

than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(8), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(8), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: October 14, 2008.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. E8-24725 Filed 10-16-08; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 10 a.m. on Tuesday, October 7, 2008, the Corporation's Board of Directors determined, on motion of Vice Chairman Martin J. Gruenberg, seconded by Director Thomas J. Curry (Appointive), concurred in by Director John M. Reich (Director, Office of Thrift Supervision), Director John C. Dugan (Comptroller of the Currency), and Chairman Sheila C. Bair, that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Memorandum and resolution re: Interagency Notice of Proposed Rulemaking on Capital Treatment of Certain Claims on or Guaranteed by, the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac).

The Board further determined, by the same majority vote, that no notice earlier than October 2, 2008, of the change in the subject matter of the meeting was practicable.

Dated: October 14, 2008.

Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. E8-24757 Filed 10-16-08; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

DATE AND TIME: Tuesday, October 21, 2008 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED: Compliance matters pursuant to 2 U.S.C. 437g. Audits conducted pursuant to 2 U.S.C. 437g, 438(b), and Title 26, U.S.C. Matters concerning participation in civil actions or proceedings or arbitration. Internal personnel rules and procedures or matters affecting a particular employee.

PERSON TO CONTACT FOR INFORMATION: Mr. Robert Biersack, Press Officer, Telephone: (202) 694-1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. E8-24545 Filed 10-16-08; 8:45 am]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in Permissible Nonbanking Activities or To Acquire Companies That Are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated

or the offices of the Board of Governors not later than November 3, 2008.

A. Federal Reserve Bank of San Francisco (Kenneth Binning, Vice President, Applications and Enforcement) 101 Market Street, San Francisco, California 94105-1579:

1. *NHB Holdings, Inc. and Proficio Mortgage Ventures, LLC*, both of Jacksonville, Florida, to engage *de novo* in a joint venture with Home Avenue Mortgage, Clearwater, Florida, in conducting mortgage banking activities, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, October 14, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8-24699 Filed 10-16-08; 8:45 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

October 10, 2008.

AGENCY: Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide targeted liability protections for pandemic countermeasures based on a credible risk that an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

DATES: This notice and the attached declaration are effective as of the date of signature of the declaration.

FOR FURTHER INFORMATION CONTACT: RADM W.C. Vanderwagen, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Highly pathogenic avian influenza A viruses have been spread by infected migratory birds and exports of poultry or poultry products from Asia through Europe and Africa since 2004, and could be spread into North America in 2008 or later, and have caused disease in humans with an associated high case fatality. Section

319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), which was enacted by the Public Readiness and Emergency Preparedness Act, is intended to alleviate certain liability concerns associated with pandemic countermeasures, and, therefore, ensure that the countermeasures are available and can be administered in the event an avian influenza virus spreads and evolves into a strain capable of causing a pandemic of human influenza.

HHS Secretary's Declaration for the Use of the Public Readiness and Emergency Preparedness Act for the Influenza Antivirals

Oseltamivir Phosphate (Tamiflu®) and Zanamivir (Relenza®)

Whereas highly pathogenic avian H5N1 influenza A viruses have spread, through various mechanisms, from Asia through Europe and Africa since 2004 and have caused disease in humans with an associated high case fatality. The real possibility that these viruses could be spread into North America exists as well as the possibility that these H5N1 viruses could participate directly or indirectly in development of a human pandemic strain;

Whereas avian influenza A viruses might evolve into strains capable of causing a pandemic of human influenza;

Whereas there are countermeasures to treat, identify, or prevent adverse health consequences or death from exposure to highly pathogenic avian influenza A viruses or pandemic influenza in humans;

Whereas such countermeasures include Oseltamivir Phosphate (Tamiflu®) and Zanamivir (Relenza®);

Whereas such countermeasures may be used and administered in accordance with Federal contracts, cooperative agreements, grants, interagency agreements, and memoranda of understanding, and may also be used and administered at the Regional, State, and local level in accordance with the public health and medical response of the Authority Having Jurisdiction;

Whereas, the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F–3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d–6d(b)) (“the Act”);

Whereas, immunity under section 319F–3(a) of the Act should be available to governmental program planners for distributions of Covered

Countermeasures obtained voluntarily, such as by (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles;

Whereas, the extent of immunity under section 319F–3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such Covered Countermeasures;

Whereas, in accordance with section 319F–3(b)(6) of the Act, I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasures with respect to the category of disease and population described in sections II and IV below, and have found it desirable to encourage such activities for the covered countermeasures; and

Whereas, to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV below, it is advisable, in accordance with section 319F–3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F–3(i)(2) of the Act, and to include as such covered persons such other qualified persons as I have identified in section VI of this declaration;

Therefore, pursuant to section 319F–3(b) of the Act, I have determined there is a credible risk that the spread of avian influenza viruses and resulting disease could in the future constitute a public health emergency.

I. Covered Countermeasures (As Required by Section 319F–3(b)(1) of the Act)

Covered Countermeasures are defined at section 319F–3(i) of the Act.

At this time, and in accordance with the provisions contained herein, I am recommending the manufacturing,

testing, development, and distribution; and, with respect to the category of disease and population described in sections II and IV below, the administration and usage of the pandemic countermeasures, influenza antiviral drugs oseltamivir phosphate (Tamiflu®) and Zanamivir (Relenza®). The immunity specified in section 319F–3(a) of the Act shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding involving countermeasures that are used and administered in accordance with this declaration, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasure following a declaration of an emergency, as defined in section IX below. In accordance with section 319F–3(b)(2)(E) of the Act, for governmental program planners, the immunity specified in section 319F–3(a) of the Act shall be in effect to the extent they obtain Covered Countermeasures through voluntary means of distribution, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles. For all other covered persons, including other program planners, the immunity specified in section 319F–3(a) of the Act shall, in accordance with section 319F–3(b)(2)(E) of the Act, be in effect pursuant to any means of distribution.

This declaration shall subsequently refer to the countermeasures identified above as “Covered Countermeasures.”

This declaration shall apply to all Covered Countermeasures administered or used during the effective period of the declaration.

II. Category of Disease (As Required by Section 319F–3(b)(2)(A) of the Act)

The category of disease, health condition, or threat to health for which I am recommending the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian influenza A viruses or other highly pathogenic influenza viruses causing a pandemic following exposure to the viruses.

III. Effective Time Period (As Required by Section 319F-3(b)(2)(B) of the Act)

With respect to Covered Countermeasures administered and used in accordance with present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding, the effective period of time of this Declaration commences on signature of the declaration and extends through December 31, 2015.

With respect to Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, the effective period of time of this Declaration commences on the date of a declaration of an emergency and lasts through and includes the final day that the emergency declaration is in effect including any extensions thereof.

IV. Population (As Required by Section 319F-3(b)(2)(C) of the Act)

Section 319F-3(a)(4)(A) of the Act confers immunity to manufacturers and distributors of the Covered Countermeasure, regardless of the defined population.

Section 319F-3(a)(3)(C)(i) of the Act confers immunity to covered persons who may be a program planner or qualified persons with respect to the Covered Countermeasure only if a member of the population specified in the declaration uses the Covered Countermeasure or has the Covered Countermeasure administered to him and is in or connected to the geographic location specified in this declaration, or the program planner or qualified person reasonably could have believed that these conditions were met.

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the Federal government or pursuant to a contract, grant, or cooperative agreement with the Federal government; (2) any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration

of an emergency; (3) any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized under an Emergency Use Authorization; and (4) any person who receives a Covered Countermeasure in human clinical trials being conducted directly by the Federal Government or pursuant to a contract, grant, or cooperative agreement with the Federal Government.

V. Geographic Area (As Required by Section 319F-3(b)(2)(D) of the Act)

Section 319F-3(a) of the Act applies to the administration and use of a Covered Countermeasure without geographic limitation.

VI. Other Qualified Persons (As Required by Section 319F-3(i)(8)(B) of the Act)

With regard to the administration or use of a Covered Countermeasure, section 319F-3(i)(8)(A) of the Act defines the term "qualified person" as a licensed individual who is authorized to prescribe, administer, or dispense the Covered Countermeasure under the law of the State in which such covered countermeasure was prescribed, administered or dispensed.

Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: (1) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency, and (2) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization.

VII. Additional Time Periods of Coverage After Expiration of Declaration (As required by section 319F-3(b)(3)(B) of the Act)

I have determined that, upon expiration of the time period specified in section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition and covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

VIII. Amendments

This Declaration has not previously been amended. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-3(b)(4) of the Act.

IX. Definitions

For the purpose of this declaration, including any claim for loss brought in accordance with section 319F-3 of the PHS Act against any covered persons defined in the Act or this declaration, the following definitions will be used:

Administration of a Covered Countermeasure: As used in section 319F-3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Authority Having Jurisdiction: Means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (e.g., city, county, tribal, State, or Federal boundary lines) or functional (e.g. law enforcement, public health) range or sphere of authority.

Covered Persons: As defined at section 319F-3(i)(2) of the Act, include the United States manufacturers, distributors, program planners, and qualified persons. The terms "manufacturer," "distributor," "program planner," and "qualified person" are further defined at sections 319F-3(i)(3), (4), (6), and (8) of the Act.

Declaration of Emergency: A declaration by any authorized local, regional, State, or federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a federal declaration in support of an emergency use authorization under section 564 of the FDCA unless such declaration specifies otherwise.

Pandemic Countermeasures: Means the neuraminidase class of Antivirals Oseltamivir Phosphate (e.g., Tamiflu® and Zanamivir (e.g., Relenza®).

This 10th day of October, 2008.

Michael O. Leavitt,
Secretary of Health and Human Services.

Appendix I

List of U.S. Government Contracts

Contract	Manufacturer	Covered countermeasure	Pub. L. 85-804 coverage*
HHSO1002006000015I	Roche	Oseltamivir Phosphate (Tamiflu®)	No.
HHSO1002006000016I	GlaxoSmithKline	Zanamivir (Relenza®)	No.
HHSO1002006000015I	Roche	Acquisition of Tamiflu, 75 mg (state purchases).	No.
HHSO1002006000016I	GlaxoSmithKline	Acquisition of Relenza, 5 mg (state purchases).	No.
797HH7282	Roche	Oseltamivir, 75 mg (Tamiflu) (SNS)	No.
797HH7283	GlaxoSmithKline	Relenza (Zanamivir) 5 mg (SNS)	No.
797HH8113	GlaxoSmithKline	Relenza (Zanamivir) 5 mg (SNS)	No.
797HH8112	Roche	Oseltamivir 75 mg (Tamiflu) (SNS)	No.
		Oseltamivir 45 mg (Tamiflu).	
		Oseltamivir 30 mg (Tamiflu).	

[FR Doc. E8-24733 Filed 10-14-08; 4:15 pm]

BILLING CODE 4150-37-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act

October 10, 2008.

AGENCY: Office of the Secretary (OS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. 247d-6d) to provide targeted liability protections for *Botulism* countermeasures based on a credible risk that the threat of exposure to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source constitutes a public health emergency.

DATES: This notice and the attached declaration are effective as of the date of signature of the declaration.

FOR FURTHER INFORMATION CONTACT: RADM W.C. Vanderwagen, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue, SW., Washington, DC 20201, Telephone (202) 205-2882 (this is not a toll-free number).

HHS Secretary's Declaration for Utilization of Public Readiness and Emergency Preparedness Act for Botulism Countermeasures

Whereas exposure to botulinum toxin(s) and the resulting disease(s) from manmade or natural sources may cause harm to the general population sufficient to constitute a public health emergency;

Whereas the Secretary of the Department of Homeland Security has determined that botulinum toxins present a material threat against the United States population sufficient to affect national security;

Whereas botulinum toxins are extremely potent and lethal;

Whereas there are covered countermeasures to treat, identify, or prevent adverse health consequences or death from botulinum toxins;

Whereas such botulism countermeasures, including antitoxins, for potential pre-exposure and for post-exposure prevention and treatment, diagnostics to identify such exposure, and additional countermeasures for treatment of adverse events arising from use of these botulism countermeasures exist, or may be the subject of research and/or development;

Whereas such countermeasures may be used and administered in accordance with Federal contracts, cooperative agreements, grants, interagency agreements, and memoranda of understanding, and may also be used and administered at the Regional, State, and local level in accordance with the public health and medical response of the Authority Having Jurisdiction;

Whereas the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F-3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d-6d(b)) ("the Act");

Whereas immunity under section 319F-3(a) of the Act should be available to governmental program planners for distributions of Covered Countermeasures obtained voluntarily, such as by (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise

voluntarily obtained Covered Countermeasures from State, local, or private stockpiles;

Whereas the extent of immunity under section 319F-3(a) of the Act afforded to a governmental program planner that obtains Covered Countermeasures except through voluntary means is not intended to affect the extent of immunity afforded other covered persons with respect to such Covered Countermeasures;

Whereas in accordance with section 319F-3(b)(6) of the Act, I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasures with respect to the category of disease and population described in sections II and IV below, and have found it desirable to encourage such activities for the covered countermeasure; and

Whereas to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV below, it is advisable, in accordance with section 319F-3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F-3(i)(2) of the Act, and to include as such covered persons such other qualified persons as I have identified in section VI of this declaration;

Therefore pursuant to section 319F-3(b) of the Act, I have determined there is a credible risk that botulinum toxin(s) and the resulting disease(s) from a