



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 Declaration of Emergency Justifying Emergency
Use Authorization (EUA) of Certain In Vitro Diagnostic Tests

Dear Dr. Frieden:

This letter is to provide advance notice of the termination of the above-referenced declaration of emergency that was issued by the then Acting Secretary of the Department of Health and Human Services 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 EUAs for in vitro diagnostics for detection of 2009 H1N1 influenza virus. The declaration will terminate when the Public Health Emergency determination for 2009 H1N1 influenza expires on June 23, 2010. Therefore, after June 23, 2010, the in vitro diagnostic tests that were authorized by FDA for use by clinical laboratories to detect the 2009 H1N1 virus will no longer be authorized by FDA.

FDA recognizes that there remain a significant number of clinical laboratories that have purchased and are using authorized tests for detection of 2009 H1N1 virus and that these devices will remain in laboratory inventories, within their expiration dates, after the June 23, 2010 EUA termination date. After June 23, 2010, FDA intends to exercise enforcement discretion regarding such devices if they are already within clinical laboratory inventories on or before that date. FDA encourages manufacturers of the authorized 2009 H1N1 virus detection devices to work with FDA to submit the additional information that may be necessary to obtain FDA clearance or approval for their device. FDA is fully prepared and welcomes the opportunity to work with the manufacturer of each of the authorized in vitro diagnostic devices for detection of 2009 H1N1 virus to help facilitate the rapid efficient review of such tests.

Advance notice of termination will be published in the Federal Register, pursuant to section 564(b)(4) of the Act.

Sincerely,

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

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