DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2007

Mr. Jizhong Jin
Senior Regulatory Affairs Associate
3M Company
3M Center: 275-5W-06
St. Paul, Minnesota 55144-1000

Re: K062070
Trade Name: 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies
Evaluation of Automatic Class III Designation
Regulation Number: 21 CFR 880.6260
Regulation Name: Filtering facepiece respirator for use by the general public in public health medical emergencies
Classification: Class II
Product Code: NZJ

Dear Mr. Jin,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition for classification of the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies as over-the-counter devices, under 21 CFR 801 Subpart C. The 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies is a filtering facepiece respirator device. It is intended to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as influenza pandemic. The 3M™ Respirator (Model No. 8612F and 8670F) for Use by the General Public in Public Health Medical Emergencies also protects the wearer from splash and spray of body fluids. FDA concludes that these devices should be classified into class II. This order, therefore, classifies the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies, into class II under the generic name, Filtering facepiece respirator for use by the general public in public health medical emergencies. This order also identifies the special controls applicable to this device, and substantially equivalent devices of this generic type.

FDA identifies this generic type of device as:

21 CFR 880.6260 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 the risk of exposure to pathogenic biological airborne particulates during a public health medical emergency. The device is made of polymeric materials and is intended to fit closely to the face and to function by filtering particulate material.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device type. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On October 3, 2006, FDA filed your petition requesting classification of the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies into class II. The petition was submitted under section 513(f)(2) of the act. In accordance with section 513(f)(1) of the act, FDA had issued an order on August 30, 2006, automatically classifying this device into class III, because it was not substantially equivalent to a legally marketed class I or class II device.

In order to classify the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies into class II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the classification petition and supplements provided in response to FDA questions, FDA has determined that the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies, as indicated above, can be classified into class II with the establishment of special controls. FDA believes that class II special controls, in addition to the general controls under the act, provide reasonable assurance of the safety and effectiveness of the device type.

In addition to the general controls of the act, the 3M™ Respirator Model Nos. 8612F and 8670F for Use by the General Public in Public Health Medical Emergencies are subject to the following special controls: (1) 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 (2007); and (2) The FDA guidance document entitled: "Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies."

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: assuring filtration and breathability, assuring proper fit, avoiding adverse skin reaction, and assuring proper use.

A. Assuring filtration and breathability

For this type of respirator to reduce wearer exposure to pathogenic biological airborne particulates, it must 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 must also permit adequate respiration.

B. Assuring proper fit

The device must 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.

C. 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 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 the respirator itself becoming a vector of transmission.

Table 1 – Issues Requiring Special Control and Recommended Mitigation Measures

Identified Issues	Mitigation Measures
Assuring adequate filtration and breathability	**NIOSH Certification**
Assuring proper fit	**Fit Assessment testing** **Labeling**
Avoiding adverse skin reaction	**Biocompatibility testing**
Assuring proper use	**Labeling**

FDA believes that these special controls, in addition to general controls, will provide reasonable assurances of the safety and effectiveness of the 3M filtering facepiece respirators for use by the general public in public health medical emergencies and substantially equivalent devices.

Section 510(m) of the act provides that FDA may exempt a class II device from premarket notification requirements under section 510(k) of the act, if FDA determines that a premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device type is not exempt from the premarket notification requirements. Thus, persons who intend to market this type of device must submit to FDA a premarket notification submission containing information on the particular Filtering facepiece respirator for use by the general public in public health medical emergencies that they intend to market. They must receive clearance to market the device from FDA prior to introducing their device into commercial distribution.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market this device, subject to the general control provisions of the act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Sheila A. Murphey, M.D., at 240-276-3747.

Sincerely yours,

Miriam C. Provost

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