

COVID-19-Emergency Request to Temporarily Suspend
Regulatory Requirements and/or Permit Conditions

In accordance with Governor Wolf's Proclamation of Disaster Emergency of March 6, 2020 and the Governor's powers pursuant to the Emergency Management Code, 35 Pa.C.S. §7301, the Governor has authority to suspend regulatory obligations and other legal obligations within his jurisdiction where strict compliance will prevent, hinder, or delay necessary action in coping with the COVID-19 emergency.

*If you are requesting suspension of a Federal requirement, under only Federal authority, please contact US EPA Region III and refer to the US EPA March 26, 2020 Memorandum (COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program). To the extent the request relates to a federal program delegated to Pennsylvania, Pennsylvania will review requests submitted in this format.

Submit completed and signed requests to the email resource account:

RA-EPCOVID19SuspReq@pa.gov

Background
<p>A. Identify the Regulated Entity or Permittee, including an address for the location of the permitted or regulated activity (if no address, DEP Permit No. can be used), and a point of contact for this request with email and phone number. Venatorx Pharmaceuticals, 30 Spring Mill Drive, Malvern, PA 19355</p>
<p>B. Describe what permitted or regulated activity you are engaged in. Pharmaceutical Research and Development</p>
<p>C. If you were issued a permit by DEP for the permitted or regulated activity described above, identify the type of permit and permit number. Please list the DEP Office, Conservation District, Oil and Gas District Office, or District Mining Office that issued the permit or authorization. Materials License No. PA-1573</p>
<p>D. Identify what regulatory requirement(s) or permit condition(s) or other requirement(s) you seek a temporary suspension of. Please cite the specific regulatory requirement(s), condition(s) and/or other requirement(s). 10 CFR 20.1101 as incorporated into PA Code (Annual Program Audit)</p>

Reasons for Requested Suspension
<p>For each regulatory requirement or permit condition or requirement listed above, please state clearly why you are seeking the temporary suspension, addressing at least the following in detail:</p>
<p>A. How will strict compliance with the subject requirement(s) prevent, hinder, or delay necessary action in coping with the COVID-19 emergency? Be as specific as possible. We use an outside contractor (IES Engineers) to perform this audit and at this time we have not re-opened the facility. Even if we do reopen before the 15th due to the COVID-19 emergency we will be keeping staff to a minimum and attempting to keep outside personnel to an absolute minimum (emergencies only).</p>

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<p>B. How has COVID-19 restricted your ability to comply with the environmental regulatory requirement, permit condition or other requirements for which you are seeking a suspension? Our facility is currently closed. If we re-open prior to the 15th we will want to keep the number of people onsite, especially those outside critical staff as low as possible.</p>
<p>C. What other aspects or parts of your operation(s) are being shut down or are not functioning due to the COVID-19 restrictions? And, are you requesting any suspensions or waiver(s) from other government agencies? If so, from what agencies and for what requirements? All onsite and laboratory operations including RAM use are currently shut down.</p>
<p>D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted? We could do a virtual meeting with IES to discuss last year's audit report and draft a report for this year based on memory or we could delay until business operations can safely resume.</p>
<p>E. Do you believe cost gouging or supply hoarding is negatively effecting your ability to comply? If so, please explain and provide cost information and/or availability information from your supply chain history. No.</p>
<p>F. How long do you expect to be unable to comply with the regulatory requirement(s), permit condition(s) or other requirement and identify what circumstances must exist for you to return to compliance. Specify the period of time for which you are requesting the suspension. Suspensions will not be issued initially beyond June 30, 2020. We respectfully request a suspension until June 30th to allow as much time as possible for us to re-open and safely complete this requirement.</p>
<p>G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance. We can review last year's report and update as well as possible from memory.</p>

<p>Evaluate Risk to Public Health and the Environment</p>
<p>A. Will the temporary suspension, if granted, result in an increase in the risk of additional pollution (e.g. increased emissions, increased concentrations of any pollutant and/or releases of new or more pollutants) and/or will it result in less monitoring, reporting, and/or supervision of pollution incidents, accidents or equipment failures? No.</p>
<p>(i) If yes, please identify what pollutants and the nature of the risk. N/A</p>

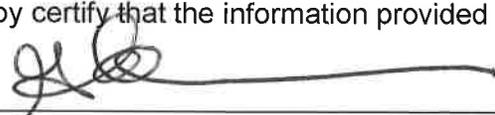
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<p>(ii) If yes, please identify the potential extent of increased pollution, including any increases in risk to human health, safety or the environment. N/A</p>
<p>(iii) If no, explain how increased pollution will be avoided. N/A</p>
<p>B. What public health and/or safety benefits will result if the temporary suspension is granted? We will continue to follow the shelter in place order and minimize contact between people outside the same single family.</p>
<p>C. Is the restriction on your ability to comply generally applicable to others engaged in your industrial classification or industry? If no, please explain why your situation is unique. Yes, if their 2019 Annual Program Audit was completed in May.</p>
<p>D. Would you possess a unique advantage over your competitors, or others in the same industry, if a suspension is granted? No.</p>
<p>E. What would be the negative consequences to your operation if the temporary suspension is not granted? What would be the negative consequences to the Commonwealth's response to the COVID-19 emergency if your requested temporary suspension is not granted? Yes, we would be non-compliant with the Annual Program Audit regulatory requirement.</p>

CERTIFICATION

Pursuant to the prohibition against unsworn falsification to authorities, 18 Pa.C.S.A. §4904, I am an authorized representative of the requestor and have personal knowledge of the facts set forth in this temporary suspension request.

I hereby certify that the information provided herein is true and accurate.



 Signature and title of Certifier

Dr. Glen Coburn, Radiation Safety Officer and Director, Virology

 Print Name and Title

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