



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2025-D-7121]**

### **Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators.” This draft guidance document provides a proposed compliance policy for and information about respirators approved by the Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) in accordance with 42 CFR part 84, specifically: surgical N95 respirators and N95 filtering facepiece respirators (FFRs) classified under 21 CFR 878.4040; other NIOSH approved, non-surgical respirators including powered air-purifying respirators (PAPRs), non-powered, air-purifying particulate FFRs, and reusable respirators (e.g., elastomeric half and full facepiece respirators); and FFRs for use by the general public in public health medical emergencies classified under 21 CFR 880.6260. These devices are collectively referred to in the guidance and this notice as “certain FFRs and reusable respirators.” This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices. This draft guidance is not final nor is it for implementation at this time.

**DATES:** Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure

that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2025-D-7121 for “Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or between 9 a.m. and 4 p.m., Monday through Friday, at the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

- *Confidential Submissions:* To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled “Enforcement Policy for Premarket and Other Requirements for Certain NIOSH Approved Respirators” to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Erica Takai, Center for Devices and Radiological Health, Food and Drug Administration, 301-796-6353.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA has a long history of coordinating with NIOSH to help ensure that respirators used for medical purposes are safe, effective, and available. All the devices that are within scope of this guidance document are also subject to approval by NIOSH in accordance with 42 CFR Part 84.

Since 1988, surgical N95 respirators 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, body fluids, and particulate material generally have been classified as class II devices under 21 CFR 878.4040. Likewise, N95 FFRs used in healthcare settings during other procedures, including dental, isolation, and other medical procedures, to protect both the patient and healthcare personnel, are also generally classified as class II devices under 21 CFR 878.4040. In November 2017, FDA entered into a Memorandum

of Understanding (MOU) with NIOSH, which outlines an agreement between the agencies conditioned on certain surgical N95 respirators and N95 FFRs becoming exempt from premarket notification requirements under section 510(k) of the FD&C Act. The MOU became effective on May 17, 2018, when FDA issued a final order exempting from 510(k) requirements certain surgical N95 respirators and N95 FFRs (product code MSH), subject to certain conditions and limitations.

FDA considers other types of non-surgical respirators, including: PAPRs, non-powered air-purifying particulate FFRs (e.g., N95, N99 FFRs), and reusable respirators (e.g., elastomeric half and full facepiece respirators), that are NIOSH Approved and intended to prevent wearer exposure to pathogenic biological airborne particulates and used in healthcare settings, to be postamendments devices. A postamendments device for which FDA has not issued a classification order (or reclassification order under section 513(f)(3) of the FD&C Act) is referred to as a “not-classified device,” and is one for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application. In 2020, FDA addressed its policy regarding not-classified, NIOSH Approved FFRs and reusable respirators when it took a number of actions to help address the COVID-19 public health emergency, including issuing emergency use authorizations (EUAs) for such devices with a medical purpose. On March 2, 2020, FDA issued an EUA authorizing NIOSH Approved FFRs to be distributed to healthcare personnel for use in healthcare settings intended to prevent wearer exposure to pathogenic biological airborne particulates. On March 11, 2020, FDA clarified that such respirators are devices because they are intended for a medical use, *i.e.*, to mitigate further transmission of COVID-19.

In 2007, FDA issued a final rule that classified FFRs for use by the general public in public health emergencies under 21 CFR 880.6260 as class II devices. In issuing the classification regulation for this type of device, FDA also issued a special control requiring that,

among other things, this device type be certified by NIOSH as a non-powered air-purifying particulate respirator with a minimum filtration efficiency classification of N95.

FDA is proposing the compliance policy described in the draft guidance for certain FFRs and reusable respirators based on NIOSH's regulatory oversight of these devices, including the performance characteristics of these devices, and FDA's review of its postmarket data. These devices may provide a public health benefit in accordance with current CDC respiratory virus prevention recommendations. This guidance, once finalized, is intended to facilitate more efficient and effective use of resources, consistent with the least burdensome policies for devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, once finalized, will represent the current thinking of FDA on "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators." 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. As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

## II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. Persons unable to download an electronic copy of "Compliance Policy Regarding Premarket and Other Requirements for Certain NIOSH Approved Air-Purifying Respirators" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the

document. Please use the document number GUI00007063 and complete title to identify the guidance you are requesting.

### III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
807, subpart E	Premarket notification	0910-0120
800, 801, and 830	Medical Device Labeling Regulations; Unique Device Identification	0910-0485
803	Medical Device Reporting	0910-0437
806	Medical Devices; Reports of Corrections and Removals	0910-0359
807, subparts A through D	Medical Device Registration and Listing	0910-0625
814, subparts A through E	Premarket approval	0910-0231
860, subpart D	De Novo classification process	0910-0844
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”	Q-submissions and Early Payor Feedback Request Programs for Medical Devices	0910-0756
820	Current Good Manufacturing Practice (CGMP); Quality Management Systems (QMSR) Regulation	0910-0073
“Emergency Use Authorization of Medical Products and Related Authorities” and section 564 of the FD&C Act	Emergency Use Authorization	0910-0595

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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