Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies

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Food and Drug Administration
Center for Devices and Radiological Health

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Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to **Regulations.gov (http://www.regulations.gov)**. Please identify your comments with the docket

number listed in the notice of availability that publishes in the Federal Register announcing the availability of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. 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 use the document number 1626 to identify the guidance you are requesting.

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Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies

1. Introduction

This guidance document was developed as a special control guidance to support the classification of the filtering facepiece respirator for use by the general public in public health medical emergencies into class II (special controls). The device is a disposable half-facepiece 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. This guidance is issued in conjunction with a Federal Register notice announcing the classification of the filtering facepiece respirator for use by the general public in public health medical emergencies.

Following the effective date of the final rule classifying the device, any firm submitting a premarket notification (510(k)) for a filtering facepiece respirator for use by the general public in public health medical emergencies will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness. Further, the device must meet the additional special control specified in the classification regulation. (See **Section 4. Scope**)

The firm must show that its device addresses the issues of safety and effectiveness identified in this guidance, either by meeting the recommendations of this guidance or by some other means that provides equivalent assurances of safety and effectiveness.

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The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to follow the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "**A Suggested Approach to Resolving Least Burdensome Issues (/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm)**" document.

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2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of the filtering facepiece respirator for use by the general public in public health medical emergencies. Thus, a manufacturer who intends to market a device of this generic type must (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements

described in 21 CFR 807 Subpart E, (2) address the issues of safety and effectiveness presented by a filtering facepiece respirator for use by the general public in public health medical emergencies that require special controls, as identified in this guidance, (3) satisfy the other special control designated in 21 CFR 880.6260, the classification regulation for this type of device, and (4) obtain a substantial equivalence determination from FDA prior to marketing the device.

This special control guidance document identifies the classification regulation and product code for the filtering facepiece respirator for use by the general public in public health medical emergencies(Please refer to **Section 4. Scope)**. In addition, other sections of this special control guidance document list issues requiring special controls identified by FDA and describe measures that, if followed by manufacturers and combined with the other special control designated for this device type and the general controls, will help to provide a reasonable assurance of the safety and effectiveness of the filtering facepiece respirator for use by the general public in public health medical emergencies. All recommendations in this document apply solely to filtering facepiece respirators for use by the general public in public health medical emergencies, and unless specifically indicated otherwise, all references to "respirators" in this document refer only to filtering facepiece respirators intended for use by the general public in public health medical emergencies. This document supplements other FDA documents regarding the content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87, **Format for Traditional and Abbreviated 510(k)s**,[1] and "**How to Prepare a 510(k) Submission**" on FDA Device Advice.[2]

As described in the guidance document entitled, **The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)**, a manufacturer may submit a Traditional 510(k) or has the option of submitting either an Abbreviated 510(k) or a Special 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Manufacturers considering certain modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

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3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g);

therefore, we recommend that you include a summary report. The report should describe how this special control guidance document was used during the device development and testing and should briefly describe the methods or tests used and a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of section 807.87 as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed Labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Please refer to **Section 10. Labeling**for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary Report

We recommend the summary report contain the following:

Description of the device and its intended use

We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Please refer to **Section 5. Device Description** for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[3]

Description of device design requirements

We recommend that you include a brief description of the device design requirements.

Identification of the risk analysis method

We recommend that you identify the Risk Analysis method(s) you used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Please refer to **Section 6. Issues Requiring Special Controls** for the issues influencing the safety and effectiveness of this device that FDA has identified.)

Discussion of the device characteristics

We recommend that you discuss the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

Description of the performance aspects

We recommend that you include a brief description of the test method(s) you have used or intend to use to address each performance aspect identified in **Sections 7, 8, & 9** of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[4] (See also 21 CFR 820.30, Subpart C - Design Controls for the Quality System Regulation.)

Reliance on standards

If you choose to rely on a recognized standard for any part of the device design or testing, you may include either a:

- statement that testing will be conducted and meet specified acceptance criteria before the device is marketed; or
- declaration of conformity to the standard.[5]

Because a declaration of conformity is based on results from testing, we believe you cannot properly submit a declaration of conformity until you have completed the testing the standard describes. For more information, please refer to section 514(c)(1)(B) of the Act and the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073752.htm)**.

If it is not clear how you have addressed the issues identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions. Manufacturers considering certain modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for a filtering facepiece respirator for use by the general public during medical emergencies.

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4. Scope

The scope of this document is limited to the following class II device, described in 21 CFR 880.6260 (product code NZJ):

21 CFR 880.6260 Filtering facepiece respirator for use by the general public in public health medical emergencies

Identification. A filtering facepiece respirator for use by the general public in public health medical emergencies is a device that is a disposable half-facepiece 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 during a public health medical emergency. These devices are made of polymeric materials and are intended to fit closely to the face and to function by filtering particulate material.

In addition to this guidance document, these devices are subject to a special control requiring certification by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84. (21 CFR 880.6260(b)(1)). This additional special control is discussed in section 7 of this guidance.

Respirators intended for surgical use are included in 21 CFR 878.4040 and are not within the scope of this guidance.

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5. Device Description

We recommend that you identify your device by the regulation and product code described in section 4, Scope. We recommend that you compare your device to the predicate device. We recommend that you provide information to show how the new device is both similar to and different from the legally marketed predicate device. Side by side comparisons, whenever possible, are desirable. We also recommend that you describe how any differences may affect the comparative

safety and performance of your new device. We recommend that you describe the material composition of the respirator. A description of material composition should include the following, if applicable:

Type of fabric, e.g.

- polypropylene
- spunbonded, meltblown or wetlaid.

Other materials:

- metals, if used in nose features
- chemical additives (we recommend you provide the material safety data sheet (MSDS) for each chemical additive used)
- elastic materials, if used in headbands.

We also recommend you provide the following information describing your device:

- size(s)
- dimensions
- mask style, such as cone shaped, duck bill, or other
- elastic band or other attachment.

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6. Issues Requiring Special Controls

FDA believes that special controls are needed to help address the following issues affecting the safety and effectiveness of the filtering facepiece respirator for use by the general public in public health medical emergencies.

A. Assuring filtration and breathability

For this type of respirator to reduce wearer exposure to pathogenic biological airborne particulates, it needs to be made of filter material that is highly efficient in filtering such particles. At the same time, because this type of device depends on the wearer's normal respiration to draw ambient air through the respirator materials and into the lungs, the respirator material should also permit adequate respiration.

B. Assuring proper fit

The device should fit closely to the wearer's face without any gaps that would allow air to reach the wearer's respiratory tract without passing through the filter material. Otherwise, improper fit of the respirator could result in inhalation of pathogenic biological airborne particulates carried in air that passes around the sides of the device.

C. Avoiding adverse skin reaction

Reducing wearer exposure to pathogenic biological airborne particulates requires that the device be properly fitted to the face. If the respirator material in contact with the skin is not biocompatible, it may cause adverse reactions such as redness, pruritus, and skin irritation.

D. Assuring proper use

While a filtering facepiece respirator for use by the general public in public health medical emergencies can help to reduce wearer exposure to pathogenic biological airborne particulates in a public health medical emergency where there is a serious risk from such exposure, these devices do not provide complete protection against infection. Even when used correctly and consistently, a filtering facepiece respirator does not eliminate all respiratory exposure, and for many pathogens that may be transmitted through airborne particulates, transmission via other routes is also possible. (Because filtering facepiece respirators for use by the general public in public health medical emergencies have not been tested against specific microorganisms, the extent of protection to be expected against specific pathogens is not known and would vary with particular conditions in any event.)

The respirator should always be used in conjunction with other infection control and respiratory protection measures. In addition, because the outside of the respirator may be contaminated with infectious materials during normal use, proper handling and disposal is important to avoid the respirator itself becoming a vector of transmission of infectious agents.

Further, failure of the user to assure proper fit of the respirator could result in exposure to pathogenic biological airborne particles. Certain populations such as children will be unlikely to achieve a proper fit because respirators are designed and sized for adults.

For users with certain underlying cardiac, pulmonary or related medical conditions, achieving the fit necessary to help reduce their exposure to pathogenic biological airborne particulates may unduly exacerbate their underlying medical conditions raising a concern about their safe use for these populations.

Finally, these respirators have not been established to be safe or effective if reused, and use of a single respirator by multiple users may result in adverse health consequences as the respirator itself may serve as a vector of transmission.

FDA has identified measures that address each of the issues identified above, to help provide a reasonable assurance of the safety and effectiveness of the device. In Table 1, FDA briefly summarizes the issues and recommended measures for addressing each, as further discussed in this guidance document. In addition to the measures recommended in this guidance, the classification regulation for this type of device specifies an additional special control intended to address some of these issues, indicating that a device within this type must be certified by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84, See 21 CFR 880.6260(b)(1). This special control requirement is further discussed in Section 7 of this guidance document.

Table 1 – Issues Requiring Special Control and Recommended Mitigation Measures

Identified Issues	Mitigation Measures
Assuring filtration and breathability	NIOSH Certification (21 CFR 880.6260(b)(1) and Section 7)
Assuring proper fit	Fit Assessment testing (Section 8) Labeling (Section 10)
Avoiding adverse skin reaction	Biocompatibility testing (Section 9)
Assuring proper use	Labeling(Section 10)

Before submitting your 510(k), you should also conduct a risk analysis to identify any other risks specific to your device. The 510(k) should describe the risk analysis method and include the results. If you elect to use an alternative approach to address a particular issue identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

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7. NIOSH Certification

To help assure filtration of pathogenic biological airborne particulates as well as breathability of the respirator, FDA regulations at 21 CFR 880.6260(b)(1) require as a special control that your device be certified by the National Institute for Occupational Safety and Health (NIOSH) as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95, in accordance with 42 CFR part 84.[6] The respirators that were the subject of the initial classification order establishing this classification and that are the initial legal predicate devices under it were certified by NIOSH under these requirements, as revised as of October 1, 2006. FDA's determination that NIOSH certification is an appropriate special control to help assure the safety and effectiveness of the respirator for its intended use under this classification rests on the assurance of filtration efficiency and breathability provided by NIOSH certification under these requirements, as effective on May 8, 2007, the date of FDA's classification order. Should NIOSH

revise the requirements for certification in the future, FDA will evaluate whether certification under such revised NIOSH regulations is an appropriate special control for devices within this classification and may revise FDA's regulation using appropriate procedures.

NIOSH's regulations for certification of respirators require that the respirator pass NIOSH-administered testing establishing that the filter media filters at least 95% of a test particle aerosol which has been established to be of the most penetrating type.[7] This high level of filtration efficiency helps to reduce wearer exposure to pathogenic biological airborne particulates, reducing risk in a public health medical emergency when the nature and concentration of the pathogen may not be known. At the same time, NIOSH certification also ensures that the critical balance between filtration and breathability is maintained by establishing maximum airflow resistance for the respirator,[8] ensuring that wearers can maintain adequate respiration. You should include a copy of the NIOSH certification letter for your respirator in your submission.[9]

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8. Fit Assessment

As previously noted, the reduction in wearer exposure provided by a respirator for use by the general public is dependent upon having a respirator that is designed to fit closely to the face and is correctly donned and worn, as well as on the filtration efficiency of the respirator. In order to address the need for proper fit, we recommend that you conduct a fit assessment and address respirator donning and fit instructions in your labeling (see **Section 10. Labeling**, below). For the fit assessment, FDA recommends that you evaluate the fit characteristics of your device in a panel of subjects who adequately represent the intended users of your device, consistent with your proposed labeling. FDA recommends the use of a panel of test subjects defined for this purpose whose characteristics and utility are supported by published scientific studies. Examples of test panels include the Bivariate Panel, recently described by NIOSH's National Personal Protective Technology Laboratory (NPPTL), and the older Los Alamos National Laboratory Panel.[10],[11] If you use another panel or a panel modified from its original description, you should describe the differences in the test panel, the scientific justification for the different panel composition and explain how these differences allow the modified panel to adequately represent the intended users of your device.

The size of the test panel should be adequate to provide a valid statistical analysis of your performance test results. The panel subjects should have no prior experience wearing occupational respirators and should never have undergone occupational respirator training or fit testing[12] before you conduct fit assessment testing of your respirator with them, because their performance is intended to represent that of the general public. Members of the public are not expected to have had such occupational respirator fit training and testing prior to using your respirator. FDA recommends that the test panel subjects be provided with the intended labeling for your device that

contains instructions for donning and use of your respirator. The test subjects should be asked to read these instructions carefully and then should don the respirator and undergo quantitative fit evaluation.

FDA recommends that the fit characteristics and performance of your respirator be evaluated with a quantitative fit test method that has been well described in published scientific articles.[13] The quantitative fit test method used should have well-defined performance characteristics and its outcome/error rate (errors being the risk of incorrectly identifying pass/fail rates for correct fit tests) should be described in the scientific literature. FDA recommends that the fit factor measurements be obtained by following the general fit testing procedure described in 29 CFR 1910.134, Appendix A, Part 1, A, with the exception of the grimace exercise. The number of test replicates for each subject should be based on the scientific literature on fit testing. FDA recommends triplicate testing or more of each test subject. Several recent studies of N95 respirator performance from the National Personal Protective Technology Laboratory of NIOSH have found the PortaCount Plus with the N95 Companion from TSI to be a suitable method for fit testing.[14],[15]

For each filtering facepiece respirator model that you test, FDA recommends that you identify the fraction of the population who achieved various Fit Factor levels[16] in all fit tests such as Fit Factors of 5 or 10 when a respirator is selected and donned in accordance with your instructions which should include instructions for a user seal check.

FDA recommends that you perform a statistical analysis of your fit test results and describe the degree of variation and their confidence intervals. We recommend that you use the performance data to calculate the percentage of subjects who obtain specified fit factors for at least 95% of the donnings and present your results, percent time and users, along with the 95% confidence interval for a Fit Factor of 2, 5, 10, 50 and 100. A tabular format is desirable, as shown in Appendix A. The rationale and methodology for the recommended analysis are also explained in Appendix A.

The variability among measurements of the fit factor can be divided into two components: between-subject and within-subject. The between-subject variability stems from the heterogeneity of the population of potential users with respect to individual characteristics that affect the performance of a respirator. The within-subject variability refers to the fluctuation over repeated measurements in the level of protection that a given user receives. We recommend you take into account these two sources of variability in a quantitative analysis of fit factor measurements. See Appendix A for the statistical approach FDA recommends.

You should provide an explanation of how the fit test performance in your test population demonstrates that the respirator will help reduce wearer exposure to pathogenic biological airborne particulates for wearers of your device. Please address the degree of variation in your fit factor test results in your explanation. If any test subject fails to obtain at least a Fit Factor of 2, this may suggest that respirator fit will not be sufficient to assure that the device will help reduce wearer exposure to pathogenic biological airborne particulates.

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9. Biocompatibility Testing

In order to address the identified risk of adverse skin reaction, FDA recommends you evaluate the biocompatibility of the respirator materials as described in the FDA guidance, **Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing**[17], for limited contact devices, contacting intact skin. You should select tests appropriate to the duration and level of contact of your device. If identical materials and identical material processing are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of providing biocompatibility testing. The presence of chemical additives in respirator material can change the reactivity of the material in biocompatibility testing. If a submission includes respirator materials with different chemical additives from those used in the predicate device, you should perform biocompatibility testing for each material containing a new chemical additive.

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10. Labeling

Respirators for use by the general public in public health medical emergencies are intended for over-the-counter (OTC) use. T he following suggestions are intended to help you prepare labeling for these devices that satisfies the requirements of 21 CFR Part 801, and the Act.[18] In addition, in order to address the identified issues requiring special controls of improper fit and improper use, FDA provides some more specific recommendations for addressing use and fit in labeling.

A. Labeling issues relating to NIOSH certification of respirators

Because filtering facepiece respirators for use by the general public in public health medical emergencies closely resemble other products not legally marketed for device uses, FDA recommends consideration of the following in developing labeling for your device:

As noted above, under 21 CFR 880.6260(b)(1), filtering facepiece respirators for use by the general public in public health medical emergencies must be NIOSH-certified. Under NIOSH regulations, respirators may belong to one of several classifications, designated in relation to their established filtration efficiency. See 42 CFR 84.170. If your device labeling, including your product name, uses "N95" or any of the other NIOSH classification terms defined in 42 CFR 84.170, that reference should accurately correspond to the certification of your product provided by NIOSH. Otherwise, your labeling may be false or misleading, rendering your devices misbranded under 21 USC 352(a).

Second, only FDA-evaluated respirators may be sold for device uses, but there are many other respirators that are NIOSH-certified that are marketed for other uses. To help consumers identify product that has been evaluated for use by the general public in public health medical emergencies, FDA will not object if manufacturers include the following statement on the outer box of filtering facepiece respirators for use by the general public in public health medical emergencies: "FDA has cleared this respirator for use by the general public in public health medical emergencies to help reduce wearer exposure to pathogenic biological airborne particulates. NIOSH does not evaluate respirators for use as medical devices." In labeling containing the preceding statement, the phrase "airborne germs" could be used in place of, or as a parenthetical explanation of, the phrase "pathogenic biological airborne particulates".

B. Labeling to assure proper use

The filtering facepiece respirators described in this special controls guidance document are intended for use by the general public during public health medical emergencies. The labeling should indicate to the user how to determine when public health medical emergencies in which wearer exposure to pathogenic biological airborne particulates may occur, for example, by consulting public health authorities, and from what sources the home user could seek additional public health information during public health medical emergencies. (With regard to this latter consideration, FDA advises that because users may stockpile these devices for use in future public health medical emergencies, manufacturers should avoid overly-specific references that may become outdated.)

Filtering facepiece respirators for use by the general public in public health medical emergencies are intended to cover the nose and the mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency. While these respirators may provide protection against the inhalation of infectious airborne particles, transmission via other routes is still possible. FDA recommends that the device labeling include statements making the user aware that your respirator is intended to be used in conjunction with other infection control and respiratory protection measures and that the product does not provide complete protection against infection. We suggest giving examples of such additional measures, such as hand-washing, cough hygiene and proper disposal of contaminated materials.

Device labeling should emphasize to users that proper fit of the respirator is critical to reducing wearer exposure to pathogenic airborne biological particulates, and that users should read the instructions for use carefully. If filtering facepiece respirators for use by the general public in public health medical emergencies are packaged with multiple devices to a box, manufacturers should strongly consider attaching labeling to each individual respirator that, at a minimum, advises users of the importance of consulting full instructions for use located elsewhere in the packaging.

In addition, the device labeling should caution users that in occupational settings, respirator training and fit testing programs are required by the Occupational Safety and Health Administration (OSHA) for workers exposed to occupational respiratory hazards. Occupational wearers who have received

OSHA respirator training and fit testing will generally obtain a greater reduction in exposure than an untrained wearer of a respirator. The risk of exposure to airborne particulates decreases as the fit of the respirator to the face increases.

C. Labeling Instructions for Use

In developing instructions for use, FDA recommends the use of pictures or diagrams, in addition to written instructions. The language should be intended for the general public and should be suitable for readers with limited literacy skills. The instructions should address three basic areas: donning and fitting, removal and disposal, and storage before use.

Respirator labeling should include clear instructions on how the user should don the respirator and conduct a user seal check, emphasizing the need to conduct this seal check. Labeling should advise users that if they do not get a good fit even after following the instructions, they should try a different model of respirator.

In addition, the instructions for use should address how users should remove and handle the respirator to minimize the risk of contamination from infectious particles present on the used respirator. FDA recommends that the user be instructed to wash their hands or use a waterless hand hygiene product after handling a used respirator.

Because such devices are likely to become contaminated with infectious materials and because their continued adequate performance if reused has not been established, the device labeling should indicate that the respirator is disposable and for single-use. In addition, FDA recommends that the device labeling caution users that respirators should not be washed, disinfected, reused, or shared with others. FDA recommends that the user be instructed on the proper disposal procedure for the used respirator, including the need for timely disposal.

The labeling should include information for the user on proper home storage of the respirator before use by the general public during public health medical emergencies. As an example, users should be instructed to not store filtering facepiece respirators before use in areas where they might be exposed to water, dirt, excessive heat or cold, etc. If the respirator has a stated shelf life, the labeling should clearly explain what that means in a manner that can be understood by the general public.

Users of your respirator may have questions about storage, donning, and disposal of your device or may wish to report problems they have had in using your device. FDA suggests that providing contact information to receive timely assistance with such issues would be very helpful.

The labeling should include appropriate warnings, precautions, or limitations defining the populations in which your respirator should be used. For example, labeling should indicate that individuals with chronic respiratory, cardiac or other conditions which increase the work of breathing may experience difficulty breathing through the respirator. Respirator labeling should also

warn against use by children, who are unlikely to obtain adequate respirator fit, may have greater difficulty breathing through a respirator than healthy adults, and may not understand how to indicate respiratory distress if it occurs while they are wearing the respirator. Potential users should be informed that facial hair in the areas where the mask must seal to the skin may interfere with proper fit and render the respirator less effective.

As already noted, because respirators for use by the general public in public health medical emergencies are likely to become contaminated with infectious materials during use, they should be labeled as disposable and for single-use. In addition, FDA recommends that the device labeling caution users that respirators should not be washed, disinfected, reused, or shared with others.

D. Labeling regarding specific features

If the respirator contains natural rubber latex, for example in the headband, the labeling must include the natural rubber latex caution statement in accordance with 21 CFR 801.437.

Filtering facepiece respirators for use by the general public in public health medical emergencies may or may not be fluid resistant. The labeling should indicate whether your device is fluid resistant. If devices are fluid resistant, the labeling should describe the testing that was performed (e.g., ASTM F 1862). If the respirator has not been evaluated for fluid resistance, the labeling should indicate this.

Some settings in which these devices are used may have ignition sources. All materials will burn if a high-intensity heat source is applied to them, especially in the presence of elevated oxygen levels. The labeling should whether your device is flammable. If a respirator's materials have not been flammability tested, the device labeling should indicate this, e.g., "Not flammability rated." If you have determined the flammability status of your device, the labeling should describe the test method and results in language understandable by the general public.

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Appendix A
Recommended Analysis of Fit Assessment Test Results

The variability among measurements of the fit factor can be divided into two components: between-subject and within-subject. The between-subject variability stems from the heterogeneity of the population of potential users with respect to individual characteristics that affect the performance of a respirator. The within-subject variability refers to the fluctuation over repeated measurements in the level of protection that a given user receives. We recommend you take into account these two sources of variability in a quantitative analysis of fit factor measurements.

One possible approach is to model the two sources of variability explicitly through the following analysis of variance (ANOVA) model with a random effect. Since fit factor measurements tend to be skewed to the right, we suppose that a logarithmic transformation is applied to the original fit factor measurements and write X_{ij} for the j^{th} measurement of the log fit factor for the i th user in the sample. We associate each subject with a subject-specific mean (on the log scale), for example μ_i, and assume that given μ_i, the X_{ij} are conditionally independent and each follows a normal distribution with mean μ_i and variance σ^2. The variance σ^2 of the measurement error represents the with-subject variability. Across subjects, the μ_i may be assumed to form a random sample, say from a normal distribution with mean v and variance τ^2. Here the variance τ^2 represents the between-subject variability. The preceding specification implies that, for each i, the X ij are jointly normally distributed with identical variance $\tau^2+\sigma^2$ and covariance τ^2, without conditioning on μ_i. Estimates of v and the variance components can be obtained from standard statistical software packages.

In light of the two sources of variability described above, we believe an informative measure of the performance of a respirator is the proportion of users who will achieve a specified level of protection (e.g., a log fit factor greater than x) with a sufficiently large probability (e.g., 95%). The quantity of interest, denoted by p, can be expressed in terms of parameters in the ANOVA model specified earlier. Under this model, a potential user with subject-specific mean μ will achieve a log fit factor of μ-1.645σ or better 95% of the time. Then the proportion p is just the proportion of users for whom the preceding display exceeds x. In the population of users, μ is a normal variable with mean v and variance τ^2, while σ is a constant. It now follows from simple algebra that $p = \Phi((v-1.645\sigma-x)/\tau)$, where Φ denotes the standard normal distribution function. An estimate of p can be obtained by substituting estimates of v, σ, and τ in the above display. A confidence interval can be constructed using, for example, a bootstrap procedure. Repeating this calculation for different values of x would provide further insight into the performance of the respirator. The results of these calculations can be presented in a tabular format, as shown in the example below.

Fit Factor	% Times the Respirator is Donned	% Users	95% CI
2	95	100	(86, 100)
5	95	100	(86, 100)
10	95	99	(84, 100)
50	95	95	(80, 100)
100	95	90	(75, 98)

The numerical entries in the example above are hypothetical. In the above example, the level of protection is expressed in terms of the original (as opposed to log transformed) fit factor for ease of interpretation; in other words, e^x instead of x is shown in the first column. The second column (% Times the respirator is Donned) presents the probability, expressed as a percentage, with which a specified fit factor is to be achieved over repeated donning by the same user. The third column gives a point estimate of p for each combination of values specified in the other two columns. 95%

confidence intervals for p are shown in the last column. For example, the fourth row of the table indicates that 99% of users (CI: 84% - 100%) are estimated to achieve a fit factor of 10 or greater 95% of the times that the respirator is donned.

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[1] **Format for Traditional and Abbreviated 510(k)s (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm)**

[2] **Premarket Notification 510(k) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm)**

[3] Refer to **Indication for Use Form (http://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm360431.pdf)** (PDF File Size: 1.03MB) for the recommended format.

[4] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[5] See **Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions) (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142706.htm)**.

[6] NIOSH's respirator certification program was developed to support occupational health and safety requirements applicable under the Occupational Safety and Health Act, Mine Safety and Health Act, and other occupational health authorities. In occupational settings, use of respirators as part of respiratory protection programs generally involves individual user training and fitting which provides more assurance of proper fit for each individual user than reliance solely on written instructions. However, this type of fit training and testing must be performed for each individual model of mask worn by a person and is not generally available outside an occupational setting. NIOSH does not evaluate respirators for use as devices within the meaning of the FFDCA, and does not evaluate them for use by the general public, in nonoccupational settings. See Section 10 of this guidance for recommendations regarding labeling for filtering facepiece respirators falling within this device classification.

[7] See 42 CFR 84.181.

[8] See 42 CFR 84.180.

[9] For information on obtaining NIOSH certification, see 42 CFR part 84 and the **Standard Application Procedure for the Certification of Respirators under 42 CFR 84 (http://www.cdc.gov/niosh/npptl/resources/certpgmspt/pdfs/SAPJul2005.pdf)**.

[10] Coffey, C et al Journal of Occupational and Environmental Hygiene 2004 1;262-271.

[11] Zhuang, Z et al Journal of Occupational and Environmental Hygiene 2005 2:567-576.

[12] For example, OSHA regulations specify how respirator training and fit testing should be conducted as part of respiratory protection programs in occupational settings. See 29 CFR 1910.134 and Appendices.

[13] Such test methods typically require testing during performance of specific exercises, designed to stress the facepiece-to-face interface, that are intended to approximate fit (and resultant exposure reduction) that may be experienced during real world use. However, normal activities can result in different fit, and consequently, sometimes lower fit factors than the average fit factor measured under the circumstances of the fit assessment testing. Consequently, FDA does not consider fit assessment test data evaluated in premarket submissions to establish an assured minimum level of performance for individual real world users.

[14] Zhuang, Z et al Journal of occupational and Environmental Hygiene 2005 2: 641-649

[15] Coffey, C et al Journal of Occupational and Environmental Hygiene 2006 3: 44-52.

[16] Fit Factor is a means of expressing the difference in particle concentration inside the mask and outside the mask during use. For example, a fit factor of 2 means that the concentration of particles within the mask is ½ or 50% of the concentration outside the mask; a fit factor of 5 means the concentration of particles within the mask is 1/5 th or 20% of the concentration outside the mask.

[17] **Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices May 1, 1995 (G95-1) (ssLINK/ucm080735.htm)**.

[18] Among other requirements, a device is misbranded unless its labeling provides adequate directions for use and adequate warnings. (FFDCA section 502(f). 21 USC 352(f)). FDA regulations regarding what constitutes adequate directions for use are found in 21 CFR 801.5. Other labeling requirements for OTC devices are found in 21 CFR part 801, Subpart C.

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More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)