



October 15, 2008

Mr. Paul Tran
Center for Drug Evaluation & Research (HFD-21)
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Tran:

3M respectfully submits these comments in response to the U.S. Food and Drug Administration's (FDA) call for comments in preparation for the Joint Meeting of the Antiviral Drugs Advisory Committee and the Nonprescription Drugs Advisory Committee being held on October 29th.

These comments are for consideration by the Committees as they discuss and evaluate the potential contents that might be include in an influenza antiviral "MedKit" for the treatment or prophylaxis of pandemic influenza that may be available for general public stockpiling and subsequent use during a non-seasonal influenza outbreak.

There may be proposals to the FDA for respirators or facemasks to be included in a home medical kit. The CDC's "Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic"¹ discusses the use of NIOSH-approved respirators and FDA-cleared facemasks during an influenza pandemic and should serve as a reference for the committees. 3M is not advocating a position regarding whether or not to include respirators and facemasks in a "MedKit", however, we believe it is important to provide background to the committee regarding the use, benefits and limitations of these devices in a home setting.

Respiratory Protective Devices

The CDC's interim guidance states individuals may consider wearing a "respirator to help prevent exposure to respiratory secretions from symptomatic individuals."¹ "Certain practices related to taking care of a person infected with influenza at home can create potentially infectious aerosols and require more stringent precautions (e.g., use of a respirator by a caregiver in the home). Examples include giving nebulizer treatments to children with asthma who have influenza and providing care (e.g., suctioning) for people with chronic respiratory conditions."

Respiratory protective devices are typically designed to cover the nose and mouth. Respirators can help reduce the number of particles, including airborne disease-causing organisms the wearer may inhale. However, a respirator cannot stop the inhalation of all particles (including particles containing viruses) in the air and use of a respirator does not eliminate the risk of disease or illness. Additionally, they will not prevent entry of germs

through skin, eyes, or other parts of the body. Therefore, respiratory protective devices do not include disease prevention claims. If a public health medical emergency occurs, a FDA-cleared respirator should be used as part of a total personal protection system including hand washing, social distancing, etc.

The FDA has cleared several models of NIOSH-approved respirators for use by the general public in public health medical emergencies, such as an influenza pandemic, to help reduce wearer exposures to airborne germs. Users in the public setting cannot easily determine exposure levels nor do they have ready access to the type of training, medical evaluation, and fit testing needed to be in compliance with workplace respirator standards (e.g. OSHA). Part of the FDA-cleared product's evaluation shows that following the respirator fitting instructions is important to help reduce wearer exposure to airborne germs. It is important for the user to understand that no respirator will eliminate the inhalation of all particles and/or airborne organisms and will not eliminate the risk of disease, illness, or death. For example, for 3M's respirators that are NIOSH-approved and FDA-cleared for use by the general public in public health medical emergencies, 3M has created a website, "My3MN95.com" in addition to the user instructions and packing that accompany the respirators.

The respirator's ability to help reduce wearer exposure to airborne germs depends on the filtration capabilities of the materials it is made of and on how well it fits the wearer. The FDA-cleared general public respirator is required to be certified by NIOSH as an N95 respirator, which thereby addresses the filtration capability of the device. With respect to understanding the facial fit of respiratory protective devices, the FDA required that the device be tested on a group of healthy adults not previously trained on respirator use and representing a range of facial characteristics. The respirator fit test measured how many airborne test particles were able to get inside the respirator through small leaks between the edges of the respirator and the wearer's face. While individual results varied, all participants tested achieved some reduction in exposure to airborne test particles.

The respirators cleared by the FDA for the general public in public health medical emergencies are designed for adult faces. The FDA has not cleared respirators for use by children.

Facemasks

The CDC's interim guidance¹ describes facemasks and their use:

"Facemasks are loose-fitting, disposable masks that cover the nose and mouth. These include products labeled as surgical, dental, medical procedure, isolation, and laser masks. Facemasks help stop droplets from being spread by the person wearing them."¹
"Individuals with a respiratory illness should wear a facemask to contain respiratory secretions (e.g., to cover coughs and sneezes) if they are in the presence of others."¹

Facemasks are different from respirators. Facemasks are not designed to help reduce the wearer's exposure to airborne particles, including particles containing viruses and

bacteria. Facemasks are not designed to form a tight seal to the face. Therefore, particles smaller than 100 microns (μm) that can remain airborne², and can follow the airstream around the edges of the mask have the potential to enter the wearer's breathing zone. Facemasks with fluid resistance claims may also help prevent sprays and splashes of bodily fluids from reaching the wearer's nose and mouth.

At this time, the FDA has not cleared facemasks for use by the general public in public health medical emergencies, such as an influenza pandemic.

Thank you for allowing the public to provide comments to the committees for consideration.

Best regards,



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References

¹Centers for Disease Control and Prevention. 2008. Interim Public Health Guidance for the Use of Facemasks and Respirators in Non-Occupational Community Settings during an Influenza Pandemic.

http://www.pandemicflu.gov/plan/community_maskguidancecommunity.cfm

²Lenhart, S.W., Seitz, T., Trout, D. And N. Bollinger. 2004. Issues affecting respirator selection for workers exposed to infectious aerosols: Emphasis on Healthcare Settings. Applied Biosafety 9(1): 20-36.