Life Sciences

COVID-19: Clearing Up Confusion Regarding Emergency Use Authorization for N95 Respirators and Face Masks

Background: N95 Respirators

As the COVID-19 pandemic unfolds, physicians, nurses, and other caregivers nationwide are facing a shortage of N95 respirators and face masks, putting the safety of patients and clinicians at risk.

The "N95" designation means that when subjected to careful testing, the respirator blocks at least 95% of very small (0.3 micron) test particles. When an N95 respirator is labeled for use in a hospital setting, it is a Class II medical device regulated by the U.S. Food and Drug Administration (FDA). This is a surgical respirator with the product code MSH. According to **21CFR 878.4040**:

Surgical N95 respirators and N95 filtering facepiece respirators are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter subject to 878.9, and the following conditions for exemption:

i. The user-contacting components of the device must be demonstrated to be biocompatible.
ii. Analysis and nonclinical testing must:
    a. Characterize flammability and be demonstrated to be appropriate for the intended environment of use.
    b. Demonstrate the ability of the device to resist penetration by fluids, such as blood and body fluids, at a velocity consistent with the intended use of the device.
iii. National Institute for Occupational Safety & Health (NIOSH) approved under its regulation.

When an N95 respirator is labeled for occupational use it is regulated by NIOSH.

Both types of respirators are evaluated by NIOSH. NIOSH approval criteria can be found **here**.

Emergency Use Authorization for N95 Respirators

On March 2, 2020, the U.S. Department of Health and Human Services secretary declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak. Manufacturers and strategic stockpilers can submit a request to the FDA in order to have their products added to the Emergency Use Authorization (EUA).

FDA issued an EUA for:

1. All disposable filtering facepiece respirators (FFRs) approved by NIOSH, in accordance with 42 CFR Part 84, as nonpowered air purifying particulate FFRs.
2. FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, for use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

What Does This Mean?

N95 respirators that were evaluated by NIOSH for occupational uses (e.g., construction) are automatically approved. This includes expired respirators; however, FDA needs to be informed first.

N95 respirators that have been approved by NIOSH as nonpowered air purifying particulate FFRs can now be distributed and used as a medical device. FDA has a listing of all NIOSH approvals on its **website**.

N95 respirators that are being used as medical devices at this time are **listed here**.

How Do You Get a Mask On the List?

Send a request to the FDA.

Who is Authorized to Make This Request?

CDC, the manufacturer, or strategic stockpiler.

What Else Do Manufacturers and Stockpilers Need to Know?

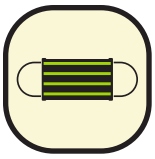
Strategic stockpilers and manufacturers should notify the FDA of their intent to use expired respirators listed in Appendix B via email at **CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov**. Specify the manufacturer, model number, and product expiry date (if no expiry date is available, please provide the date of manufacture or receipt date).

It is very important that stockpilers and manufacturers report adverse events to the FDA when they become aware of an event that led to or could have led to serious injury.

What About New Devices?

FDA has **a webpage explaining** how N95 respirators and surgical masks are different and how they are regulated.

At the time of this paper's publication, the FDA has **NOT** announced an EUA guidelines for marketing new personal protection equipment (PPE). Other PPE is regulated by the FDA in a more typical way. Surgical masks and other PPE are:



Surgical masks

Surgical gowns

Surgical mask with antimicrobial/antiviral agent

Isolation gowns and surgical apparel accessories

Pediatric/child facemask

Surgical suits

What Should Manufacturers Do if They Want to Start Manufacturing New Devices?

According to the FDA: "The FDA is collaborating with manufacturers of PPE to help facilitate mitigation strategies related to the COVID-19 outbreak. The FDA's door is open, and we are available to collaborate with stakeholders. To help alleviate supply pressures, the FDA may consider expedited review of manufacturing site changes or premarket submissions — manufacturers of PPE (particularly surgical masks and surgical or isolation gowns) may contact FDA regarding plans to increase availability of these products to the U.S. market."

Additional information can be found **here**.

What About Homemade Face Masks?

In ordinary times, supplying homemade face masks to hospitals for use in critical care situations could land a person or company in big trouble with the FDA. These are not ordinary times. In fact, the CDC has recommended that medical professionals use bandannas as a last resort. In this situation, homemade masks would be considered equivalent to a bandanna. However, here is advice for those who begin manufacturing and selling masks on a large scale:

- DO NOT forget you are making these masks to protect people, so make them as safe as possible.
- DO NOT call them or label them as a medical or surgical mask.
- DO NOT make any medical claims unless you receive authorization, clearance, or approval from the FDA for the specific claim. Even if you are not making medical claims, please do keep records of any complaints you receive and report any serious injury to the FDA.
- Test the fabric before you start manufacturing. Major considerations need to be made for dimensions and the fabric chosen. Keep in mind, if the fabric is too thin it is less protective; but if it is overly thick, a user cannot breathe through it. If the fabric contains toxic chemicals common to raw fabric, dirt, germs, or fine particulate, it could make clinicians sick. Also, use fabrics that will not cause skin irritation.
- If the FDA or CDC issue guidance, follow it immediately.
- If the FDA or CDC reach out to you, cooperate, cooperate, cooperate.

The FDA and CDC are showing incredible flexibility and doing everything they can to meet public health and safety needs.

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