

Trans No.	Acquiring	Acquired	Entities
20081682	GeNx360 Capital Partners, L.P	GSC Recovery IIA, L.P	No. 7 Ltd., Taiwan Branch.
20081703	AEP Industries Inc	Atlantis Plastics, Inc	Precision Partners, Inc.
			Atlantis Plastic Films, Inc.
			Linear Films, Inc.
20081711	Ecopetrol S.A	Chevron Corporation	Union Oil Company of California.
20081718	Fortune Brands, Inc	Pernod Ricard SA	Cruzan Viril, Ltd.
			The Absolut Spirits Company, Inc.
			V&S Vin Spirit AB.

TRANSACTIONS GRANTED EARLY TERMINATION—09/15/2008

20080831	Reed Elsevier PLC	ChoicePoint Inc	ChoicePoint Inc.
20080832	Reed Elsevier NV	ChoicePoint Inc	ChoicePoint Inc.
20080987	Fresenius Medical Care AG & Co. KGaA.	Daiichi Sankyo Company, Limited ..	Luitpold Pharmaceuticals, Inc.
20081648	Kulicke and Sofia Industries	Orthodyne Electronics Corporation ..	Orthodyne Electronics Corporation.
20081666	JDA Software Group, Inc	i2 Technologies, Inc	i2 Technologies, Inc.

TRANSACTIONS GRANTED EARLY TERMINATION—09/16/2008

20081683	The Middleby Corporation	TurboChef Technologies, Inc	TurboChef Technologies, Inc.
20081684	Johnson & Johnson	SurgRx, Inc	SurgRx, Inc.
20081695	Eli Lilly and Company	Monsanto Company	Monsanto Company.
20081706	Orkla ASA	Benson Holdings, Inc	Benson Industries LLC.
20081720	Assurant, Inc	General Electric Company	General Electric Company.
20081729	Alberto-Culver Company	The Procter & Gamble Company	Noxell Corporation.
20081735	Arbor Investments II, L.P	Bradshaw International, Inc	Bradshaw International, Inc.
20081737	J.P. Morgan Chase & Co	X-Rite, Incorporated	X-Rite, Incorporated.
20081738	The Hanover Insurance Group, Inc ..	AIX Holdings, Inc	AIX Holdings, Inc.
20081742	Covanta Holding Corporation	Ridgewood Electric Power Trust IV ..	Indeck Maine Energy, LLC.

TRANSACTIONS GRANTED EARLY TERMINATION—09/18/2008

20081783	Barclays PLC	Lehman Brothers Holdings Inc., a debtor-in-possession.	LB 745 LLC. Lehman Brothers Inc.
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TRANSACTIONS GRANTED EARLY TERMINATION—09/19/2008

20081665	Owens & Minor, Inc	Mr. George Burrows	The Burrows Company.
20081719	Chesapeake Energy Corporation	Cinco County Barnet Shale, LLC	DDJET Limited LLP.
20081743	Covanta Holding Corporation	Ridgewood Electric Power Trust V ..	Indeck Maine Energy, LLC.
V20081746	Riverside Capital Appreciation Fund V, L.P.	Commercial Markets Holdco, Inc	JohnsonDiversey Canada, Inc. JohnsonDiversey, Inc.

FOR FURTHER INFORMATION CONTACT:

Sandra M. Peay, Contact Representative
or Renee Hallman, Contact
Representative, Federal Trade
Commission, Premerger Notification
Office, Bureau of Competition, Room H-
303, Washington, DC 20580, (202) 326-
3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E8-23330 Filed 10-3-08; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of the Secretary****Declaration Under the Public Readiness and Emergency Preparedness Act**

October 1, 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 anthrax countermeasures based on a credible risk that the threat of exposure to *Bacillus anthracis* and the resulting disease 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 Anthrax Countermeasures

Whereas significant changes in the nature, regularity and degree of threats to health posed by the use of infectious agents as weapons of biological warfare have generated increased concern for the safety of the general American population particularly following the deliberate exposure of citizens in the

United States to *Bacillus anthracis* (*B. anthracis*) spores in 2001 that demonstrated the ease of dissemination, infectivity, and mortality;

Whereas the Secretary of Homeland Security has determined that *B. anthracis* and multi-drug-resistant *B. anthracis* present a material threat against the United States population, sufficient to affect national security;

Whereas there are covered countermeasures to treat, identify, or prevent adverse health consequences or death from exposure to *B. anthracis*;

Whereas such countermeasures, including vaccines, antimicrobials/antibiotics, and antitoxins for pre-exposure and post-exposure prevention and treatment, diagnostics to identify such exposure, and additional countermeasures for treatment of adverse events arising from use of these 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 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 threat of exposure of *B. anthracis* and the resulting disease constitutes 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 manufacture, testing, development, distribution, dispensing; and, with respect to the category of disease and population described in sections II and IV below, the administration and usage of anthrax countermeasures as defined in section IX below. The immunity specified in section 319F-3(a) of the Act shall only be in effect with respect to: (1) Present (see Appendix I) 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 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 time period of the declaration. This declaration also shall apply to all Covered Countermeasures (see Appendix I) administered or used by or on behalf of the Department of Defense.

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 anthrax, which may result from exposure to *B. anthracis*.

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 as persons who use the Covered Countermeasure or to whom such a Covered Countermeasure is administered, 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 are 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: Department of Defense military personnel and supporting civilian-employee and contractor personnel; any person conducting research and development of Covered Countermeasures directly by the Federal government or pursuant to a contract, grant, or cooperative agreement with the Federal government; 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; 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; any person who receives a Covered Countermeasure as an investigational new drug 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. 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 who is authorized to prescribe, administer, deliver, distribute or dispense Covered Countermeasures to Department of Defense military personnel and supporting civilian-employee and contractor personnel, (2) 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 (3) Any person authorized to prescribe, administer, or dispense Covered Countermeasures or who is otherwise authorized under an Emergency Use Authorization, including, but not limited to Department of Defense military personnel and supporting civilian employee and contractor personnel.

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 manufacturers and other 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. Further, as to doses shipped by the CDC to the DoD pursuant to the DoD/CDC Interagency Agreement (IAA) dated March 10, 2008, an additional period of time of liability protection shall extend for as long as the SNS or its successor exists and the IAA remains in effect, plus, if the additional twelve (12) months following the time period in Section III above has expired, an additional twelve (12) months upon expiration of the IAA.

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 Covered Countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

Anthrax Countermeasure: Any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat anthrax or adverse events from such countermeasures (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR Part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.

Authority Having Jurisdiction: 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 an 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 anthrax 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.

This first 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	PL 85–804 coverage*
HHSO100200500007C	Cangene	Anthrax immune globulin—AIG	No.
HHSO100200500006C	HGS	Anthrax monoclonal antibody—ABThrax	No.
HHSO100200600019C	Emergent Biodefense Operations	BioThrax (Anthrax Vaccine Adsorbed, AVA)	Yes.
HHSO100200700037C	Emergent Biodefense Operations	BioThrax (Anthrax Vaccine Adsorbed, AVA)	No.
W9113M–04–D–0002	BioPort (Emergent Biosolutions)	BioThrax (Anthrax Vaccine Adsorbed, AVA)	Yes.
DAMD 17–97–D–00003	BioPort (Emergent Biosolutions)	BioThrax (Anthrax Vaccine Adsorbed, AVA) Ship- ping.	Yes.
HHSN 272200700035C	Elusys	Anthrax monoclonal antibody—ETI–204	No.
HHSN 272200700033C	Pharmathene	Anthrax monoclonal antibody—Valortim	No.
HHSN 272200700034C	Emergent BioSolutions	Anthrax immune globulin—AIG	No.
NO1–A1–30052	Avecia (Pharmathene)	Recombinant protective antigen (rPA) anthrax vaccine.	No.
V797P–5777x	Shering Corp.	Cipro 250mg/5ml; 100ml suspension	No.
V797P–5977x	Cobalt Pharmaceuticals	Cipro 500mg tablets	No.
V797P–5941x	Blu Pharmaceuticals	Doxycycline 100mg tablets	No.
V797P–5883x	Pfizer, Inc	Doxycycline 25mg/5ml suspension 60ml	No.
V797P–5669x	Abraxis Bioscience, Inc	Doxycycline 100mg vial IV	No.
V797–DSNS–8002	Sandoz, Inc	Amoxicillin 500mg capsules	No.
V797–DSNS–8002	Sandoz, Inc	Amoxicillin 400mg/5ml; 100ml suspension	No.
V797BPA0015	Bedford Labs	Rifampin 600mg vial IV	No.
V797P–5396x	Hospira	Clindamycin 150mg/ml 6ml vial IV	No.
V797P–5669x	Abraxis Bioscience, Inc	Vancomycin 1 g vial IV	No.
V797P–1020x	McKesson	Penicillin GK 20 million unit vial IV	No.
V797P–5387x	Johnson and Johnson Healthcare	Levofloxacin 5mg/ml 150ml bag IV	No.

* Status of indemnification coverage under P.L. 85–804 (An Act to authorize the making, amendment and modification of contracts to facilitate the national defense.)

[FR Doc. E8–23547 Filed 10–1–08; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination and Declaration Regarding Emergency Use of Doxycycline Hyclate Tablets Accompanied by Emergency Use Information

AGENCY: Office of the Secretary (OS), HHS.

ACTION: Notice.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) is issuing this notice pursuant to section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 360bbb–3(b)(4), to justify the emergency use of doxycycline hyclate tablets accompanied by emergency use information, contained in emergency kits for eligible United States Postal Service (USPS) Cities Readiness Initiative (CRI) participants and their household members in advance of a potential attack involving *Bacillus anthracis*. *Bacillus anthracis* is a

biological agent known to cause anthrax. The Secretary, HHS, provides notice of the determination of the Secretary of Homeland Security on September 23, 2008 that there is a significant potential for a domestic emergency involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents—in this case, *Bacillus anthracis*, although there is no current domestic emergency involving anthrax, no current heightened risk of an anthrax attack, and no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*. The Secretary also provides notice that, on the basis of such determination, he has declared an emergency justifying the authorization of emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued by the Food and Drug Commissioner under 21 U.S.C. 360bbb–3(a).

DATES: This Notice and referenced HHS declaration are effective as of October 1, 2008.

FOR FURTHER INFORMATION CONTACT:

RADM W.C. Vanderwagen, M.D., 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:

I. Background

The CRI, begun in 2004, is a federally supported effort to prepare 72 major U.S. metropolitan areas to effectively respond to a large-scale bioterrorist event by dispensing antibiotics to their entire identified population within 48 hours of the decision to do so. Over the past several years, HHS and the USPS have developed and tested in three U.S. cities—Seattle, Philadelphia and Boston—the ability of letter carriers to quickly deliver door-to-door a few days' worth of antibiotics to residential addresses. This quick-strike capability is intended to buy time for State and local public health authorities to set up points of dispensing for further provision of antibiotics across the community, as needed.

Under Section 564 of the FFDCA, the Secretary of Homeland Security may determine 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.