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# **Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency**

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## **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 <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> 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](mailto:CDRH-Guidance@fda.hhs.gov) to receive a copy of the guidance. Please include the document number 20020 and complete title of the guidance in the request.

## Questions

For questions about this document, contact 1-888-INFO-FDA or [CDRH-COVID19-PPE@fda.hhs.gov](mailto:CDRH-COVID19-PPE@fda.hhs.gov).

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# Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

## 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 the Agency) plays a critical role in protecting the United States from threats such as 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 surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves 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 HHS Secretary in accordance with section 319(a)(2) of the Public Health Services (PHS) Act.

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, 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)

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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.

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 "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.<sup>1</sup> In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.<sup>2</sup>

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 gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

## **III. Scope**

There are many products marketed in the United States as gowns, other apparel, and gloves<sup>3</sup> that offer a range of protection against potential health hazards. Gowns, other apparel, and gloves are regulated by FDA when they meet the definition of a device under section 201(h) of the FD&C Act.

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

<sup>2</sup> 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/>.

<sup>3</sup> For the purposes of this guidance, the terms "gowns," "other apparel," and "gloves" refer to products that may or may not meet the definition of a device under section 201(h) of the FD&C Act. Non-surgical gowns, surgical gowns, other surgical apparel, surgeon's gloves, and patient examination gloves are subsets of these three terms and include products that meet the definition of a device under section 201(h) of the FD&C Act.

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Generally, gowns, other apparel, and gloves fall within this definition when they are intended for a medical purpose, including for use by health care professionals.<sup>4</sup> Gowns, other apparel, and gloves that are not intended for a medical purpose, are not medical devices, as described in further detail below.

Gowns and other apparel are products intended to protect the wearer from the transfer of materials in the wearer’s environment. Gloves are products worn on a hand or finger to protect the wearer from the transfer of materials in the wearer’s environment.

The classification regulation and associated product codes for FDA-regulated gowns and other apparel<sup>5</sup> to which the policies in this guidance apply are listed in Table 1:

**Table 1**

<b>Classification Regulation</b>	<b>Device Type</b>	<b>Product Code<sup>6</sup></b>	<b>Class</b>
21 CFR 878.4040	Conductive Shoe and Shoe Cover	BWP	I (exempt)
21 CFR 878.4040	Operating-Room Shoes	FXW	I (exempt)
21 CFR 878.4040	Surgical Apparel Accessory	LYU	I (exempt)
21 CFR 878.4040	Non-surgical isolation gowns	OEA	I (exempt)
21 CFR 878.4040	Surgical suits	FXO	I (exempt)
21 CFR 878.4040	Operating-room shoe covers	FXP	I (exempt)
21 CFR 878.4040	Surgical helmets	FXZ	I (exempt)
21 CFR 878.4040	Surgical dress	FYE	I (exempt)
21 CFR 878.4040	Surgical caps	FYF	I (exempt)
21 CFR 878.4040	Surgical gown/toga	FYA	II
21 CFR 878.4040	Patient gown	FYB	II
21 CFR 878.4040	Surgical isolation gown	FYC	II
21 CFR 878.4040	Surgical hood	FXY	II

FDA-regulated gloves<sup>7, 8</sup> to which the policies in this guidance apply are listed in Table 2:

**Table 2**

<b>Classification Regulation</b>	<b>Device Type</b>	<b>Product Code</b>	<b>Class</b>
21 CFR 880.6250	Patient examination glove	FMC	I (reserved)

<sup>4</sup> 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.

<sup>5</sup> For further clarification regarding the current requirements for FDA-regulated gowns and other apparel, refer to Sections IV.C-D below.

<sup>6</sup> For more information see the Product Classification Database at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

<sup>7</sup> For further clarification regarding the current requirements for FDA-regulated gloves, refer to Sections V.C-D below.

<sup>8</sup> Powdered surgeon’s and patient examination gloves are banned devices under 21 CFR 895.102 and 895.103 and are outside the scope of this guidance.

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21 CFR 880.6250	Latex Patient Examination Glove	LYY	I (reserved)
21 CFR 880.6250	Polymer Patient Examination Glove	LZA	I (reserved)
21 CFR 880.6250	Finger Cot	LZB	I (exempt)
21 CFR 880.6250	Vinyl Patient Examination Glove	LYZ	I (reserved)
21 CFR 880.6250	Powder-Free Guayle Rubber Examination Glove	OIG	I (reserved)
21 CFR 880.6250	Powder-Free Polychloroprene Patient Examination Glove	OPC	I (reserved)
21 CFR 880.6250	Radiation Attenuating Medical Glove	OPH	I (reserved)
21 CFR 880.6250	Specialty Patient Examination Glove	LZC	I (reserved)
21 CFR 878.4460	Surgeon's Gloves	KGO	I (reserved)
21 CFR 878.4460	Powder-Free Non-Natural Rubber Latex Surgeon's Gloves	OPA	I (reserved)

This guidance does not apply to face masks or filtering facepiece respirators, which are addressed in the guidance “[Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency.](#)”<sup>9</sup>

FDA recognizes that when alternatives, such as FDA-cleared gowns, other surgical apparel, and/or gloves, are unavailable, individuals, including healthcare professionals, might improvise personal protective equipment (PPE). FDA does not intend to object to individuals' distribution and use of improvised PPE when no alternatives, such as FDA-cleared gowns, other surgical apparel, and/or gloves, are available.

## **IV. Policy for Gowns and Other Apparel**

### **A. Overview**

FDA is taking steps to help expand the availability of gowns and other apparel 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 gowns and other apparel, including these products' associated indications and claims.<sup>10</sup>

For the purposes of this guidance document:

Minimal or Low Barrier protection refers to:

<sup>9</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-face-masks-and-respirators-during-coronavirus-disease-covid-19-public-health>.

<sup>10</sup> FDA has also sent two letters to healthcare providers that discussed conservation strategies for surgical gowns and gloves during the COVID-19 public health emergency. For more information, these letters are available at: <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers> and <https://www.fda.gov/medical-devices/letters-health-care-providers/medical-glove-conservation-strategies-letter-health-care-providers>.

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- ANSI/AAMI PB70<sup>11, 12</sup> Level 1 protection or equivalent; or
- ANSI/AAMI PB70 Level 2 protection or equivalent.

Moderate or High Barrier protection refers to:

- ANSI/AAMI PB70 Level 3 protection or equivalent; or
- ANSI/AAMI PB70 Level 4 protection or equivalent.

## **B. Gowns and Other Apparel Not Intended for a Medical Purpose**

Gowns and other apparel 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 gowns and other apparel 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, when marketed for these non-medical applications, 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 these products.

Gowns and other apparel are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Gowns and other apparel are not devices when they are intended for a non-medical purpose, such as for use in manufacturing or research and development. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider 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. Non-surgical Gowns and Minimal-to-Low Barrier Protection Surgical Apparel**

As set forth in the guidance, “[Premarket Notification Requirements Concerning Gowns Intended for](#)

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<sup>11</sup> ANSI/AAMI PB70: *Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.*

<sup>12</sup> 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>.

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Use in Health Care Settings,”<sup>13</sup> it is the current view of the Agency that a gown that is not intended for use as a “surgical gown” is a class I device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act. Minimal-to-low barrier protection surgical apparel such as shoe covers, caps, and surgical suits are also class I exempt devices pursuant to 21 CFR 878.4040(b)(2).

When evaluating whether a gown under 21 CFR 878.4040(b) is not a “surgical gown,” FDA will consider whether:

- it is labeled as a gown other than a surgical gown (e.g., isolation gown);
- it is not described in its labeling as a surgical gown; and
- it includes statements relating to barrier protection, and such statements are for only minimal or low barrier protection (e.g., ANSI/AAMI PB70 barrier protection Level 1 or 2).

An example of devices that FDA considers to be non-surgical gowns includes gowns that are intended to protect the wearer from the transfer of microorganisms and bodily fluids in low- or minimal-risk patient isolation situations and that are not intended for use during surgical procedures, invasive procedures, or when there is a medium or high risk of contamination.

In the circumstances described above the labeling or descriptions of the device, along with any minimal or low barrier protection (or no barrier protection) claims, may be considered by FDA as evidence that its intended use is as a non-surgical gown. As set forth in prior Agency guidance, such a gown is considered to be a class I device, exempt from premarket notification requirements pursuant to 21 CFR 878.4040(b)(2), and subject to the limitations of exemptions in 21 CFR 878.9, as “surgical apparel other than surgical gowns and surgical masks.”<sup>14</sup> The device is considered to be a class I exempt device because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and the device is not intended for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, under sections 513(a)(1)(A) and 510(l)(1) of the FD&C Act.

In general, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment that should be used during the COVID-19 outbreak.<sup>15</sup> Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.<sup>16</sup> FDA recognizes the urgent need during the COVID-19 public health emergency for gowns not intended for use as “surgical gowns” and other minimal-to-low-barrier protection surgical apparel due to increased use and demand which has caused shortages in their availability.

As noted above, gowns not intended for use as “surgical gowns” and other minimal-to-low barrier

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<sup>13</sup> <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings>.

<sup>14</sup> See “Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings>.

<sup>15</sup> <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

<sup>16</sup> See 29 CFR 1910 subpart I.

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protection surgical apparel are not subject to premarket notification requirements; however, they are subject to general controls. To help foster the availability of these types of gowns and apparel during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of gowns not intended for use as “surgical gowns” and other low-to-minimal barrier protection surgical apparel that does not comply with the following regulatory requirements where the gowns and apparel do not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR Part 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a “gown,” or “toga,” or other apparel (as opposed to a “surgical gown,” or “surgical toga”) 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 a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected, use in a clinical setting where Level 3 or 4 protection is warranted, and use in the presence of high intensity heat source or flammable gas; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, 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.

### **D. Moderate-to-High Barrier Protection Surgical Gowns**

When evaluating the classification of a gown under 21 CFR 878.4040(b), per FDA guidance,<sup>17</sup> FDA will consider whether:

- it is labeled as such;
- it is described as such in its labeling;
- it has statements relating to moderate or high-level barrier protection; and/or
- it has statements that it is intended for use during sterile procedures.

An example of devices FDA considers to be “surgical gowns” includes gowns that are intended for use in health care settings requiring moderate or high liquid barrier protection levels (e.g., ANSI/AAMI PB70 barrier protection Level 3 or 4) and that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material in moderate- or high-risk situations.

In these circumstances, the terminology (e.g., “surgical gown” or “surgical isolation gown”); description in the gown’s labeling (e.g., “this gown is suitable as a surgical gown”); and/or Level 3 or

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<sup>17</sup> See “Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings,” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-notification-requirements-concerning-gowns-intended-use-health-care-settings>.

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4 barrier protection claims, may be considered by FDA as evidence that the gown is intended for use as a “surgical gown” (which includes “surgical isolation gown”). Surgical gowns are considered class II devices under 21 CFR 878.4040(b)(1) and are subject to premarket notification requirements pursuant to section 501(k) of the FD&C Act. The Agency considers gowns that claim moderate to high level barrier protection, such as ANSI/AAMI PB70 Level 3 or 4, to be a higher risk device than those that claim minimal or low levels of barrier protection, such as ANSI/AAMI PB70 Level 1 or 2. Because of such devices’ substantial importance in preventing impairment of human health, the Agency considers such gowns to be “surgical gowns” within the meaning of 21 CFR 878.4040(b)(1).

Statements in the labeling that a gown is a surgical gown (which includes “surgical isolation gown”) provide strong evidence that the gown is a “surgical gown,” as that term is used in 21 CFR 878.4040(b)(1), even if there are claims that the gown only provides minimal or low barrier protection.

In general, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment that should be used during the COVID-19 outbreak.<sup>18</sup> Health care employers must also comply with standards of OSHA that require PPE to protect workers and that apply to infectious disease hazards.<sup>19</sup> FDA recognizes the urgent need during the COVID-19 public health emergency for moderate-to-high barrier protection surgical gowns due to increased use and demand which has led to shortages in their availability. To ensure the availability of these types of surgical gowns during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not comply with the following regulatory requirements, where such surgical gowns do 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,<sup>20</sup> Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product:
  - Meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70 for the critical zone areas;<sup>21</sup>
  - Meets the Class I or Class II flammability standard per 16 CFR Part 1610; and
  - Has been demonstrated to be sterile if intended for use in surgical settings.<sup>22</sup>

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<sup>18</sup> CDC’s recommendations on the use of PPE during the COVID-19 outbreak are available at <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

<sup>19</sup> See 29 CFR 1910 subpart I.

<sup>20</sup> 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>.

<sup>21</sup> Because of the controlled nature of surgical procedures, “critical zone areas” of protection have been described by voluntary consensus standards. Depending on the type of gown, the critical zones will be in different places on the device.

<sup>22</sup> See the FDA guidance document “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,” available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled> for more information about sterility information for devices subject to premarket notification.

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- The product includes labeling that accurately describes the product’s sterility status (sterile or non-sterile), including any sterilization method used, barrier protection as Level 3, flammability classification (Class I or Class II), and a list of the body contacting materials;
- The product includes labeling with general statements and makes recommendations that would sufficiently reduce the risk of use, for example, a general statement about devices that have not been cleared by FDA, recommendations against use when FDA-cleared surgical gowns are available, and recommendations against use of non-sterile products in surgical settings; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection; uses for infection prevention or reduction; or is labeled as having ANSI/AAMI PB70 Level 4 liquid barrier protection.

## **V. Policy for Gloves**

### **A. Overview**

FDA is taking steps to help expand the availability of gloves 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 gloves.

### **B. Gloves Not Intended for a Medical Purpose**

Gloves 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 gloves 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 these products.

Gloves are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Gloves are not devices when they are intended for a non-medical purpose, such as for use in construction. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider 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. Patient Examination Gloves**

A non-powdered patient examination glove is a disposable device intended for a medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.<sup>23</sup> A non-powdered patient examination glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

These devices are class I (reserved) and subject to premarket notification requirements under section 510(k) of the FD&C Act because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and the devices are intended for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, under sections 513(a)(1)(A) and 510(l)(1) of the FD&C Act.

In general, FDA recommends that health care providers follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-19 outbreak.<sup>24</sup> Health care employers must also comply with standards of OSHA that require PPE to protect workers and that apply to infectious disease hazards.<sup>25</sup> FDA recognizes the urgent need during the COVID-19 public health emergency for patient examination gloves due to increased use and demand which has led to shortages in their availability. To help ensure the availability of these devices during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of patient examination gloves that do not comply with the following regulatory requirements, where the gloves do 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,<sup>26</sup> Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, reports of corrections and removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as an “unpowdered glove” (as opposed to a surgeon’s or patient examination glove), accurately describes its sterility status when individually packaged (non-sterile), does not claim the product as being free of a specific material (e.g., latex free), and includes a list of the body contacting materials;
- The product includes labeling with general statements and makes recommendations that would reduce sufficiently the risk of use, for example, a general statement about devices that have not been cleared by FDA and recommendations against use: when FDA-cleared gloves are available, in surgical settings or where significant exposure to liquid bodily or other hazardous fluids may be expected, and in clinical settings where the infection risk level is

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<sup>23</sup> See 21 CFR 880.6250.

<sup>24</sup> CDC’s recommendations on the use of PPE during the COVID-19 outbreak are available at <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

<sup>25</sup> See 29 CFR 1910 subpart I.

<sup>26</sup> 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>.

## *Contains Nonbinding Recommendations*

high; and

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses with chemotherapy drugs, fentanyl, and other opioids, uses for allergy or dermatitis prevention, uses for antimicrobial or antiviral protection, or uses for infection prevention or reduction.<sup>27</sup>

### **D. Surgeon's Gloves**

A non-powdered surgeon's glove is a device intended to be worn on the hands of operating room personnel to protect a surgical wound from contamination.<sup>28</sup> A non-powdered surgeon's glove does not incorporate powder for purposes other than manufacturing. The final finished glove includes only residual powder from manufacturing.

These devices are class I (reserved) and subject to premarket notification requirements under section 510(k) of the FD&C Act because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and the devices are intended for a use which is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury, under sections 513(a)(1)(A) and 510(l)(1) of the FD&C Act.

In general, FDA recommends that health care providers follow current CDC guidance regarding PPE that should be used during the COVID-19 public health emergency.<sup>29</sup> Health care employers must also comply with standards of OSHA that require PPE to protect workers and that apply to infectious disease hazards.<sup>30</sup> FDA recognizes the urgent need during the COVID-19 public health emergency for surgeon's gloves due to increased use and demand which has led to shortages in their availability. To help ensure the availability of these devices during the COVID-19 public health emergency, FDA does not intend to object to the distribution and use of surgeon's gloves that do not comply with the following regulatory requirements where the surgeon's gloves do 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,<sup>31</sup> Registration and Listing requirements in 21 CFR 807, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product meets the standard specification consistent with the consensus standard ASTM D3577: *Standard Specification for Rubber Surgical Gloves*;
- The product includes labeling that accurately describes the product as being unpowdered, accurately describes its sterility status (sterile) and the sterilization method used, does not

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<sup>27</sup> Gloves are subjected to additional performance testing in support of such uses. For example, gloves that are for uses with chemotherapy drugs are typically tested to ASTM D6978: *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*. The absence of such supporting testing would create an undue risk in light of the public health emergency.

<sup>28</sup> See 21 CFR 878.4460.

<sup>29</sup> <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>.

<sup>30</sup> See 29 CFR 1910 subpart I.

<sup>31</sup> 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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claim the product as being free of a specific material (e.g., latex free), and includes a list of the body contacting materials;

- The product includes labeling with general statements and makes recommendations that would reduce sufficiently the risk of use, for example, a general statement about devices that have not been cleared by FDA and recommendations against use when FDA-cleared surgeon's gloves are available; and
- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses with chemotherapy drugs, fentanyl, and other opioids, uses for allergy or dermatitis prevention, uses for antimicrobial or antiviral protection, or uses for infection prevention or reduction.<sup>32</sup>

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<sup>32</sup> Gloves are subjected to additional performance testing in support of such uses. For example, gloves that are for uses with chemotherapy drugs are typically tested to ASTM D6978: *Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs*. The absence of such supporting testing would create an undue risk in light of the public health emergency.