



June 22, 2010

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

Re: Disposition of Certain Personal Respiratory Protection Devices Authorized for Emergency Use

Dear Dr. Frieden:

This letter responds to your request regarding the disposition of certain personal respiratory protection devices upon termination of the authorization of emergency use that was issued on April 27, 2009, pursuant to section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360bbb-3.

CDC should consider advising recipients of all of the personal respiratory protection devices that were deployed from the SNS that the Emergency Use Authorization (EUA) will terminate on June 23, 2010; therefore, after June 23, 2010, the personal respiratory protection devices identified in the EUA are no longer authorized by the FDA for use to help reduce wearer exposure to pathogenic biological airborne particulates during a public health medical emergency involving the H1N1 Influenza virus.

For the following FDA cleared, NIOSH-certified N95 respirator models (identified in the table below), FDA suggests that CDC advise all states that received these respirators from the CDC/SNS that they may choose to:

- (1) hold remaining units of such models in accordance with manufacturer labeling and current good manufacturing practice requirements, for example as described by 21 Code of Federal Regulations (CFR) Part 820 (or analogous program), for potential use in future emergencies, should there be another emergency declaration authorizing use of such models for uncleared uses; or
- (2) hold remaining units of such models in accordance with manufacturer labeling and current good manufacturing practice requirements, as required by 21 Code of Federal Regulations (CFR) Part 820, and distribute such models as appropriate for the intended use for which these models were cleared by FDA; or
- (3) hold remaining units of such models in accordance with manufacturer labeling and distribute remaining units of such models as appropriate for which these models are otherwise legally marketed consistent with NIOSH certification.

FDA cleared, NIOSH certified N95 respirators (single use respirators):		
Manufacturer	Model	Size
Moldex-Metrics	3000	XS
	3001	S
	3002	M
	3003	L
3M	1860	M/L
	1870	One Fits All
Gerson	1730	M/L
Kimberly-Clark	46727	Reg
	46827	S

For the following non-FDA cleared, NIOSH-certified N95 respirator models (identified in the table below), CDC should consider advising all states that received products from the CDC/SNS that FDA no longer authorizes these units to be used as medical devices unless appropriate additional clearance or approval is sought. Accordingly, they may choose to:

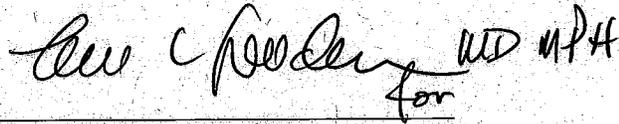
- (1) hold remaining units of such models in accordance with manufacturer labeling and current good manufacturing practice requirements, for example as described in 21 Code of Federal Regulations (CFR) Part 820 (or an analogous program), for potential use in future emergencies, should there be another emergency declaration authorizing use of such models for uncleared uses; or
- (2) hold remaining units of such models in accordance with manufacturer labeling and distribute remaining units of such models as appropriate for which these models are otherwise legally marketed consistent with NIOSH certification.

Non FDA cleared, NIOSH certified N95 respirators (nonmedical N95 respirators):		
Manufacturer	Model	Size
3M	8210	M/L
	8000	M/L
	9210	M/L
Moldex	2200	M/L
	2212	M/L
	2201	S

Note: for products that have a use by date/expiration date on the product packaging, no information has been provided to FDA to support functionality or integrity of these devices past the labeled expiry dating

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

Sincerely,

Handwritten signature in black ink, appearing to read "Margaret Hamburg" with "MD MPH" written to the right and "for" written below the signature.

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