

Accession Number: H0567	ECRI Priority: Normal	Published: 03/10/2020
Channel: Devices	FDA: Not Specified	Last Updated: 03/19/2020

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

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 [MedWatch website](#).

Geographic Region(s)

U.S.

Suggested Distribution

Risk Management/Continuous Quality Improvement, Materials Management

Comment

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

Miscellaneous

References:

- United States. Food and Drug Administration. News Release. Coronavirus update: FDA and FTC warn seven companies selling fraudulent products that claim to treat or prevent COVID-19 [online]. 2020 Mar 9 [cited 2020 Mar 9]. Available from Internet: [Click here](#).

Accession Number: H0567 01	ECRI Priority: Normal	Published: 04/01/2020
Channel: Devices	FDA: Not Specified	Last Updated: 04/01/2020

[COVID-19] FDA and FTC Warn of Fraudulent COVID-19 Products [Update]

Summary

Update Reason: FDA and FTC issue warning letters to three additional companies for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure COVID-19. This Alert provides new information based on FDA source material regarding [Hazard Report H0567](#).

Problem

In a March 31, 2020, [News Release](#), FDA states that it and FTC have issued warning letters to three companies for selling fraudulent products with claims to prevent, treat, mitigate, diagnose, or cure COVID-19. The companies warned included the following:

- [Halosense](#): Sells salt therapy products with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.
- [Bioactive C60/FullerLifeC60](#): Sells an unapproved and unauthorized product, “FullerLifeC60,” with misleading claims that it can build up immunity to help treat or prevent COVID-19 in people.
- [JRB Enterprise Group dba Anti Aging Bed](#): Offers colloidal silver products for sale in the U.S. with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.

FDA also states that with these warning letters, it is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.

Action Needed

The following actions are those listed in [Hazard Report H0567](#). 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 [MedWatch website](#).

Geographic Region(s)

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Miscellaneous

References:

United States:

- Food and Drug Administration. News Release. Coronavirus update: FDA and FTC warn seven companies selling fraudulent products that claim to treat or prevent COVID-19 [online]. 2020 Mar 9 [cited 2020 Mar 9]. Available from Internet: [Click here](#).
- Food and Drug Administration. News Release. Coronavirus (COVID-19) update: daily roundup [online]. 2020 Mar 31 [cited 2020 Apr 1]. Available from Internet: [Click here](#).

Accession Number: H0567 02	ECRI Priority: Normal	Published: 04/15/2020
Channel: Devices	FDA: Not Specified	Last Updated: 04/15/2020

[COVID-19] FDA and FTC Warn of Fraudulent COVID-19 Products [Update]

Summary

Update Reason: FDA and FTC issue warning letters to three additional companies for selling fraudulent products with claims to prevent or treat COVID-19. This Alert provides new information based on FDA source material regarding Hazard Reports [H0567](#) and [H0567 01](#).

Problem

In an April 14, 2020, [News Release](#), FDA states that it and FTC have issued warning letters to three companies for selling fraudulent COVID-19 products. The companies warned included the following:

- [Herbs of Kedem](#): Sells unapproved and misbranded herbal products for the prevention and treatment of COVID-19.
- [The GBS dba Alpha Arogya India Pvt Ltd](#): Offers unapproved and misbranded Ayurvedic products, including “Alpha 11” and “Alpha 21,” for sale in the U.S. with misleading claims about the prevention or treatment of COVID-19.
- [Gaia Arise Farms Apothecary](#): Offers unapproved and misbranded products, including “True Viral Defense,” also referred to as “Viral Defense Tincture.” The company makes misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19 in people.

FDA also states that there are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their healthcare provider.

Action Needed

The following actions are those listed in [Hazard Report H0567](#). 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 [MedWatch website](#).

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United States:

- Food and Drug Administration. News Release. Coronavirus update: FDA and FTC warn seven companies selling fraudulent products that claim to treat or prevent COVID-19 [online]. 2020 Mar 9 [cited 2020 Mar 9]. Available from Internet: [Click here](#).
- Food and Drug Administration. News Release. Coronavirus (COVID-19) update: daily roundup [online]. 2020 Mar 31 [cited 2020 Apr 1]. Available from Internet: [Click here](#).
- Food and Drug Administration. News Release. Coronavirus (COVID-19) update: daily roundup [online]. 2020 Apr 14 [cited 2020 Apr 15]. Available from Internet: [Click here](#).