insufficient to support production of pharmaceuticals or medical supplies;
2. In calculating the total operating hours for a given requirement for a Covered Generator for a time period that includes the NAA, the relevant facility may exclude the days it operates pursuant to the NAA;
3. To the best of its ability, while the NAA is in effect, each facility with a Covered Generator will report on fuel consumption and hours of operation for the time prior to this NAA as required by its permits or any applicable regulations;
4. Facilities with a Covered Generator shall comply with all conditions imposed by territory or local authorities on these emergency operations;
5. Facilities with a Covered Generator shall comply with all other conditions related to their Covered Generator in their Title V or other permits and in applicable regulations;
6. Facilities with a Covered Generator shall comply with all other applicable provisions of 40 C.F.R. Part 60, Subparts IIII and JJJJ and/or 40 C.F.R. Part 63, Subpart ZZZZ; and
7. Facilities with a Covered Generator shall maintain records documenting the hours of operation and fuel consumption of each Covered Generator while the NAA remains in effect.

The facilities in Attachment 1 must each submit a report to the EPA within two weeks of the termination of the NAA containing the following information:

1. The name, address, and contact information for the person submitting the report;
2. A description of the total hours of operation and total fuel used for each Covered Generator during the period this NAA is in effect; and
3. A description of how the energy was used, including any benefits provided to the public.

The report referenced above must be sent by email to Gregory Fried, Chief, Stationary Source Enforcement Branch, within EPA's Air Enforcement Division, at fried.gregory@epa.gov and Harish Patel, Team Leader, Air Compliance Branch, within EPA Region 2, at patel.harish@epa.gov. The report must be in portable document format (PDF) and be clearly labeled as "Report for Generators NAA for [Name of the Reporting Facility]." Where the information for these reports is not available due to the emergency circumstances, the EPA would accept instead an explanation of those circumstances and specifically how they prevented the collection or transmission of that information.

This NAA terminates at 11:59 PM Atlantic Standard Time, on the earliest of 1) June 1, 2020, or 2) written notice from the EPA terminating this NAA. The EPA will assess whether an extension to or revision of this NAA is necessary and appropriate. The EPA reserves the right to revoke or modify the NAA if the EPA believes that such action is necessary to protect public health and the environment or the NAA is no longer appropriate. This NAA does not apply to any other federal requirements that may apply to regulated activities at this facility other than those listed above.

The issuance of an NAA for this period of time is in the public interest. Through today's NAA, the EPA is continuing its commitment to address the very difficult circumstances caused by the recent earthquakes. Nothing in this NAA is intended to over-ride Puerto Rico or local authorities.

Please contact Gregory Fried, Chief, Stationary Source Enforcement Branch, with questions. Mr. Fried can be reached at (202) 564-7016 or fried.gregory@epa.gov.

Sincerely,

Susan Parker Bodine

cc: Peter D. Lopez, Regional Administrator, EPA Region 2

Attachment 1

Name	Address
Amgen Manufacturing Limited	PR Road 31 KM 24.6 Juncos, PR 00777
Baxter Healthcare	PR Road 144 KM 20.6 Jayuya, PR 00664
Baxter Healthcare	PR Road 721 KM 0.3 Aibonito, PR 00705
Becton Dickinson (BD) Biosciences	735 Lot #6, Vicks Drive Cayey, PR 00737
Bristol Myers Squibb Holdings Pharma Ltd	PR Road 686 KM 2.3 Manati, PR 00674
Bristol Myers Squibb Manufacturing Co.	PR Road 3 KM 77.8 Humacao, PR 00791
CooperVision Manufacturing Puerto Rico LLC	500 Road 584 Juana Diaz, PR 00795
Patheon Puerto Rico, Inc.	PR Road 670 KM 2.7 Manati, PR 00674
Teva Puerto Rico LLC	PR Road 195 KM 1.1 Fajardo, PR 00738