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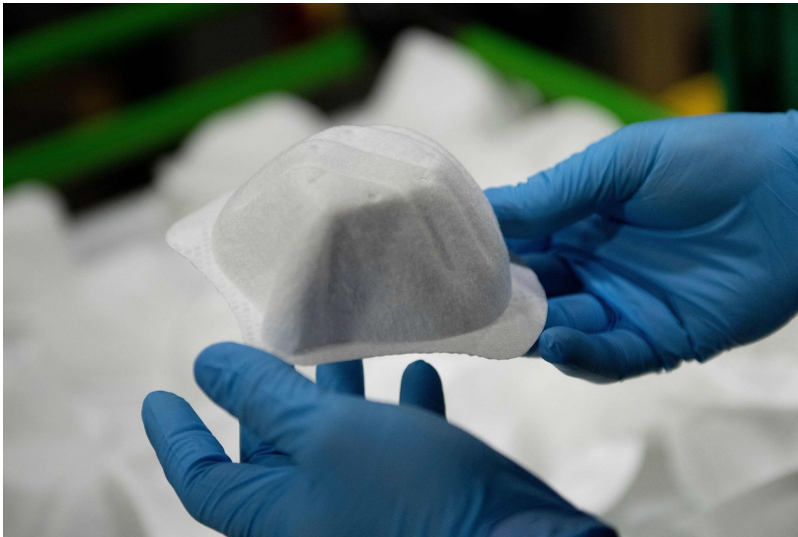
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<https://www.wsj.com/articles/fda-pulls-approval-for-dozens-of-mask-makers-in-china-11588873151>

◆ WSJ NEWS EXCLUSIVE | BUSINESS

## FDA Pulls Approval for Dozens of Mask Makers in China

Tests during the pandemic have shown many imported masks fall well short of N95 filtration standards



The coronavirus pandemic has created huge demand for N95 masks, which offer a high degree of protection.

PHOTO: BRENDAN SMIALOWSKI/AGENCE FRANCE-PRESSE/GETTY IMAGES

By [Austen Hufford](#) and [Mark Maremont](#)

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Federal officials withdrew approval for more than 60 manufacturers in China to export N95-style masks to the U.S. after finding what they said were a large number of low-quality products from those companies.

The Food and Drug Administration said Thursday that it had cut the number of mask makers in China approved to make N95-style masks for use in the U.S. to 14, from around 80. That reversed an April 3 decision to allow imports from manufacturers whose masks hadn't been tested by U.S. authorities but had been reviewed by an independent laboratory.

The shift illustrates the challenge to federal officials who are trying to help meet huge demand for masks from front-line workers battling the coronavirus pandemic, while also ensuring that

medical gear works effectively.

“We’ve been using all of our authorities to increase availability,” an FDA official said in an interview. “There were a growing number of respirators that failed to meet the expedited performance standards.”

The move follows a report by The Wall Street Journal that found U.S. regulators and state officials had identified a significant number of imported N95-style masks that were falling below standards.

Recent tests by the National Institute for Occupational Safety and Health, which is part of the Centers for Disease Control and Prevention, found that about 60% of 67 different types of imported N95-style masks in at least one sample allowed in more tiny particles than U.S. standards normally permit, the Journal reported.

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“Some were grossly under that,” a CDC official said.

Masks from one company in China that had its approval removed on Thursday filtered out between 24% and 35% of particles, well below the 95% standard that gives N95 masks their name, the Niosh tests found. That mask’s packaging promoted its filter level as five stars and used an unauthorized FDA logo, according to Niosh’s test results.

Niosh also tested other imported masks from manufacturers that weren’t on the list of approved manufacturers. One brand filtered out as little as 1% of particles, while others fell well below the 95% threshold.

Some hospitals have said they have checked recent purchases from new suppliers against the FDA’s list of authorized mask makers. Manufacturers in China also have promoted the emergency approvals of their products on their websites.

The FDA said on Thursday that it will continue to allow imports from manufacturers in China certified under U.S. standards or by authorities in certain regions, such as the European Union.

Other parts of the U.S. government are also working to crack down on a flood of counterfeit masks. U.S. Immigration and Customs Enforcement is working together with big U.S. companies, including 3M Co. MMM -3.82% ▼ and Amazon.com Inc., to reduce the importation of low-quality products.

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