pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

TSR-182

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
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. Sanofi Pasteur, Discovery Drive, Swiftwater, PA 18370-0187, aka "Sanofi" Technical Contact: Jeffery Smith, Deputy Director HSE | jeffery.smith2@sanofi.com Office (570) 957-3871 | Cellular (570) 269-4260
B. Describe what permitted or regulated activity you are engaged in. Sanofi Pasteur manufactures and distributes vaccines for use in humans against a number of deseases, including: Influenza, Diphtheria, Meningitis, Pertussis, Tetanus, and Yellow Fever. The facility, which is located on Route 611 in Swiftwater, Monroe County, Pennsylvania, is owned by parent company, Sanofi, headquartered in Paris, France. The Swiftwater site employs approximately 2500 employees and several hundred contractors and temporary workers. The property is divided into "Main Campus" and "South Campus" totaling nearly 600 acres with over 50 structures. Operations on Main Campus include research, manufacturing, formulation, filling, inspection and packaging. As part of these activities, reguated medical waste (RMW) is generated; some of which is decontaminated on-site. The focus of this request, are the processes and inactivation activities for RMW related to supporting R&D vaccine development for SARS-CoV-2, aka corona virus - the visrus that causes COVID-19.
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. The site operates in agreement with a number of PADEP issued permits. Of particular interest to this request is the General Permit for Processing/Disinfection of Regulated Medial Waste - WMGI005D003 (Date Issued: July 27, 2017). This permit was issued by the Department's Bureau of Waste Management, Division of Municipal and Residual Waste; with oversight by both the Central (Harrisburg) and Northeast Regional (Wilkes-Barre) offices. However, this current general permit and associated

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

Facility Specific Reference Table for processing of RMW does not encompass the specific inactivation procedures discussed here-in.

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).
Sanofi requests continued suspension of requirements of 25 Pa. Code Chapter 284 as it relates to the inclusion of additional facility specific conditions into the existing site permit. To this end, Sanofi seeks authorization prior to obtaining the approval of the amended permit for chemical and/or thermal inactivation to satisfy disinfection requirements (as detailed in the specified regulated medical waste requirements). Sanofi will continue to use qualified and scientifically valid decontamination processes that are equally effective as current operating procedures for these requested activities.

This request is for the continued approval of activities as detailed in the addendum to the Facility Specific Reference Table for processes and inactivation activities for RMW related to supporting R&D vaccine development for SARS-CoV-2, aka corona virus - the virus that causes COVID-19.

NOTE: This addendum was separately (previously) transmitted to the Bureau of Waste Management staff within the Department's Central and Northeast Region offices. The most recent revision of this amendment, which addresses comments on claims/formatting of business confidential information, was provided to the Department on 29-May 2020.

Reasons for Requested Suspension

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:

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.
Not being able to secure the requested suspension of the applicable regulations will likely delay and/or lead to greater risks in the anticipated COVID-19 vaccine development research activities. With the requested expedited approval of the amended facility specific general permit conditions, Sanofi will be allowed to implement necessary viral inactivation practices for the management of regulated medical wastes generated from future COVID-19 clinical studies. The temporary suspension will not apply to non-COVID-19 related wastes.

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?
Critical need and timing does not allow for completion of normal processing of the permit application.

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

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?
N/A

D. What alternate compliance options have you explored to address the issues or environmental compliance hurdles with which you are confronted?
The primary alternative compliance option is not to undertake the planned research & development activities for the purposes of supporting world-wide efforts in the licensure of a vaccine for SARS-CoV-2, aka corona virus - the virus that causes COVID-19.

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.
N/A

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.
As discussed with representatives from PADEP, which is documented in an email from Mr. Jason Dunham dated 3-Jun-2020, suspension of permit requirements for work with COVID-19 is requested to be continued through an extension of the current TSR (dated 17-Apr-2020) until such time that the associated permit modification request (transmitted to PADEP on 19 Mar 2020) is approved.

As noted in Background | Item D - The most recent revision of this amendment, which addresses comments on claims/formatting of business confidential information, was provided to the Department on 29-May 2020.

G. If applicable, identify how you will account for all reporting obligations for the period of noncompliance.
Sanofi will continue to operate within the terms of the existing infectious waste general permit as it regards recordkeeping and reporting. Compliance with these existing conditions will continue.

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

Evaluate Risk to Public Health and the Environment
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
(i) If yes, please identify what pollutants and the nature of the risk.
(ii) If yes, please identify the potential extent of increased pollution, including any increases in risk to human health, safety or the environment.
(iii) If no, explain how increased pollution will be avoided. Use of the designed and qualified viral inactivation systems will minimize the risk to both employees and the general public. By allowing use of such systems, including the effluent decontamination system and decontamination autoclaves, Sanofi will be able to safely process the expected quantities of generated COVID-19 related waste (both solids and liquids).
B. What public health and/or safety benefits will result if the temporary suspension is granted? Use of the designed and qualifed viral inactivation systems will minimize the risk to both employees and the general public. Completion of the planned vaccine activities will have a significant impact on the nation's health and safety while contributing to worldwide efforts to develop a vaccine for the prevention of COVID-19.
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. N/A - limited number of facilities with the capabilities required.
D. Would you possess a unique advantage over your competitors, or others in the same industry, if a suspension is granted? N/A
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

pennsylvania
DEPARTMENT OF ENVIRONMENTAL PROTECTION

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF ENVIRONMENTAL PROTECTION

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

Commonwealth's response to the COVID-19 emergency if your requested temporary suspension is not granted?
Denial of the extension for temporary approval for suspension of the noted regulatory requirements will significantly limit Sanofi's ability to achieve the mission to reduce or eliminate suffering for millions around the world through vaccination. Timely progress for the completion of planned clincal studies will contribute to vaccine development that is of importance for the Commonwealth and nation.

Sanofi requests that the current temporary suspension (# TSR-28); granted from 6-Apr-2020 to 30-Jun-2020, be extended for a period of not more that 90-days from the date of expiration of this TSR or to the date that the requested modification to Permit No. WMGI005 is granted, whichever occurs first.

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.

Mark Nemitz, Sr. Director HSE

Signature and title of Certifier

Mark Nemitz, Sr Director HSE

Print Name and Title

Note: Electronic signatures are not accepted.

Submit completed and signed requests to the email resource account:
RA-EPCOVID19SuspReq@pa.gov

EXHIBIT I

Email 03-Jun-2020 - RE: TSR-28_Nemitz_Sanofi Pasteur

[redacted]

Smith, Jeffery /US

From: Dunham, Jason <jadunham@pa.gov>
Sent: Wednesday, June 03, 2020 8:44 AM
To: Smith, Jeffery /US; Craig.Wilson
Cc: Solloway, Christopher; Bellas, Roger
Subject: [EXTERNAL] FW: TSR-28_Nemitz_Sanofi Pasteur

EXTERNAL : Real sender is jadunham@pa.gov

Gentlemen,

See below regarding extension of Sanofi's existing TSR. The mechanism will be the same as the one used initially. Please submit a new TSR form, and provide justification for the extension. I recommend getting that in as soon as possible to give time for Governor's Office and DEP review. Please advise whether or not you'd still like to have a call tomorrow to discuss.

Jason Dunham | Environmental Engineer Specialist
Department of Environmental Protection | Bureau of Waste Management
Rachel Carson State Office Building
400 Market St. | Hbg PA 17101
Phone: 717.787.1982
www.dep.pa.gov

From: Digilarmo, Robert <rdigilarmo@pa.gov>
Sent: Wednesday, June 3, 2020 8:02 AM
To: Shaffer, Valerie <valshaffer@pa.gov>; Bakshi, Neil <nebakshi@pa.gov>
Cc: Tarquino Morris, Ali <altarquino@pa.gov>; Ramamurthy, Krishnan <kramamurth@pa.gov>; Dunham, Jason <jadunham@pa.gov>
Subject: RE: TSR-28_Nemitz_Sanofi Pasteur

Please have them submit a new TSR form, referencing the initial approval and the reasons for the extension. Once received, we will process it through the traditional TSR process.

Robert M. DiGilarmo | Director
Department of Environmental Protection
Office of Program Integration
Rachel Carson State Office Building
400 Market Street | Hbg PA 17101
Phone: 717.772.1839
www.dep.pa.gov

From: Tarquino Morris, Ali <altarquino@pa.gov>
Sent: Tuesday, June 2, 2020 2:04 PM
To: Ramamurthy, Krishnan <kramamurth@pa.gov>; Shaffer, Valerie <valshaffer@pa.gov>
Cc: Dunham, Jason <jadunham@pa.gov>
Subject: Re: TSR-28_Nemitz_Sanofi Pasteur

Krish,

In early April, Sanofi Pasteur, submitted the attached TSR request for a waiver from the requirements contained in Section A and Condition C.24 of WMGI005, which require Sanofi to modify it's coverage under WMGI005 so that it may process regulated medical waste resulting from SARS-CoV-2 vaccine development. WMGI005 requires in Section A and Condition C.24 that regulated medical waste is processed in accordance with the Approved Facility Specific Reference Table. SARS-CoV-2 has not been previously approved in the Sanofi's Facility Specific Reference Table. Sanofi has applied to DEP for the modification to its coverage, but requested approval to process SARS-CoV-2 waste while DEP processes the application. The TSR was approved on April 17.

Sanofi's application had to be returned due to some issues with what they had designated as confidential business information, and therefore, it will not be able to be processed prior to the expiration of their TSR on June 30, 2020. Sanofi is already asking for an extension.

My recollection is that the June 30, 2020, date for the TSR's was set forth by the governor's office. We wanted to reach out to see if you had heard anything about the extension of TSR's beyond that date, or if the program should begin considering another mechanism for allowing Sanofi to continue this important work, while staff continue to processing Sanofi's application.

Do you have any guidance as to who we should follow-up with to address a possible extension?

Jason Dunham in the Division of Municipal & Residual Waste is the POC, if you have any follow-up questions on Sanofi's operation.

Ali Tarquino Morris | Program Manager, Division of Municipal and Residual Waste
Bureau of Waste Management | Department of Environmental Protection
Rachel Carson State Office Building
400 Market Street | Harrisburg, PA 17105
Phone: 717.783.2630 | Fax: 717.787.1904
www.dep.state.pa.us

EXHIBIT II

Email Transmittal Letter 17-Apr-2020 – RE: Application of Sanofi Pasteur to Continue Business Operations at its Physical Locations (Request #TSR-28)

COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE GOVERNOR

April 17, 2020

Mark Nemitz
Sanofi Pasteur
Discovery Drive
Swiftwater, PA 18370
Jeffery.Smith2@sanofi.com

Transmitted via email

RE: Application of Sanofi Pasteur to Continue Business Operations at its Physical Locations (Request # TSR-28)

Dear Mark Nemitz:

By Executive Order dated March 19, 2020, and pursuant to powers granted to us by law, we ordered that no person or entity shall operate a place of business that is not a life-sustaining business, regardless of whether the business is open to members of the public. These orders (the "COVID-19 Orders") are necessary to stop the spread of the novel coronavirus COVID-19. Those businesses that have been determined life-sustaining or have received an exemption from the COVID-19 Orders are authorized to operate in compliance with the applicable state law and regulatory requirements.

You submitted the attached request for a temporary suspension of certain environmental compliance requirements. 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. Based upon the information in your request, pursuant to the powers granted to the Governor and to prevent and control the spread of disease, it has been determined that certain compliance requirements if strictly followed, could prevent, hinder, or delay necessary action in coping with the COVID-19 emergency. Based on that determination, the requested temporary suspension of requirements established in Section A and Condition C.24 of Waste Management General Permit No. WMGI005 is granted from April 6, 2020 until DEP approves Sanofi Pasteur's application to modify its coverage under Permit No. WMGI005 or to June 30, 2020, whichever occurs first, at the physical location identified in your application.

This temporary suspension is subject to continuance of and compliance with the social distancing and other mitigation measures to protect employees and the public, including virtual and telework operations (e.g. work from home) as the primary option when available, which were submitted with your request and which have been established by the Department of Health and the Centers for Disease Control and Prevention to date and going forward. In-person work at a business site is only to be performed on the most limited basis possible but in compliance with applicable laws and regulations to deliver the services or goods of life-sustaining business.

Sincerely,

Tom Wolf
TOM WOLF
Governor

RACHEL L. LEVINE, M.D.
Secretary of Health

EXHIBIT III

Email 29-May-2020 - RE: Sanofi Pasteur IWGP UPDATED Modification Application Transmittal

Smith, Jeffery /US

Sent: Friday, May 29, 2020 1:43 PM
To: Dunham, Jason
Cc: Nemitz, Mark /US; Craig.Wilson; Lubin, Joshua /US; Michlowski, Melissa Maria /US; Solloway, Christopher; Bellas, Roger
Subject: Sanofi Pasteur IWGP UPDATED Modification Application Transmittal
Attachments: 5-29-20_IWGP Application Retransmittal_PART1.pdf; 5-29-20_IWGP Application Retransmittal_PART2.pdf

Good Afternoon,

Based on your email earlier today, please find attached the final transmittal of the updated application requesting the modification of the Sanofi Pasteur Infectious Waste General Permit (IWGP).

We are happy to provide any additional information or answer any questions that you may have in order to support securing timely approval of this modification to our site-specific requirements.

We appreciate your time and attention to our request. Take care and have a great weekend.

Respectfully submitted,

Jeff Smith
SANOFI pasteur
P: 570.957.3871 | C: 570.269.4260

From: Dunham, Jason <jadunham@pa.gov>
Sent: Friday, May 29, 2020 1:15 PM
To: Smith, Jeffery /US <Jeffery.Smith2@sanofi.com>
Cc: Nemitz, Mark /US <Mark.Nemitz@sanofi.com>; Craig.Wilson <Craig.Wilson@klgates.com>; Lubin, Joshua /US <Joshua.Lubin@sanofi.com>; Michlowski, Melissa Maria /US <Melissa.Michlowski@sanofi.com>; Solloway, Christopher <csolloway@pa.gov>; Bellas, Roger <rbellas@pa.gov>
Subject: RE: [External] RE: IWGP Transmittal_22-May 2020

EXTERNAL : Real sender is jadunham@pa.gov

Jeff,

The way you addressed the confidential information in the draft application is acceptable. Please submit a final version of the application at your convenience. Have a great weekend.

Jason Dunham | Environmental Engineer Specialist
Department of Environmental Protection | Bureau of Waste Management
Rachel Carson State Office Building
400 Market St. | Hbg PA 17101
Phone: 717.787.1982
www.dep.pa.gov

From: Smith, Jeffery /US <Jeffery.Smith2@sanofi.com>
Sent: Friday, May 22, 2020 11:24 AM
To: Dunham, Jason <jadunham@pa.gov>; Bellas, Roger <rbellas@pa.gov>; Solloway, Christopher <csolloway@pa.gov>
Cc: Nemitz, Mark /US <Mark.Nemitz@sanofi.com>; Wilson, Craig P. <Craig.Wilson@klgates.com>; Lubin, Joshua /US <Joshua.Lubin@sanofi.com>; Michlowski, Melissa Maria /US <Melissa.Michlowski@sanofi.com>
Subject: [External] RE: IWGP Transmittal_22-May 2020

Good Morning,

I am sending you this message as a follow-up to my transmittal early this morning. It appears several of you have been able to access and download the rather large PDF's sent via the file sharing portal. My apologies for any difficulties. As such, I have since worked to rescan the newly included redacted files to reduce the size of the PART1 PDF – hopefully this is more manageable. The two parts of the application are attached in this email for your convenience.

To summarize, this transmittal has been made to provide you the revised DRAFT of the Sanofi Pasteur IWGP application that addresses outstanding concerns with confidentiality claims. This resubmission of the application has been reformatted so that the majority of the transmittal is now included in PART 1 (Public or Non-Confidential components). In as much, references to buildings; operations and/or specific procedures as well as the planned activities with polio virus, which are believed to have legitimate claims of confidentiality, are detailed in separately transmitted PART 2 (Confidential components).

PLEASE NOTE:

- Three (3) white papers presented in PART 1 ATTACHMENT 1D have been redacted as it regards references to polio. The unredacted, full copies of these white papers are presented in PART 2.
- Except for the file size of the PART1 PDF; the attached files are no different in content than the files for download from the portal. Please use whatever is more beneficial to you.

We appreciate your time and attention to review this transmittal in preparation of our discussion at our meeting next Wednesday.
Please contact me at (570) 269-4260.

Be well – have a great holiday weekend.

Respectfully submitted,
Jeff

Jeff Smith
SANOFI pasteur
P: 570.957.3871 | C: 570.269.4260

From: Smith, Jeffery /US <Jeffery.Smith2@sanofi.com>
Sent: Friday, May 22, 2020 12:15 AM
To: Chris Solloway <csolloway@pa.gov>; Roger Bellas - PADEP (rbellas@pa.gov) <rbellas@pa.gov>; Dunham, Jason <jadunham@pa.gov>
Cc: Nemitz, Mark /US <Mark.Nemitz@sanofi.com>; Wilson, Craig P. <Craig.Wilson@klgates.com>; Lubin, Joshua /US <Joshua.Lubin@sanofi.com>; Michlowski, Melissa Maria /US <Melissa.Michlowski@sanofi.com>

Subject:
Importance: High

Good Day,

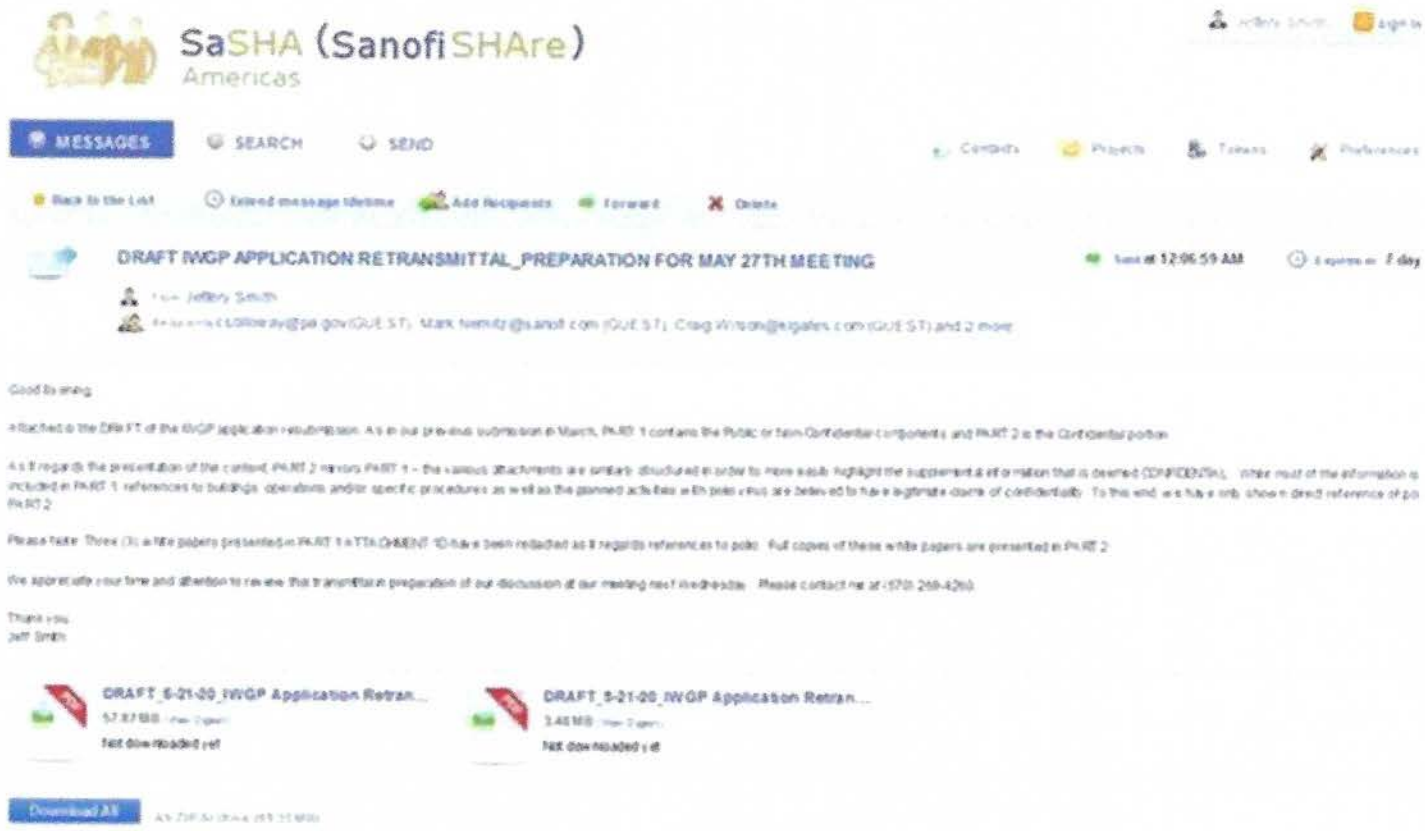
FYI – I have initiated a SaSHA data transmittal to the Department as indicated below in the image from the portal.

Due to the reassembly of the revised PART 1 PDF, which includes several scanned documents – the complete document is nearly 60 MB.

The PART 2 file is roughly 4MB.

Hopefully all goes well with your receipt/download of the files. Please advise accordingly if you have any problems securing these files.

Be well – have a good weekend.
Jeff



Jeffery W. Smith
Deputy Director HSE | SANOFI Pasteur
Discovery Drive (Mail Stop 49D30) - Swiftwater, PA 18370
P: 570.957.3871 | C: 570.269.4260

SANOFI Empowering Life