

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/nppt/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.

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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

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), FDA¹ 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 Products From the Neuraminidase Class of Antivirals, Zanamivir and Oseltamivir Phosphate

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 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 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 26, 2009, CDC requested and, on April 27, 2009, FDA issued EUAs for zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use instructions, which are authorized under the EUAs. On April 27, 2009, FDA also amended the EUAs for zanamivir and oseltamivir phosphate, including the emergency use instructions authorized under the EUAs.

III. Electronic Access

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

IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the act are met, FDA has authorized the emergency use of certain zanamivir inhalation powder and certain oseltamivir phosphate capsules and oral suspension for the treatment and prophylaxis of influenza, accompanied by emergency use information, subject to the terms and conditions of the authorizations.

The Authorization (as amended) for certain zanamivir inhalation powder follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
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) for the emergency use of zanamivir inhalation powder for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

¹ 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 (DHHS) determined that a public health emergency exists involving Swine Influenza A that affects or has 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 DHHS then declared an emergency justifying the authorization of the emergency use of certain zanamivir products subject to the terms of any authorization issued under section 564(a) of the Act (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 of certain zanamivir products¹ for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza 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 zanamivir products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain zanamivir products, when used for the treatment and prophylaxis 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 zanamivir products for the treatment and prophylaxis of influenza.²

Therefore, I have concluded that the emergency use of certain zanamivir products for the treatment and prophylaxis of influenza 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 of authorized zanamivir products for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A. The emergency use of authorized zanamivir products 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.

The authorized zanamivir products are as follows:

- Relenza (zanamivir) Inhalation Powder

Zanamivir products are approved and indicated for the treatment of uncomplicated acute illness due to influenza A and B virus in adults and pediatric patients 7 years of age and older who have been symptomatic for no more than 2 days. Zanamivir products are also approved and indicated for prophylaxis of influenza in adults and pediatric patients 5 years of age and older.³

1. The above zanamivir products are authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).
2. The above zanamivir products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription).
3. The above zanamivir products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers⁴ and recipients:
 - Fact Sheet for Health Care Provider
 - Fact Sheet for Recipients

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 zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

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 zanamivir products, when used for the treatment and prophylaxis of influenza, 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 zanamivir products may be effective for the treatment and prophylaxis 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 zanamivir products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the zanamivir products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to 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 holding of authorized zanamivir products by CDC and other public health authority(ies) for a period of ninety days.

IV. Conditions of Authorization

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

CDC

- A. CDC will verify that authorized zanamivir products distributed to the Receive, Stage, Storage (RSS) sites are within their labeled expiration dates.
- B. CDC will ensure that the appropriate state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- C. CDC will make available to the appropriate state and/or local public health authority(ies) through appropriate means the authorized Fact Sheet for Health Care Providers, authorized Fact Sheet for Recipients, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.
- D. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Recipients. Such requests will be made by contacting FDA concerning FDA review and approval.

State and/or Local Public Health Authority(ies)

- E. The appropriate state and/or local public health authority(ies) will ensure that authorized zanamivir products 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 prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.
- F. The appropriate state and/or local public health authority(ies) will make available through appropriate means authorized Fact Sheets for Health Care Providers, authorized Fact Sheets for Recipients, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized zanamivir products.

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

- G. 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 zanamivir products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized zanamivir products 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 FDA is authorizing the emergency use of Relenza (zanamivir) inhalation powder for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain zanamivir product(s)" and "authorized zanamivir product(s)."

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

³ Zanamivir products are not recommended for treatment or prophylaxis of influenza in individuals with underlying airways disease (such as asthma or chronic obstructive pulmonary disease) due to risk of serious bronchospasm. Zanamivir products have not been proven effective for treatment of influenza in individuals with underlying airways disease. Zanamivir products have not been proven effective for prophylaxis of influenza in the nursing home setting. Zanamivir products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use zanamivir products. There is no evidence for efficacy of zanamivir in any illness caused by agents other than Influenza A and B. Patients should be advised that the use of zanamivir products for treatment of influenza has not been shown to reduce the risk of transmission of influenza to others.

⁴It is possible that public health officials or other volunteers might distribute authorized zanamivir products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

(Please note that certain written emergency use information was also amended).

The Authorization (as amended) for certain oseltamivir phosphate capsules and oral suspension follows and

provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

Richard E. Besser, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Rd, MS D-14
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) for the emergency use of certain oseltamivir phosphate capsules and oral suspension for treatment and prophylaxis of influenza, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

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 (DHHS) determined that a public health emergency exists involving Swine Influenza A that affects or has 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 DHHS then declared an emergency justifying the authorization of the emergency use of certain oseltamivir phosphate products subject to the terms of any authorization issued under section 564(a) of the Act (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 of certain oseltamivir phosphate products¹ for the treatment and prophylaxis of influenza, subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza 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 oseltamivir phosphate products may be effective for the treatment and prophylaxis of influenza, and that the known and potential benefits of certain oseltamivir phosphate products, when used for the treatment and prophylaxis 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 oseltamivir phosphate products for the treatment and prophylaxis of influenza.²

Therefore, I have concluded that the emergency use of certain oseltamivir phosphate products for the treatment and prophylaxis of influenza 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 of authorized oseltamivir phosphate products for the treatment and prophylaxis of influenza for individuals exposed to Swine Influenza A. The emergency use of authorized oseltamivir phosphate products 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.

The authorized oseltamivir phosphate products are as follows:

- Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules
- Tamiflu (oseltamivir phosphate) oral suspension

Oseltamivir phosphate products are approved and indicated for the treatment of uncomplicated acute illness due to influenza infections in patients 1 year and older who have been symptomatic for no more than 2 days. Oseltamivir phosphate products are also approved and indicated for the prophylaxis of influenza in patients 1 year and older.³

1. The above oseltamivir phosphate products are authorized for use in patients less than 1 year old. Such products are also authorized for use at later time points (i.e., patients who are symptomatic for more than 2 days) and/or in patients sick enough to require hospitalization (i.e., patients who do not have "uncomplicated acute illness" per se).

2. The above oseltamivir phosphate products labeled consistent with the manufacturer's label are authorized to be distributed under this EUA. Such products are authorized to be distributed or dispensed without the requisite prescription label information under section 503(b)(2) of the Act (e.g., name and address of dispenser, serial number, date of prescription or of its filling, name of prescriber, name of patient, if stated on prescription, directions for use and cautionary statements, if contained in the prescription).

3. The above oseltamivir phosphate products may include products that are deployed from the Strategic National Stockpile (SNS) and that are authorized to have their expiration date extended under the federal government's Shelf Life Extension Program (SLEP).

4. The above oseltamivir phosphate products are authorized to be accompanied by the following written information pertaining to the emergency use, which are authorized to be made available to health care providers⁴ and recipients:

- Fact Sheet for Health Care Provider
- Fact Sheet for Patients and Parents

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 oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization. (See section IV).

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 oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza, 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 oseltamivir phosphate products may be effective for the treatment and prophylaxis 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 oseltamivir phosphate products, when used for the treatment and prophylaxis of influenza in the specified population, meet the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.⁵

Subject to the terms of this EUA and under the circumstances set forth in the Secretary of DHHS's determination under section 564(b)(1)(C) described above and the Secretary of DHHS's corresponding declaration under section 564(b)(1), the oseltamivir phosphate products described above are authorized for the treatment and prophylaxis of influenza for individuals exposed to 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 holding of authorized oseltamivir phosphate products by CDC and other public health authority(ies) for a period of ninety days.

IV. Conditions of Authorization

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

CDC

- A. CDC will verify that authorized oseltamivir phosphate products distributed to the Receive, Stage, Storage (RSS) sites are within their labeled (or SLEP-re-labeled) expiration dates.
- B. CDC will ensure that the appropriate state and/or local public health authority(ies) are informed of this EUA, including the terms and conditions herein.
- C. CDC will make available to the appropriate state and/or local public health authority(ies) through appropriate means the authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.
- D. Only CDC may request changes to the authorized Fact Sheet for Health Care Providers and authorized Fact Sheet for Patients and Parents. Such requests will be made by contacting FDA concerning FDA review and approval.

State and/or Local Public Health Authority(ies)

- E. The appropriate state and/or local public health authority(ies) will ensure that authorized oseltamivir phosphate products 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 prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency.
- F. The appropriate state and/or local public health authority(ies) will make available through appropriate means authorized Fact Sheet for Health Care Providers, Fact Sheet for Patients and Parents, and at least one representative FDA-approved package insert that covers the dosage forms and strengths of authorized oseltamivir phosphate products.

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

G. 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 oseltamivir phosphate products that is consistent with, and does not exceed, the terms of this letter of authorization.

The emergency use of authorized oseltamivir phosphate products 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 FDA is authorizing the emergency use of Tamiflu (oseltamivir phosphate) (30 mg, 45 mg, and 75 mg) capsules and oral suspension for treatment and prophylaxis of influenza as described in the scope section of this letter (Section II). For ease of reference, this letter of authorization will use the terms "certain oseltamivir phosphate product(s)" and "authorized oseltamivir phosphate product(s)."

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

² No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

³ The following points should be considered before initiating treatment or prophylaxis with oseltamivir phosphate products. Oseltamivir phosphate products are not a substitute for early vaccination on an annual basis as recommended by the Centers for Disease Control and Prevention Advisory Committee on Immunization Practices. Influenza viruses change over time. Emergence of resistance mutations could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use oseltamivir phosphate products.

⁴ It is possible that public health officials or other volunteers might distribute authorized oseltamivir phosphate products to recipients, if permitted, in accordance with applicable state and local law and/or in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasures, and their officials, agents, employees, contractors, or volunteers following a declaration of an emergency. For ease of reference, this letter will use the term "health care provider(s)" to refer collectively to these individuals.

⁵ Please note that with respect to authorized oseltamivir phosphate products for use in patients less than 1 year old, the conclusions above are based on limited data available for review under the limited timeframe given the circumstances of the emergency. The conclusions above may evolve as the emergency circumstances evolve and as more information becomes available.

(Please note that certain written emergency use information was also amended).

Dated: June 30, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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CFDA Number: 93.583.

Legislative Authority: The Refugee Act of 1980 as amended, Wilson-Fish Amendment, 8 U.S.C. 1522(e)(7); section 412(e)(7)(A) of the Immigration and Nationality Act.

Amount of Award: \$1,744,533.

Period Of Support: 09/30/2009-09/29/2010.

SUMMARY: The Office of Refugee Resettlement (ORR) announces the award of program expansion supplements to five Wilson-Fish Program grantees. The Wilson-Fish Program is an alternative to traditional State-administered refugee assistance programs and provides integrated assistance and services to refugees, asylees, Amerasian Immigrants, Cuban and Haitian Entrants, Trafficking Victims and Iraqi/Afghani Special Immigrant Visas (SIVs). The five

supplemental awards will allow the grantees to provide cash and medical assistance to arriving refugees and to others who are also eligible for refugee benefits through the remainder of Fiscal Year (FY) 2009. The expansion supplement awards will enable the grantees to provide services needed to a higher number of arrivals than originally planned. The Refugee Act of 1980 mandates that the ORR reimburse State agencies and Wilson-Fish projects for the costs of cash and medical assistance for newly arriving refugees. Since 1991, ORR has reimbursed State agencies and Wilson-Fish agencies for providing cash and medical assistance to eligible individuals during their first eight months in the United States. The following Wilson-Fish Program grantees are awarded program expansion supplemental funding:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families; Office of Refugee Resettlement

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Notice to Award Five Program Expansion Supplements to Wilson-Fish Projects.

Grantee organization	Location	Amount of award
Catholic Social Services	Anchorage, AK	\$86,931
Colorado Department of Human Services	Denver, CO	798,411
Catholic Charities of Louisville	Louisville, KY	575,000
Catholic Charities Diocese of Baton Rouge	Baton Rouge, LA	94,368
Massachusetts Office of Refugees and Immigrants	Boston, MA	189,823

FOR FURTHER INFORMATION CONTACT: Carl Rubenstein, Wilson-Fish Program

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