



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Renewal of Declaration Regarding Emergency Use of All Oral Formulations of Doxycycline Accompanied by Emergency Use Information

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

ACTION: Notice.

SUMMARY: The Secretary of Homeland Security determined 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*. On the basis of that determination, and pursuant to section 564(b) of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), the Secretary of Health and Human Services is renewing her July 20, 2011 declaration of an emergency justifying the authorization of emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued by the Commissioner of Food and Drugs under 21 U.S.C. 360bbb–3(a). This notice is being issued in accordance with section 564(b)(4) of the FD&C Act, 21 U.S.C. 360bbb–3(b)(4).

DATES: This Notice and referenced HHS declaration are effective as of July 20, 2012.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, 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: On September 23, 2008, former Secretary of Homeland Security, Michael Chertoff, determined 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*.

On October 1, 2008, on the basis of that determination, and pursuant to section 564(b) of the FD&C Act, 21 U.S.C. 360bbb–3(b), former Secretary of Health and Human Services, Michael O. Leavitt, declared an emergency justifying the emergency use of doxycycline hyclate tablets accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb–3(a).¹ On October 1, 2009 and October 1, 2010, I renewed the former Secretary’s declaration,² and on July 20, 2011, I renewed and amended the declaration to declare that the emergency justifies emergency use of all oral formulations of doxycycline accompanied

¹ Pursuant to section 564(b)(4) of the FD&C Act, notice of the determination by the Secretary of Homeland Security and the declaration by the Secretary of Health and Human Services was provided at 73 FR 58242 (October 6, 2008).

² Pursuant to section 564(b)(4) of the FD&C Act, notices of the renewal of the declaration of the Secretary of Health and Human Services were provided at 74 FR 51,279 (Oct. 6, 2009) and 75 FR 61,489 (Oct. 5, 2010).

by emergency use information subject to the terms of any authorization issued under 21 U.S.C. 360bbb-3(a).³

On the basis of the September 23, 2008 determination by the Secretary of Homeland Security and pursuant to section 564(b) of the FD&C Act, I hereby renew my July 20, 2011 declaration that the emergency justifies emergency use of all oral formulations of doxycycline accompanied by emergency use information subject to the terms of any authorization issued under 21 U.S.C. §360bbb-3(a). I am issuing this notice in accordance with section 564(b)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 360bbb-3(b)(4).

Kathleen Sebelius
Secretary

June 28, 2012 _____
Date

³ Pursuant to section 564(b)(4) of the FD&C Act, notice of the renewal and amendment of the declaration of the Secretary of Health and Human Services was provided at 76 FR 44,926 (July 27, 2011).

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