

Message

From: Nanes, Anthony (CDC/SNS/DSNS) [REDACTED]@cdc.gov]
Sent: 3/10/2020 12:41:40 PM
To: Branscum, Charity [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f1c7c1699ac48a8a39ab4aac8e4b0df-310138440]
CC: Mutschler, Charles [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=152c436d11174975823575442d7a2ddf-usd36779]
Subject: RE: Status Information on Ventilator Production

I talked to our contracting office. Please give me a call on how to move forward with this ASAP.

Tony Nanes

Logistics Management Specialist
Contracting Officer Representative
Operational Logistics Branch
Division of Strategic National Stockpile
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Wk: [REDACTED]
Cell: [REDACTED]
Fax: [REDACTED]



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From: Branscum, Charity [REDACTED]@philips.com>
Sent: Thursday, March 5, 2020 11:57 AM
To: Nanes, Anthony (CDC/SNS/DSNS) [REDACTED]@cdc.gov>; Mutschler, Charles [REDACTED]@philips.com>
Cc: Kelley, David (CDC/SNS/DSNS) [REDACTED]@cdc.gov>
Subject: RE: Status Information on Ventilator Production

Hi Tony,

Will you be able to provide the amendment modification for execution? I believe you can just attach the draft modification that I sent to Form 336 as mod 0010 and send to us for signature.

Thanks,

Charity

From: Nanes, Anthony (CDC/SNS/DSNS) [REDACTED]@cdc.gov>
Sent: Thursday, March 5, 2020 10:05 AM
To: Mutschler, Charles [REDACTED]@philips.com>

Cc: Branscum, Charity [REDACTED]@philips.com>; Kelley, David (CDC/SNS/DSNS) [REDACTED]@cdc.gov>

Subject: RE: Status Information on Ventilator Production

There are no issues with the MOD. The terms are agreeable, please start production immediately. Once you have an idea of obtaining material and manufacturing time. Please provide it. Let me know if anything else is needed.

Tony Nanes

Logistics Management Specialist
Contracting Officer Representative
Operational Logistics Branch
Division of Strategic National Stockpile
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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From: Mutschler, Charles [REDACTED]@philips.com>

Sent: Wednesday, March 4, 2020 1:38 PM

To: Nanes, Anthony (CDC/SNS/DSNS) [REDACTED]@cdc.gov>

Cc: Branscum, Charity [REDACTED]@philips.com>

Subject: RE: Status Information on Ventilator Production

Hi Tony,

Our current 510k submittal is not affecting our ability to ship product. The FDA has inquired about the details of cumulative changes of the Trilogy EVO and Trilogy EVO Universal devices since initial 510(k) clearance. It is their recommendation that Philips Respironics submit a Traditional 510(k). We have been in contact with Dr. James J. Lee of the CDRH and notified him that we are planning to submit a bundled Traditional 510(k) this month that will include both the Trilogy Evo (K181166) and the Trilogy Evo Universal (K181170). This bundled 510(k) will catch up all of the cumulative changes that have been made since the original 510(k) approval. At no time has the FDA indicated that we should stop marketing and shipping the Trilogy EVO family of devices.

Our team will evaluate what can be done to pull in shipments of the Trilogy Evo Universal from the current August timeframe. The current issues are also impacting our supply chain but we will explore what we can do within the bounds of the contract to expedite deliveries. With your approval, we will move forward to make appropriate modifications to our contract to allow for the earlier shipments. We have attached a draft contract modification. Please provide any feedback for Philips Legal approval and we will expedite the execution of this modification.

I anticipate it taking us about a week to confirm with what our supply chain can expedite.

Please let us know any additional information we can provide.

Thanks,
Charlie

From: Nanes, Anthony (CDC/SNS/DSNS) [REDACTED]@cdc.gov>
Sent: Wednesday, March 4, 2020 11:01 AM
To: Branscum, Charity [REDACTED]@philips.com>; Mutschler, Charles [REDACTED]@philips.com>
Subject: Status Information on Ventilator Production
Importance: High

Due to the current health threat there have been numerous questions and directives coming from all the way up from HHS Secretary Office that have come up to now expedite production of the ventilators. I saw there was a 510k issue and know we have modification issue to resolve. What do we need to do to get these going? I want to carefully answer my leadership on Philips position and ability at this point. I am expected to give a briefing this afternoon on the status and recommendations to have capability to support a potential pandemic event. Any input or recommendations you could provide would be very much appreciated.

Tony Nanes

Logistics Management Specialist
Contracting Officer Representative
Operational Logistics Branch
Division of Strategic National Stockpile
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

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