9/17/2020 AFL 20-71



State of California—Health and Human Services Agency

California Department of Public Health



AFL 20-71

Acting Director

September 14, 2020

TO: All Facilities

SUBJECT: Recall Notice of Advoque Safeguard N95 Particulate Filtering Respirator

All Facilities Letter (AFL) Summary

This AFL notifies healthcare facilities that Advoque Safeguard issued a regulatory notice for its N95 Particulate Filtering Respirator, model number ADV001, effective September 10, 2020. Advoque masks containing the specific National Institute for Occupational Safety and Health (NIOSH) approval number TC-84A-PH02, including masks distributed prior to September 10, 2020, may no longer be distributed and used as an N95 level respirator.

On September 11, 2020, the State received a regulatory notice from Advoque Safeguard, indicating its N95 Particulate Filtering Respirator, model number ADV001, is no longer NIOSH-approved, effective September 10, 2020. This means Advoque masks containing the specific NIOSH approval number TC-84A-PH02, including masks distributed prior to September 10, 2020, may no longer be distributed and used as an N95 level respirator.

If you have current inventory of Advoque N95 masks with the above referenced number, immediately cease use and distribution of this product. While the masks may be used as face coverings, the State requests the masks be removed from circulation as the N95 stamp may cause confusion as to whether the product is effective as a respirator for particulate filtering. If your facility received Advoque N95 masks from the State, the State's Logistics and Commodity Movement Task Force (LCMTF) will accept return of the Advoque product and will replace your remaining quantities with an alternative N95 NIOSH-approved mask.

To return the masks and request replacement product, please send an email to SOCMHCCOPS@soc.caloes.ca.gov and someone will contact you to make arrangements.

Facilities requesting replacement products from the State's LCMTF should complete the Advoque N95 Recall Survey (form.jotform.com/202574842908159), a short survey seeking specific information on the number of masks you received, the number you currently have in inventory, and the number of replacement masks you may need. This survey data will inform the State's LCMTF on how to quickly and effectively reclaim the Advoque masks and assist your facility with replacement product needs.

If you have distributed these masks to other entities, please provide this notice to the entities and request completion of the survey immediately.

If you have any questions about this AFL, please contact the CDPH Duty Officer at DutyOfficer@cdph.ca.gov.

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Sincerely,

Original signed by Heidi W. Steinecker

Heidi W. Steinecker Deputy Director

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