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Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency

Guidance for Industry and Food and Drug Administration Staff

March 2020



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19> and the FDA webpage titled "Search for FDA Guidance Documents" *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 20014 and complete title of the guidance in the request.

Questions

For questions about this document, contact Dr. James Lee, Assistant Director, Respiratory Devices at 301-796-8463 or james.j.lee@fda.hhs.gov.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of ventilators as well as other respiratory devices and their accessories during this pandemic.

This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act.

Given this public health emergency, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented

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immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

SARS-CoV-2 has demonstrated the capability to spread rapidly, leading to significant impacts on healthcare systems and causing societal disruption. The potential public health threat posed by COVID-19 is high, both globally and to the United States. To respond effectively to the COVID-19 outbreak, appropriate clinical management and infection control in conjunction with implementation of community mitigation efforts are critical.

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by helping to expand the availability of devices that facilitate respiration, including ventilators and their accessories, as well as other respiratory devices.

III. Scope

The enforcement policy described in this guidance applies to the following devices and their accessories used to provide ventilation and ventilatory support to patients with respiratory failure or respiratory insufficiency during the COVID-19 public health emergency (See Table 1):

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. Jan. 31, 2020. (Accessible at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>).

² President Donald J. Trump, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19). Mar. 13, 2020. (Accessible at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>).

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Table 1

Classification Regulation	Device Type	Product Code³	Device Classification
21 CFR 868.5895	Ventilator, Continuous, Facility Use	CBK	II
	Ventilator, Continuous, Minimal Ventilatory Support, Facility Use	MNT	II
	Continuous, ventilator, home use	NOU	II
	Ventilator, continuous, minimal ventilatory support, home use	NQY	II
	Ventilator, continuous, non-life-supporting	MNS	II
	Mechanical Ventilator	ONZ	II
21 CFR 868.5925	Ventilator, Emergency, Powered (Resuscitator)	BTL	II
21 CFR 868.5160	Gas-machine, anesthesia	BSZ	II
21 CFR 868.5905	Ventilator, non-continuous (respirator) Including masks ⁴ and interfaces under the same product code	BZD	II
	Converter, Oxygen	NFB	II
	Device, Positive Pressure Breathing, Intermittent	NHJ	II
	Resuscitator, Manual, Non Self-Inflating	NHK	II
21 CFR 868.5454	High flow/high velocity humidified oxygen delivery device	QAV	II

IV. Policy for Modifications to FDA-Cleared Devices

In the context of the COVID-19 public health emergency in which affected patients may develop respiratory illness, it is necessary to maintain an adequate supply of devices to treat patients who develop respiratory failure or respiratory insufficiency. The devices listed above, which include ventilators, anesthesia gas machines, and other respiratory devices, and their accessories, are needed to support patients who develop respiratory compromise from COVID-19 or other respiratory disorders.

Wherever possible, health care facilities should use FDA-cleared conventional/standard full-featured ventilators when necessary to support patients with respiratory failure, or a device subject to an Emergency Use Authorization (EUA), if any. However, to help ensure the availability of the greatest possible number of devices for this purpose, and as described in more

³ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁴ This reference is limited to masks used with a ventilator and does not refer to personal protective equipment, such as surgical masks (21 CFR 878.4040).

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detail below, FDA does not intend to object to limited modifications to the indications, claims, functionality, or to the hardware, software, or materials of FDA-cleared devices used to support patients with respiratory failure or respiratory insufficiency, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81⁵, for the duration of the declared public health emergency. This policy applies where a modification is made to the device that triggers the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA. Examples of such changes could include a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

More specifically, this policy will create more flexibility for manufacturers that make device modifications to address current manufacturing limitations or supply shortages. Examples may include:

- Changes to the ventilator motor to allow an alternate supplier to meet the required design specifications
- Changes to the material in the ventilator tubing to allow for more flexible material sourcing

We believe this approach will help manufacturers that want to add production lines or manufacture at alternative sites which may have different manufacturing equipment to increase manufacturing capacity and supply and reduce supply change interruptions and manufacturing bottlenecks.

A. Modifications to FDA-Cleared Indications, Claims, or Functionality

In developing this policy, FDA's intent is to foster the continued availability of safe and effective medical devices while being flexible regarding modifications made to ventilators, anesthesia gas machines and other respiratory devices, and their accessories, in response to the COVID-19 public health emergency.

As noted above, wherever possible, health care facilities should use FDA-cleared conventional/standard full-featured ventilators to treat patients who develop respiratory failure or respiratory insufficiency. However, for the duration of the public health emergency, to help foster the wider availability of devices for patients in need of ventilatory support, FDA does not intend to object to modifications to the FDA-cleared indications, claims, or functionality of these devices, without prior submission of a premarket notification where the modification will not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not create such undue risk include:

- 1) The use of powered emergency ventilators and anesthesia gas machines for patients needing mechanical ventilation;

⁵ For further guidance on modifications that trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to FDA, refer to "Deciding When to Submit a 510(k) for a Change to an Existing Device: Guidance for Industry and Food and Drug Administration Staff," <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>.

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- 2) The use of ventilators outside their cleared environment of use (for example, use of a ventilator in a health care facility when it is only cleared for use at home or during transport);
- 3) The use of devices indicated for sleep apnea (including noncontinuous ventilators delivering continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP)) to treat patients with respiratory insufficiency, provided that appropriate design mitigations are in place to minimize aerosolization;
- 4) The use of oxygen concentrators for primary supply when medically necessary and clinically appropriate.

B. Hardware, Software, and Material Changes to FDA-cleared Ventilators and Anesthesia Gas Machines

As stated above, wherever possible, health care facilities should use conventional/standard full-featured ventilators to treat patients who develop respiratory failure or respiratory insufficiency. However, for the duration of the public health emergency, in order to help foster the wider availability of devices for patients in need of ventilatory support and to help manufacturers respond to potential device component disruptions in the supply chain, FDA does not intend to object to limited modifications to the FDA-cleared hardware, software, or materials, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the modification does not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a modification would not create such undue risk include:

- 1) Modifications to motors, batteries, or other electrical components;
- 2) Material changes to components in the gas pathway or with other patient tissue contact;
- 3) Introduction of filtration to minimize aerosolization.
- 4) Software modifications intended to modify the ventilation parameters including inspiratory pressure, tidal volumes, flow rates, positive end-expiratory pressure (PEEP) in accordance with any applicable device standard;
- 5) Software modifications implementing physiological closed loop (automated) algorithms for oxygen titration where the algorithms/devices are the subject of an FDA-approved Investigational Device Exemption (IDE);
- 6) Hardware and/or software modifications implementing the capability for remote monitoring and remote adjustment of ventilator parameters (i.e., adjustment of parameters by trained health care providers from outside an isolation unit to avoid unnecessary exposures).

Additionally, FDA does not intend to object to firms making modifications or adding to the hardware/software architectures to allow for increased remote monitoring and setting adjustment capability/availability to support additional claims or indications described above. One example is the addition of wireless and/or Bluetooth capability. For any such changes, manufacturers should develop and implement appropriate cybersecurity controls to assure device cybersecurity and maintain device functionality and safety. FDA recommends firms refer to the following FDA guidance documents for consideration when pursuing these design changes:

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- [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices)⁶
- [Content of Premarket Submissions for Management of Cybersecurity in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0)⁷
- [Radio Frequency Wireless Technology in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff)⁸
- [Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices)⁹

C. Use of Ventilator and Anesthesia Gas Machine Breathing Circuit Devices Beyond Their Indicated Shelf Life and Duration of Use

Ventilators and anesthesia gas machines are designed to work as a breathing circuit, which is comprised of various ancillary devices such as the tubing that connects the ventilator to the patient, filters, and humidifiers. Constituent parts of the breathing circuit may include, but are not limited to, those identified in Table 2:

Table 2

Classification Regulation	Device Type	Product Code¹⁰	Device Classification
21 CFR 868.5240	Anesthesia breathing circuit	OFP	I
	Anesthesia breathing circuit	CAI	I
21 CFR 868.5260	Filter, Bacterial, Breathing-Circuit	CAH	II
21 CFR 868.5270	Heated breathing circuit	BZE	II
21 CFR 868.5340	Cannula, Nasal, Oxygen	CAT	I
21 CFR 868.5440	Generator, oxygen, portable	CAW	II
21 CFR 868.5450	Humidifier, Respiratory Gas, (Direct Patient Interface)	BTT	II
21 CFR 868.5580	Mask, Oxygen	BYG	I
21 CFR 868.5730	Tube, Tracheal (W/Wo Connector)	BTR	II
	Airway Monitoring System	OQU	II
21 CFR 868.5895	Accessory to Continuous Ventilator (Respirator)	MOD	II
21 CFR 868.5965	Attachment, Breathing, Positive	BYE	II

⁶ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices>.

⁷ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0>.

⁸ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff>.

⁹ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices>.

¹⁰ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

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	End Expiratory Pressure		
21 CFR 868.5975	Set, Tubing and Support, Ventilator	BZO	I

These breathing circuit devices might be labeled with specific durations of use and shelf life. Given the potential for extensive use of ventilators and anesthesia gas machines in response to the COVID-19 pandemic, and to avoid depletion of breathing circuit supplies, for the duration of the public health emergency, FDA does not intend to object to changes in the indicated shelf life and duration of use of these products for treating individual patients, without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, where the change does not create an undue risk in light of the public health emergency. Examples of circumstances where FDA currently believes a change would not create such an undue risk: the devices are used according to healthcare institutional protocols, or useful life is limited to the occurrence of malfunction or visible soiling.

D. Validation of Changes Made to Hardware, Software, Materials, or Duration of Use

In designing, evaluating, and validating changes made to hardware, software, materials or duration of use, FDA recommends doing so in accordance with FDA recognized standards for the specific device type, including (as applicable):

- IEC 60601-1: 2012: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*
- IEC 60601-1-2: 2014: *Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests*
- IEC 60601-1-11: 2015: *Medical Electrical Equipment Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment*
- Any other applicable collateral/particular standards in the IEC 60601-1: 2012 family
- IEC 62304: 2015: *Medical Device Software – Software Life Cycle Processes*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ANSI/IEEE C63.27: 2017: *American National Standard for Evaluation of Wireless Coexistence*
- AAMI TIR69: 2017: *Technical Information Report Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems*
- ISO 10993: Fifth Edition 2018-08: *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*
- ISO 18562-1 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 1: Evaluation and Testing Within a Risk Management Process*

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- ISO 10651-5 First Edition 2006-02-01: *Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 5: Gas-Powered Emergency Resuscitators*
- ISO 17510 First Edition 2015-08-01: *Medical devices -- Sleep Apnoea Breathing Therapy -- Masks and Application Accessories*
- ISO 18562-2 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 2: Tests for Emissions of Particulate Matter*
- ISO 18562-3 First Edition 2017: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 3: Tests for Emissions of Volatile Organic Compounds*
- ISO 18562-4 First Edition 2017-03: *Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications - Part 4: Tests for Leachables in Condensate*
- ISO 80601-2-12 First Edition 2011-04-15: *Medical Electrical Equipment - Part 2-12: Particular Requirements for the Safety of Lung Ventilators - Critical Care Ventilators [Including: Technical Corrigendum 1 (2011)]*
- ISO 80601-2-13 First Edition 2011-08-11: *Medical Electrical Equipment -- Part 2-13: Particular Requirements for Basic Safety and Essential Performance of an Anaesthetic Workstation [Including: Amendment 1 (2015) and Amendment 2 (2018)]*
- ISO 80601-2-69 First Edition 2014-07-15: *Medical Electrical Equipment - Part 2-69: Particular Requirements for Basic Safety and Essential Performance of Oxygen Concentrator Equipment*
- ISO 80601-2-70 First Edition 2015-01-15: *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment*
- ISO 80601-2-74 First Edition 2017-05: *Medical Electrical Equipment - Part 2-74: Particular Requirements for Basic Safety and Essential Performance of Respiratory Humidifying Equipment*
- ISO 80601-2-79 First Edition 2018-07: *Medical electrical equipment - Part 2-79: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Impairment*
- ISO 80601-2-80 First Edition 2018-07: *Medical Electrical Equipment - Part 2-80: Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency*

Manufacturers must document changes to their device in their device master record and change control records and make this information available to FDA, if requested, consistent with 21 CFR 820.30 and 21 CFR 820.180.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the [FDA Recognized Consensus Standards Database](#).¹¹ For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#).”¹²

¹¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

¹² <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

E. Labeling of Modified Devices

In addition, FDA recommends that the devices described above use labeling that helps users better understand the device modifications such as:

- 1) A clear description of the device's new indications, claims, or functions, and information on the device's performance and potential risks.
- 2) Adequate instructions for use for the intended user and indicated environment(s) of use. The labeling highlight the differences in design compared to the unmodified, FDA-cleared version of the device, along with instructions for mitigating any known risks associated with these differences.
- 3) A clear distinction delineating FDA-cleared indications and claims from those that are not FDA-cleared. In addition, FDA recommends the labeling include a general statement about changes that have not been cleared by FDA.

V. FDA's Intended Approach for EUAs for Ventilatory Support Devices

Wherever possible, health care facilities should use FDA-cleared conventional/standard full-featured ventilators to treat patients who develop respiratory failure or respiratory insufficiency. However, to support the wider availability of devices for patients in need of ventilatory support in the United States for the duration of the public health emergency, FDA is interested in interacting with manufacturers of ventilatory support devices that are not currently legally marketed in the U.S. as well as manufacturers who have not previously been engaged in medical device manufacturing with capabilities to increase supply of these devices. FDA will work interactively with these manufacturers through its Emergency Use Authorization (EUA) process.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-Ventilators@fda.hhs.gov; FDA believes this information will be valuable in assessing whether the device would be able to meet the EUA requirements. FDA believes that companies may already have available information to help support an EUA request for ventilators, such as the information outlined below. FDA will expeditiously review this information, and other required information, to determine if an EUA can be issued.

- 1) For current ventilator manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:
 - a) General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any), in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
 - b) A copy of the product labeling.
 - c) Whether the device currently has marketing authorization in another regulatory jurisdiction such as the European CE Mark, Australian Register of Therapeutic Goods

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- (ARTG) Certificate of Inclusion, Health Canada Licence, or Japan Pharmaceuticals and Medical Device (PMDA) approval (including certification number, if available).
- d) Whether the device has been designed, evaluated, and validated in accordance with the applicable FDA recognized standards identified in Section IV.D above.
 - e) Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*, or an equivalent quality system, and the manufacturer or importer has documentation of such.
 - f) Whether the device is designed with a power supply that is compatible with United States voltage, frequency, and plug type standards or is accompanied by an appropriate power supply adapter for use in the United States.

FDA will acknowledge receipt of the information provided, and intends to work interactively with these manufacturers to facilitate distribution of their products through an Emergency Use Authorization in the United States.¹³ In addition, where appropriate under the circumstances, FDA will notify the manufacturer that it does not intend to object to the distribution and use of the device while the manufacturer is preparing, and FDA is reviewing, the EUA request. Manufacturers who are unable to provide all the above information are still eligible for EUA consideration and should engage with FDA through the pre-EUA process.

- 2) For manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices

FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture ventilatory support devices. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to the address above and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

For any ventilatory support device granted an EUA, FDA will include appropriate conditions of authorization in accordance with the mandatory conditions outlined in section 564(e)(1)(A) of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that health care professionals administering the device are informed—
 - that FDA has authorized the emergency use of the device;
 - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
 - of the alternatives to the device that are available, and of their benefits and risks.
- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed—

¹³ For more information about FDA's EUA process, please see FDA's Guidance, Emergency Use Authorization of Medical Products and Related Authorities, available at <https://www.fda.gov/media/97321/download>.

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- that FDA has authorized the emergency use of the device;
 - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
 - of the option to accept or refuse use of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.
- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.
 - For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.