FDA and FTC Warn of Fraudulent COVID-19 Products Sold By Seven Companies

Medical Device Hazard Report

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Geographic Regions: U.S.

Suggested Distribution: Risk Management/Continuous Quality Improvement, Materials Management

Problem:
In a March 9, 2020, News Release, FDA states that it and FTC have issued warning letters to seven companies for selling fraudulent COVID-19 products. These products are unapproved drugs that pose significant risks to patient health and violate federal law. FDA also states that products that claim to cure, treat, or prevent serious diseases like COVID-19 may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. FDA and FTC jointly issued warning letters to Vital Silver, Quinessence Aromatherapy Ltd., Xephyr LLC doing business as N-Ergetics, GuruNanda LLC, Vivify Holistic Clinic, Herbal Amy LLC, and The Jim Bakker Show. The products cited in these warning letters are teas, essential oils, tinctures, and colloidal silver. FDA further states that it has previously warned that colloidal silver is not safe or effective for treating any disease or condition. FDA states that currently no vaccines or drugs are approved to treat or prevent COVID-19. Although there are investigational COVID-19 vaccines and treatments under development, these investigational products are in the early stages of product development and have not yet been fully tested for safety or effectiveness.

Action Needed:
FDA recommends that consumers remain cautious of websites and stores selling products that claim to prevent, mitigate, treat, diagnose, or cure COVID-19. Fraudulent COVID-19 products may come in many varieties, including dietary supplements, foods, and products purporting to be drugs, medical devices, or vaccines. U.S. consumers and healthcare professionals should report adverse events or product quality problems relating to the use of COVID-19 product to FDA’s MedWatch Adverse Event Reporting program by telephone at (800) 332-1088; by fax at (800) 332-0178; by mail (using postage-paid FDA Form 3500, available here) at Food and Drug Administration, HF-2, 5600 Fishers Lane, Rockville, MD 20852-9787; or online at the website.

References:

Comments:
- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):
- 2020 Mar 9. FDA. News Release Download