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Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (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 is being implemented without prior public comment because the Food and Drug Administration (FDA or Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). 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 COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders (<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 20018 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-SurgicalMasks@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 general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals 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 Public Health Services (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 immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

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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

On January 31, 2020, as a result of confirmed cases of COVID-19, and after consultation with public health officials as necessary, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority under section 319 of the Public Health Service Act (PHS Act), determined that a public health emergency exists and has existed since January 27, 2020, nationwide.¹ On March 13, 2020, President Donald J. Trump declared that the COVID-19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.²

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 clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

III. Scope

There are many products marketed in the United States as “face masks” that offer a range of protection against potential health hazards. Face masks and respirators are regulated by FDA when they meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, face masks fall within this definition when they are intended for a medical purpose, including for use by health care professionals.³ Face masks that are not intended for a medical purpose, are not medical devices, as described in further detail below. FDA-regulated face masks and respirators are listed in Table 1:

¹ Determination that a Public Health Emergency Exists (Jan. 31, 2020), *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

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

³ As used in this guidance “intended for a medical purpose” means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of “device” set forth in section 201(h) of the FD&C Act.

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Table 1

Classification Regulation	Device Type	Product Code⁴
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ

This policy does **NOT** apply to other types of masks including but not limited to those in Table 2.

Table 2

Classification Regulation	Device Type	Product Code
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ
21 CFR 868.5580	Mask, Oxygen	BYG
21 CFR 868.5600	Mask, Oxygen, Low Concentration, Venturi	BYG
21 CFR 868.5570	Mask, Oxygen, Non-Rebreathing	KGB
21 CFR 868.5905	Resuscitator, Manual, Non Self-Inflating	NHK
	Mask, Ventilator, Non-Continuous, Reprocessed	NMC
21 CFR 868.5560	Strap, Head, Gas Mask	BTK

FDA recognizes that, when alternatives, such as FDA-cleared masks or respirators, are unavailable, individuals, including healthcare professionals, might improvise PPE. FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared masks or respirators, are available.

IV. Definitions

For the purposes of this guidance, the following definitions are used.

Face Mask – A mask that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels.

⁴ For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

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Surgical Mask – A mask that covers the user’s nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests⁵.

Filtering Facepiece Respirator – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

N95 Respirator – A disposable half-mask filtering facepiece respirator (FFR) that covers the user’s airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).

NIOSH Approved N95 Respirator – An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

Surgical N95 Respirator – A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is a class II device, regulated by FDA under 21 CFR 878.4040 (FDA product code MSH).

V. Policy

A. Overview

FDA is taking steps to expand the availability of face masks and respirators and believes the policy set forth in this guidance may help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach and clarifying the policies that FDA intends to apply to masks and respirators, including these products’ associated indications and claims.

B. Face Masks and N95 Respirators Not Intended for a Medical Purpose

Face masks and N95 respirators are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act. Under section 201(h) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

Other face masks and filtering facepiece respirators are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is **not** required, and all the other requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of

⁵ CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

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these products.

Face masks and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks and respirators are not devices when they are intended for a non-medical purpose, such as for use in construction. When considering whether these products are intended for a medical purpose, among other considerations, FDA will look at whether:

- 1) they are labeled or otherwise intended for use by a health care professional;
- 2) they are labeled or otherwise for use in a health care facility or environment; and
- 3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

C. Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection

In general, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment (PPE) that should be used during the COVID-19 outbreak⁶. To ensure the availability of equipment that might offer some benefit to health care providers and the general public during the COVID-19 outbreak, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks (not including respirators) that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports or corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830. FDA currently believes such devices would not create an undue risk where:

- The product includes labeling that accurately describes the product as a face mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics);
- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; and
- The product is not intended for any use that would create an undue risk, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses

⁶ https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html

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for infection prevention or reduction or related uses and does not include particulate filtration claims.

D. Surgical Masks Intended to Provide Liquid Barrier Protection

Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability and biocompatibility. FDA does not intend to object where, for the duration of the declared public health emergency, surgical masks are distributed and used without prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, and the surgical masks do not create an undue risk in light of the public health emergency. FDA currently believes such devices would not create an undue risk where:

- The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F1862⁷ Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);
- The product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);
- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body contacting materials (which does not include any drugs or biologics); and
- The product is not intended for any use that would create an undue risk, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, and does not include particulate filtration claims.

VI. FDA's Intended Approach for EUAs for Masks and Respirators

A. EUAs for Reprocessing of Filtering Facepiece Respirators

FDA is responsible for the oversight of reprocessed⁸ single use medical devices and generally

⁷ For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. 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," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁸ The term 'reprocessed', with respect to a single-use device, means an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. See FDA's Guidance "Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices" available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-user-fee-and-modernization-act-2002-validation-data-premarket-notification>.

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requires the submission of a 510(k) from entities performing these activities. To facilitate the safe reuse and conservation of PPE for the duration of the public health emergency, FDA is interested in interacting with manufacturers on the reprocessing of otherwise disposable N95 particulate filtering facepiece respirators (and other Filtering Facepiece Respirators) to facilitate marketing authorization through an emergency use authorization (EUA) for reprocessed devices. FDA recommends that firms contact FDA and provide the following information to CDRH-COVID19-SurgicalMasks@fda.hhs.gov, if available. FDA will work with reprocessors through its EUA process to facilitate expedited evaluation of the request. To help facilitate the pre-EUA discussions, we recommend that you send FDA as much of the following information you have available:

- 1) A description of the process for disinfection/reprocessing controls, including:
 - a) Critical cycle parameters (e.g., concentration, time, heat, relative humidity) required for appropriate bioburden reduction.
 - b) Information on chemical indicators (CI) and biological indicators (BI) used to demonstrate that your cycle is appropriately implemented and continues to be executed as intended. CI and BI should be placed evenly throughout the load to demonstrate that at all areas of a chamber the critical process parameters have been achieved. CI and BI should provide a worst-case challenge to the cycle.
- 2) Validation of bioburden reduction/disinfection, including:
 - a) Evidence to demonstrate a robust ability to reduce bioburden on the masks. FDA recommends this include demonstration of viricidal activity (≥ 3 -log reduction) as well as either mycobactericidal (≥ 6 -log reduction) or sporicidal (≥ 6 -log reduction) activity. FDA also recommends demonstration of mycobactericidal or sporicidal activity because pathogens may be present on masks and reuse of masks between different users may increase unintended transmission of COVID-19 or other pathogens. For viricidal activity testing, FDA recommends submitting data demonstrating that the process is effective against multiple viral pathogens, specifically coronaviruses (e.g., the coronaviruses causing Sudden Acute Respiratory Syndrome [SARS], Middle East Respiratory Syndrome [MERS], transmissible gastroenteritis coronavirus [TGEV]). FDA also recommends demonstration of mycobactericidal or sporicidal activity because pathogens may be present on masks and reuse of masks between different users may increase unintended transmission of COVID-19 or other pathogens.
 - b) Evidence to demonstrate that soils (e.g., blood, mucus, sebum) are either removed or do not interfere with the bioburden reduction/disinfection processes. This information is important as it may limit the ability of masks contaminated with certain soils to undergo a specific process. For example, blood will rapidly degrade hydrogen peroxide. Therefore, masks soiled with blood should not undergo disinfection with hydrogen peroxide.
 - c) Protocols and acceptance criteria for scale-up of the process, if applicable.
- 3) Description of chain of custody and safeguards to prevent inadvertent exposure, including:
 - a) Details regarding the chain of custody of the soiled masks from the point of collection in the healthcare facility, to the reprocessing facility, through the reprocessing cycle, repackaging, and distribution back to the healthcare facility.
 - b) A description of the safety considerations through each step. At the facility where reprocessing will occur, also include a description of the safety considerations which will be in effect, including but not limited to the following:

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- i) What are the PPE requirements for personnel reprocessing respirators?
- ii) Will this be performed under biosafety level (BSL) 2 or BSL-3 conditions?
- iii) If this will occur under BSL-2 conditions, are there any additional precautions which will be implemented?
- iv) Will personnel performing reprocessing be routinely screened for COVID-19 to ensure that personnel have not been exposed due to reprocessing and that reprocessed masks are not contaminated by personnel?
- c) Describe how the respirators will be handled to ensure they are not contaminated or mixed with masks to be disinfected after masks have been disinfected/undergone the proposed reprocessing steps.
- 4) Material compatibility, including:
 - a) Evidence to demonstrate that the materials used in both the filters and the straps (elastic bands) are compatible with the proposed reprocessing cycle steps.
 - b) Identification of any mask materials known to be incompatible with your method of reprocessing. For example, cellulose-based materials are incompatible with hydrogen peroxide as hydrogen peroxide will degrade cellulose.
 - c) Evidence to demonstrate that the reprocessing residues remaining on the reprocessed respirator are insignificant to cause a health hazard or deleterious effect to the user.
 - d) Identification of the number of times a respirator may be reprocessed by the proposed method and a method for tracking the number of reprocessing cycles to which the mask has been exposed. If you are proposing to mark the mask during the reprocessing cycle to track the number of cycles a mask has undergone, FDA recommends including data to demonstrate that the markings are indelible (e.g., will not deface, smudge, change color, otherwise be removed) on the mask or strap surface.
 - e) Identification of the number of repeated cycles that the mask and the straps (elastic bands) can withstand.
- 5) Filtration performance:
 - a) Evidence to demonstrate that repeated exposure to reprocessing cycles does not interfere with the filtration ability or breathability of the masks.
- 6) Fit test data:
 - a) Evidence to demonstrate that repeated exposure to your reprocessing cycle steps does not decrease the ability of the mask to form a tight fit to the wearer's face.
 - b) Evidence to demonstrate that the reprocessing cycle steps do not compromise the integrity of the elastic bands to maintain an appropriate fit to the wearer.
- 7) A copy of the reprocessed device product labeling, which FDA recommends should:
 - a) Clearly state the mask is reprocessed.
 - b) Identify how many times the mask may be reprocessed.
 - c) Advise users to discard masks that are visibly damaged or that fit poorly and not reprocess.
 - d) Identify materials (including filter and strap/elastic band) that are incompatible with your proposed reprocessing cycle.

B. EUAs for Face Masks Intended for a Medical Purpose, Surgical Face Masks and N95 Respirators

Wherever possible, health care facilities should continue to use FDA-cleared face masks and NIOSH-approved and/or FDA-cleared N95 respirators or better. In response to the COVID-19

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pandemic, FDA has also issued EUAs that authorize certain N95 Filtering Facepiece Respirators, including NIOSH-approved disposable FFRs⁹ and imported non-NIOSH-approved disposable FFRs¹⁰, for use in healthcare settings by healthcare personnel and are intended to help increase availability of these devices to front-line personnel during the public health emergency.

For devices that do not fall within the scope of the March 2, 2020 or March 24, 2020 EUAs, FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-SurgicalMasks@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 such as the information outlined below. FDA will expeditiously review this information, and other required information¹¹, to determine whether the device can be authorized under an EUA.

- 1) For current face mask and respirator 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 (including certification number, if available).
 - d. 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.
 - e. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate. For surgical N95 respirators, FDA recommends including fluid resistance testing (liquid barrier performance).

- 2) For face mask 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 face masks and respirators. This may include US manufacturers in other manufacturing sectors. These

⁹ <https://www.fda.gov/media/135763/download>.

¹⁰ <https://www.fda.gov/media/136403/download>.

¹¹ See Section 564 of the FD&C Act.

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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 face mask or filtering facepiece respirator (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 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—
 - 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 administration 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.