DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

May 1, 2009

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Dear Dr. Besser:

As you know, on April 27, 2009, I issued a letter authorizing the emergency use of certain personal respiratory protection devices, specifically disposable respirators certified by the National Institute for Occupational Safety and Health, with a minimum filtration efficiency classification of N95. I hereby amend that letter to clarify the term "general public" is broad and includes people performing work-related duties. In addition, I hereby amend the letter and the Summary Fact Sheet to clarify that the authorization affects only requirements applicable under the Federal Food, Drug, and Cosmetic Act. The revised authorization letter is attached.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs

Attachment

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Silver Spring MD 20993

May 1, 2009

Richard E. Besser, M.D.
Acting Director
Centers for Disease Control and Prevention
Clifton Building 1, Room 6430
1600 Clifton Road, NE MS C-12
Atlanta, GA 30333

Dear Dr. Besser:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3), for the emergency use of certain personal respiratory protection devices deployed from the Strategic National Stockpile, specifically certain disposable respirators certified by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR part 84, as non-powered air-purifying particulate respirators with a minimum filtration efficiency classification of N95.[1,2]

On April 26, 2009, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of the Department of Health and Human Services (HHS) determined that a public health emergency exists involving *Swine Influenza A* that affects, or has a significant potential to affect, national security. Pursuant to section 564(b) of the Act (21 U.S.C. § 360bbb-3(b)), and on the basis of such determination, the Secretary of HHS then on April 27 declared an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(b)) are met, I am authorizing the emergency use, by the general public,[3] of certain N95 respirators to help reduce wearer exposure to pathogenic biological

[1] The specific products covered are listed below, in Section II (scope of authorization). For purposes of this document, we will refer to the devices covered by this authorization as "certain N95 respirators." Only respirators that have passed specific testing by NIOSH may be labeled as NIOSH-certified. Each NIOSH-certified respirator (also called a filtering facepiece) bears a rating which refers to its certified level of filtration efficiency: for example, N95 signifies that the respirator filters at least 95% of airborne particles (and is not resistant to oil). 42 CFR 84.170. For more information on disposable NIOSH-certified respirators, see http://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/.

[2] FDA has cleared four models of disposable N95 respirators for use by the general public in public health medical emergencies, such as influenza pandemic: 3M Respirators 8612F and 8670F, and Pasture Pharma Respirators F550G and A520G. See 21 CFR 880.6260 (product code NZJ) and http://www.fda.gov/cdrh/ode/guidance/1626.pdf. These four models of N95 respirators are already FDA-cleared for a use contemplated by this letter of authorization.

[3] For purposes of this letter of authorization, the term "general public" is broad and includes people performing work-related duties. This authorization affects only requirements applicable under the Federal Food, Drug, and

airborne particulates during a public health medical emergency involving *Swine Influenza A*, subject to the terms of this authorization.[4]

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain N95 respirators meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) *Swine Influenza A* can cause influenza, a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that certain N95 respirators may be effective in preventing influenza by reducing wearer exposure to pathogenic biological airborne particulates, and that the known and potential benefits of certain N95 respirators, when used for the prevention of influenza, outweigh the known and potential risks of such products; and

(3) there is no adequate, approved, and available alternative to the emergency use of certain N95 respirators in the prevention of influenza.[5,6]

Therefore, I have concluded that the emergency use of certain N95 respirators for the prevention of influenza through reduced wearer exposure to pathogenic biological airborne particulates meets the above statutory criteria for issuance of an authorization.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use, by the general public, of authorized N95 respirators to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving *Swine Influenza A*.

Cosmetic Act. If respirators are used for people performing work-related duties, employers must comply with the Occupational Safety and Health Administration (OSHA) Respiratory Protection Standard, 29 CFR 1910.134, found at www.OSHA.gov.

[4] FDA is authorizing the emergency use of certain N95 respirators as described in the scope section of this letter (Section II).

[5] As described in footnote 2, FDA has cleared four models of N95 respirators for use by the general public in public health medical emergencies, such as influenza pandemic. A shortage of FDA-cleared respirators is nonetheless expected for the following reasons: not all of the four cleared models have been marketed extensively to date, and in fact two such models were only recently cleared by FDA; the respirators are disposable, and so one user is expected to use multiple respirators over a span of time; and, to ensure proper fit, each user may need to try on various sizes and models of respirators before selecting one for use. There are also some models of N95 respirators that are cleared by FDA for use in certain workplace settings. However, under the circumstances of this emergency, shortage of supplies of these models is expected.

[6] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

The authorized N95 respirators are as follows:

Manufacturer	Model
3M	8210
	8000
	9210
	1860
	1870
Moldex	2200
	2212
	2201
Moldex-Metrics	3000
	3001
	3002
	3003
Gerson	1730
Kimberly-Clark	PFR95-170
	PRF95-174

The above products, as deployed from the Strategic National Stockpile before or after the signing of this letter of authorization, are authorized to be made available to recipients when accompanied by the following written information pertaining to the emergency use:

- Summary Fact Sheet for Disposable Respirators for Use During the Swine Flu Emergency, as attached[7]

In addition, they may be made available to recipients in the form (i.e., with the packaging and labeling) in which they are customarily sold for use, as long as they are accompanied by the above-mentioned Summary Fact Sheet.[8]

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of authorized N95 respirators, when used to prevent influenza by reducing wearer exposure to pathogenic biological airborne particulates, outweigh the known and potential risks of such products.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized N95 respirators may be effective for the prevention of influenza pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the information supporting the conclusions described in Section I above, and concludes that the authorized N95 respirators, when used for the prevention of influenza by reducing wearer exposure to pathogenic biological airborne particulates, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

[7] This Summary Fact Sheet contains, among other information, known and potential risks of use, including risks to children as a result of breathing difficulties and improper fit.
[8] In a work setting, OSHA requirements also apply (see note 3 of this letter).

The emergency use of authorized N95 respirators under this EUA must be consistent with, and may not exceed, the terms of this letter, including the scope and the conditions of authorization set forth below. Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the N95 respirators described above are authorized for use, by the general public, to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving *Swine Influenza A*.

This EUA will cease to be effective when the declaration of emergency is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Current Good Manufacturing Practice

I am waiving current good manufacturing practice requirements with respect to the authorized N95 respirators that are used in accordance with this emergency use authorization.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

CDC

A. CDC will ensure that the state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.

B. CDC will make available to state and/or local health authority(ies) through appropriate means the authorized Summary Fact Sheet, as attached.

C. CDC will make available to the public through appropriate means, including through internet posting, general instructions for use to assist with donning the respirators. These instructions will be categorized, or adjusted as necessary, to account for any differences related to the following different respirator designs: molded/cone, folded, and duckbill respirators.

State and/or Local Public Health Authority(ies)

D. The appropriate state and/or local public health authorities will make available through appropriate means the authorized Summary Fact Sheet, as attached.

E. The appropriate state and/or local public health authority(ies) will ensure that authorized N95 respirators are distributed to recipients in accordance with applicable state and local laws and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.

CDC and State and/or Local Public Health Authority(ies)

F. CDC and the appropriate state and/or local public health authority(ies) are also authorized to make available additional information relating to the emergency use of authorized N95 respirators that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized N95 respirators as described in this letter of authorization must comply with the conditions above and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration of emergency is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Joshua M. Sharfstein, M.D.
Principal Deputy Commissioner
Acting Commissioner of Food and Drugs