Stop Using Certain N95 Respirators Manufactured by Shanghai Dasheng - Letter to Health Care Providers

August 25, 2021

The U.S. Food and Drug Administration (FDA) is alerting health care facility risk managers, procurement staff, and health care personnel to stop using certain N95 respirators manufactured by Shanghai Dasheng Health Products Manufacturing Co., Ltd. (Shanghai Dasheng). The Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) revoked all respirator approvals previously issued to Shanghai Dasheng because the company did not implement, maintain, and control a quality management system. All previously authorized Shanghai Dasheng respirators are no longer authorized for emergency use as a result of the loss of NIOSH-approval.

How to Identify Affected N95 Respirators

Affected respirators can be identified by referring to the NIOSH approval numbers below and using the label reference from NIOSH (https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource1quest2.html). Respirators marked with a NIOSH approval label that includes any of the approval numbers listed below are no longer NIOSH-approved. In addition, respirators manufactured by Shanghai Dasheng and marketed using another brand name that include any of the approval numbers below are no longer NIOSH-approved:

TC-84A-4329, TC-84A-4330, TC-84A-4331, TC-84A-4332, TC-84A-4334, TC-84A-4335, TC-84A-4336, TC-84A-4337, TC-84A-4398, TC-84A-4399, TC-84A-4400, TC-84A-4401, TC-84A-4463, TC-84A-4464, TC-84A-4465, TC-84A-4466, TC-84A-4467, TC-84A-4468, TC-84A-4469, TC-84A-4470, TC-84A-4471, TC-84A-4472, TC-84A-4473, TC-84A-4483, TC-84A-4484, TC-84A-4485, TC-84A-4486, TC-84A-4487, TC-84A-8150, TC-84A-8425, TC-84A-8543, TC-84A-8544, TC-84A-8545, TC-84A-8546, TC-84A-8547, TC-84A-8634, TC-84A-8635, and TC-84A-8636.

Recommendations

The FDA recommends health care facility risk managers, procurement staff, and health care personnel to:

- In accordance with the CDC's recommendation, stop using N95 respirators manufactured by Shanghai Dasheng and intended for emergency use (including those bearing other brand names).

- Replace any Shanghai Dasheng respirators with respirators approved by NIOSH that are found on the NIOSH Certified Equipment List (https://www2a.cdc.gov/drds/cel/cel_form_code.asp). Respirators on the NIOSH Certified Equipment List are authorized under the Emergency Use Authorization (EUA) for NIOSH-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency (https://www.fda.gov/media/135763/download).
- Contact group purchasing organizations, distributors, and state or regional resources if you are having difficulty obtaining NIOSH-approved respirators through existing vendors.
- Report any issues with the quality or performance of respirators to the FDA. See "Reporting Problems to the FDA" below.

Background

An N95 respirator (https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-surgical-masks-and-face-masks#s3) is a respiratory protective device designed to achieve a very close facial fit and very efficient filtration of airborne particles. The edges of the respirator are designed to form a seal around the nose and mouth.

FDA Actions

The FDA is alerting health care facility risk managers, procurement staff, and health care personnel about serious concerns with the quality of certain N95 respirators manufactured by Shanghai Dasheng. The FDA is assessing the extent of the concerns and is working with NIOSH to understand and address the issue.

The FDA will continue to keep health care providers and the public informed as significant new information becomes available.

Reporting Problems to the FDA

The FDA encourages health care facility risk managers, procurement staff, and health care personnel to report any adverse events or suspected adverse events experienced with these N95 respirators.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (https://www.fda.gov/medical-devices/postmarket-

requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).

- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Additional Resources

- NIOSH Respiratory Protective Device Information: Revocation of Shanghai Dasheng Health Products Manufacture Co., Ltd. Approvals (https://www.cdc.gov/niosh/npptl/resources/pressrel/letters/respprotect/pdfs/CA-2021-1038-P.pdf)

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (DICE) (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice).