



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

June 21, 2010

Thomas R. Frieden, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Re: Termination of Declarations of Emergency Justifying Emergency
Use Authorization (EUA) of Certain Antiviral Drugs—Zanamivir, Oseltamivir Phosphate, and
Peramivir

Dear Dr. Frieden:

This letter is to provide advance notice of the termination of:

- (1) the declaration of emergency that was issued by the then Acting Secretary of the Department of Health and Human Services (HHS) Charles E. Johnson on April 26, 2009, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3, justifying the authorization of the emergency use of certain products from the neuraminidase class of antivirals Oseltamivir Phosphate and Zanamivir; and
- (2) the declaration of emergency that was issued by the Secretary of HHS on October 20, 2009, pursuant to section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3, justifying the authorization of the emergency use of the antiviral peramivir.

Both of the declarations described above will terminate when the Public Health Emergency determination for 2009 H1N1 influenza expires on June 23, 2010. Therefore, after June 23, 2010, the EUA authorizing the unapproved uses of zanamivir and oseltamivir phosphate and the use of the unapproved drug peramivir will no longer be in effect. For any patient who began a treatment course of peramivir prior to June 23, 2010, the authorization shall continue to be effective after June 23, 2010, to allow completion of that treatment course, to the extent the patient's attending physician finds continued treatment necessary. 21 U.S.C. § 360bbb-3(f)(2).

The advance notice of termination will be published in the Federal Register, pursuant to section 564(b)(4) of the Act, 21 U.S.C. § 360bbb-3(b)(4).

Sincerely,

A handwritten signature in black ink, appearing to read "Margaret A. Hamburg".

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs