FDA warns 12 companies about skin lightening products

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Twelve companies have been issued warning letters about selling over-

the-counter skin lightening products containing hydroquinone, the U.S. Food and Drug Administration announced Tuesday.

The products are unapproved drugs that are not recognized as safe and effective, according to the FDA, which has received reports of serious side effects including rashes, facial swelling and skin discoloration that may be permanent.

The FDA said consumers should not use these products due to the potential risks. Instead, they should talk to their health care provider about treatment options for certain skin conditions, including dark or age spots.

There are no FDA-approved or otherwise legally marketed over-the-counter (OTC) skin lightening products. Some manufacturers and distributors have already removed such products from the U.S. marketplace, and the FDA said it plans to take action against businesses that continue to market what it called "potentially harmful and illegal" products.

The companies that received warning letters were told to immediately correct their violations. They were given 15 days to tell the FDA what actions they've taken to address violations and prevent them from happening again.

Currently, a prescription product called Tri-Luma is the only FDA-approved therapy containing hydroquinone. Tri-Luma is approved for short-term treatment of dark spots associated with moderate-to-severe melasma (patchy brown discoloration) of the face. The FDA said Tri-Luma should only be used under the supervision of a licensed health care professional.

Consumers or health care providers are asked to report problems

associated with OTC skin lightening products to the FDA.

More information: To report problems with OTC skin lightening products, visit the FDA's MedWatch adverse event reporting program or download the form and submit via fax to 1-800-FDA-0178.