Inland Counties Emergency Medical Agency

Serving San Bernardino, Inyo, and Mono Counties

Virginia Hastings, Executive Director
Reza Vaezazizi, M.D., Medical Director

DATE: August 3, 2010

TO: ALL PROVIDERS/HOSPITALS

FROM: Virginia Hastings
ICEMA Executive Director

Maxwell Ohikuare, M.D.
San Bernardino County Health Officer

SUBJECT: DISPOSITION AND TRACKING OF N95 STATE ALLOCATED CACHES

This memo applies to all pallets of N95's distributed by ICEMA from the Federal/State allocated stockpile. The Local Health Department has decided to implement Option Two (2) as stated in the attached letter from the Department of Health and Human Services regarding the *Disposition of Certain Personal Respiratory Protection Devices Authorized for Emergency Use* for both the FDA cleared and the non-FDA cleared, NIOSH-certified N95 respirator models listed with the exception of the recalled 3M Model 8000 respirators.

According to the California Department of Public Health-Emergency Preparedness Office (CDPH-EPO), "In short, they may be distributed for uses that the products were cleared for. The goal is to put these to good use before they have to be destroyed."

ICEMA removed the 3M Model 8000 respirators from the caches earlier this year as directed by the CDPH-EPO. CDPH-EPO recovered the recalled respirators in June 2010.

All future requests for use of the caches still being housed by the County must be approved by the Medical Health Operational Area Coordinator (MHOAC) which may be the Health Officer or the Director of the EMS Agency (or their designee), depending on the event. ICEMA and the Public Health Department maintain a duty officer roster for off hour activities which can be accessed 24 hours per day via the County Communications Center.

If you have any questions, please feel free to contact Jerry Nevarez at (909) 388-5823 or at jnevarez@cao.sbcounty.gov.

VH/MO/jlm

Enclosure

c: Jerry Nevarez, ICEMA HPP Coordinator
Dora Mejia, ICEMA MEP Specialist
Matt Baca, Public Health PRP
Russ Tingley, Public Health PRP
File Copy

515 North Arrowhead Avenue ▪ San Bernardino, CA. 92415-0060
(909) 388-5823 office ▪ (909) 388-5825 fax ▪ www.icema.net

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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.

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.

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,

for MD MPH

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