Joshua M. Sharfstein, MD
Principal Deputy Commissioner
Acting Commissioner

[1] Centers for Disease Control and Prevention
[2] Nasopharyngeal swabs, nasal swabs, throat swabs, dual nasopharyngeal swabs/throat swabs, nasal aspirates.
[3] Memorandum, Determination Pursuant to § 564 of the Federal Food, Drug, and Cosmetic Act (April 26, 2009).
[4] FDA is authorizing the emergency use of the CDC Human Influenza Virus Real-time RT-PCR Detection and Characterization Panel for Respiratory Specimens **(NPS, NS, TS, NPS/TS, NA)** and Viral Culture (rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** as described in the scope section of this letter (Section II). For ease of reference, this letter will use the term the ''rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)**.''
[5] The cleared test for in vitro qualitative detection of human influenza viral RNA (The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570) is not adequate because of the need to test additional types of samples during this emergency and it is not sufficiently available because of limited availability of certain reagents. No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.
[6] The CDC rRT-PCR Flu Panel (IVD) 510(K) 080570 is indicated for the *in vitro* qualitative detection of human influenza viral RNA in nasopharyngeal swabs (NPS) and nasal swabs (NS) only.
[7] All users, analysts, and any person reporting diagnostic results from use of this device should be trained to perform and interpret the results from this procedure by a CDC instructor or designee prior to use. CDC Influenza Division will limit the distribution of this device to those users who have successfully completed training provided by CDC instructors or designees. Use is limited to designated laboratories that are qualified to receive and use the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570. See ''Conditions of Authorization'' below.
[8] These requirements are waived only for the rRT-PCR Flu Panel **(NPS, NS, TS, NPS/TS, NA)** that is authorized for emergency use. These requirements, and all other applicable statutory and regulatory requirements, continue to apply to the CDC rRT-PCR Flu Panel (IVD) 510(K) 080570.

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–18569 Filed 8–3–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0278]

Authorization of Emergency Use of Certain Personal Respiratory Protection Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization), as amended, for certain personal respiratory protection devices.[1] FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorization contains, among other things, conditions on the emergency use of the authorized personal respiratory protection devices. The Authorization follows the determination by the Acting Secretary of the Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain disposable National Institute for Occupational Safety and Health (NIOSH) certified N95 respirators, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorization, as amended, which includes an explanation of the reasons for its issuance, is reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain products from the neuraminidase class of antivirals, zanamivir and oseltamivir phosphate and the issuance of EUAs for certain in vitro diagnostic devices.

DATES: The Authorization is effective as of April 27, 2009.

ADDRESSES: Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds: ''(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military

[1] The Authorization covers 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 (certain disposable NIOSH certified N95 respirators).

emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or (C) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.''

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the act, FDA is required to publish, in the **Federal Register**, a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in a declared emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health and CDC (to the extent feasible and appropriate given the circumstances of the emergency), FDA[2] concludes: (1) That an agent specified in a declaration of emergency can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) the product may be effective in diagnosing, treating, or preventing—(1) such disease or condition; or (2) a serious or life-threatening disease or condition caused by a product authorized under Section 564, approved or cleared under this Act, or licensed under Section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as the Secretary may by regulation prescribe are satisfied.

No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the act. Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, in the **Federal Register** of July 26, 2007 (72 FR 41083), FDA announced the availability of a guidance entitled ''Emergency Use Authorization of Medical Products.'' The guidance provides more information for stakeholders and the public about the EUA authority and the agency's process for the consideration of EUA requests.

II. EUA Request for Certain Personal Respiratory Protection Devices

On April 26, 2009, under section 564(b)(1)(C) of the act, the Acting Secretary determined that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On April 26, 2009, under section 564(b) of the act, and on the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain disposable NIOSH certified N95 respirators, accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a). Notice of the determination and the declaration of the Acting Secretary is published elsewhere in this issue of the **Federal Register**. On April 27, 2009, the CDC requested and FDA issued an EUA for certain disposable NIOSH certified N95 respirators, deployed from the Strategic National Stockpile with certain written information, including emergency use instructions, which are authorized under this EUA. On May 1, 2009, in response to a CDC request to make certain clarifications, FDA amended the authorization letter and reissued the Authorization letter in its entirety.

III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at *http://www.regulations.gov*.

IV. The Authorization

Having concluded that the criteria for issuance of this Authorization under section 564(c) of the act are met, FDA has authorized the emergency use of certain disposable NIOSH certified N95 respirators. The Authorization, as amended and reissued in its entirety on May 1, 2009, follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

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]

[2] The Secretary has delegated his authority to issue an EUA under section 564 of the act to the Commissioner of Food and Drugs.

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 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*.

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
Kimberley-Clark	PFR95–170
	PFR95–174

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.

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

[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 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.

[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).

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–18570 Filed 8–3–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0276]

Authorizations of Emergency Use of Certain Antiviral Drugs—Zanamivir and Oseltamivir Phosphate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (EUAs) (the Authorizations) for certain products from the neuraminidase class of antivirals—Zanamivir and oseltamivir phosphate. FDA is issuing the Authorizations under the Federal Food, Drug, and Cosmetic Act (the act), as requested by the Centers for Disease Control and Prevention (CDC). The Authorizations contain, among other things, conditions on the emergency use of the authorized zanamivir and oseltamivir phosphate products. The Authorizations follow the determination by the Acting Secretary of the Department of Health and Human Services, Charles E. Johnson (the Acting Secretary), that a public health emergency exists involving Swine Influenza A (now known as 2009 H1N1 Influenza A or 2009 H1N1 flu) that affects, or has the significant potential to affect, national security. On the basis of such determination, the Acting Secretary declared an emergency justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals—Zanamivir and oseltamivir phosphate, accompanied by emergency use information subject to the terms of any authorization issued under the act. The Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the issuance of EUAs for certain in vitro diagnostic devices and the issuance of an EUA for certain personal respiratory protection devices.

DATES: The Authorizations are effective as of April 27, 2009.

ADDRESSES: Submit written requests for single copies of the EUAs to the Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization(s) may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

FOR FURTHER INFORMATION CONTACT: Boris Lushniak, Office of Counterterrorism and Emerging Threats (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a public health emergency that affects, or has a significant potential to affect, national security, and that involves biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency justifying the authorization based on one of the following grounds: ''(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents; (B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military