

Regulation of labeling and advertising claims for products used to protect against COVID-19

Standards applied by EPA, the FDA and the FTC

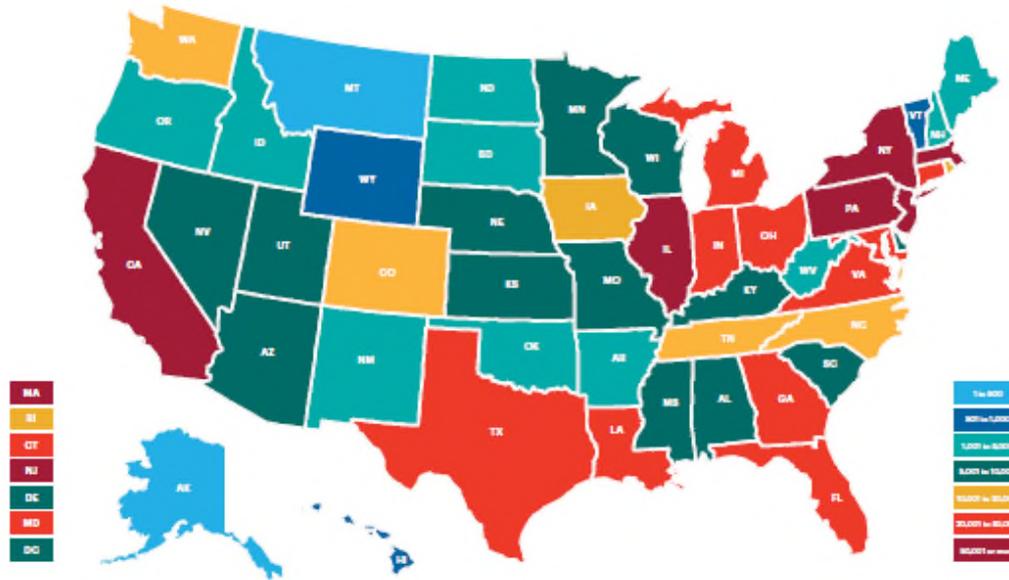
Policy Update



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Coronavirus Disease (COVID-19) in the US



Total cases: 1,229,089
 Total tests conducted: 7,759,771
 Total deaths: 73,435
 Total recovered: 189,910

States with confirmed and presumptive positive cases of COVID-19:

1 to 500

- Alaska
- Montana

501 to 1,000

- Hawaii
- Vermont
- Wyoming

1,001 to 5,000

- Arkansas
- Idaho
- Maine

- New Hampshire
- New Mexico
- North Dakota
- Oklahoma
- Oregon
- South Dakota
- West Virginia

5,001 to 10,000

- Alabama
- Arizona
- Delaware
- Kansas

- Kentucky
- Minnesota
- Mississippi
- Missouri
- Nebraska
- Nevada
- South Carolina
- Utah
- Washington, DC
- Wisconsin

10,001 to 20,000

- Colorado

- Iowa
- North Carolina
- Rhode Island
- Tennessee
- Washington

20,001 to 50,000

- Connecticut
- Florida
- Georgia
- Indiana
- Louisiana
- Maryland

- Michigan
- Ohio
- Texas
- Virginia

50,001 or more

- California
- Illinois
- Massachusetts
- New Jersey
- New York
- Pennsylvania

Date updated: May 07, 2020

Source: Johns Hopkins Coronavirus Resource Center: US Map; <https://coronavirus.jhu.edu/us-map>

Regulation of labeling and advertising claims for products used to protect against COVID-19

Introduction - Products are needed to protect against COVID-19

The subject has its own [Wikipedia page!](#)

What are some types of products out there?

- Disinfection-related products
- Hand-cleaning products
- Gargling and Inhalation
- Temperature and radiation
- Personal protective equipment
- Drugs
- Botanicals
- Food and beverages
- Exercise-related
- New and existing medications



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List of unproven methods against COVID-19

From Wikipedia, the free encyclopedia

For broader coverage of this topic, see [Misinformation related to the 2019–20 coronavirus pandemic](#).

There are many fake and unproven medical products and methods that claim to diagnose, prevent and cure COVID-19.^[1] Fake medicines sold for COVID-19 may not contain the ingredients they claim to contain, and may even contain harmful ingredients.^[2]

No vaccine for COVID-19 prevention is currently available, as of 2020, though there are many worldwide efforts to develop one as soon as possible.^{[1][3]} As of March 2020, the World Health Organization does not recommend any medicines to treat or cure COVID-19, although research is underway in many countries, including the Solidarity trial spearheaded by WHO.^[4] WHO has requested member countries to immediately notify them if any fake medicines or other falsified products are discovered.^[4] There are also many claims that existing products help against COVID; these spread through rumours online rather than conventional advertising.

Anxiety about COVID-19 makes people more willing to "try anything" that might give them a sense of control of the situation, making them easy targets for scams, according to April Thames, associate professor of psychology at the University of Southern California.^[5] Many false claims about measures against COVID-19 have circulated widely on social media, but some have circulated by text, on YouTube, and even in some mainstream media. Officials advised that before forwarding information, people should think carefully and

This article is part of a series on
Alternative and pseudo-medicine



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Public health requires effective products be made available, while protecting from false or unsupported claims

Several federal agencies have authority under existing law to establish rules regarding claims that can be made for COVID-19.



- EPA
 - Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”)
 - Pesticides



- FDA
 - Federal Food Drug and Cosmetic Act
 - Foods (including dietary supplements), drugs, devices, cosmetics



- FTC
 - Federal Trade Commission Act
 - False or misleading advertising

Today's panelists



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EPA standards



- **FIFRA** - The Federal Insecticide, Fungicide and Rodenticide Act
- Definition of “pesticide” includes types of products marketed to protect against COVID-19
 - “Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”
- FIFRA defines “pest” to include any microorganism, virus or bacteria, but excludes viruses, bacteria or other microorganisms on or in humans or other living animals, with the result that EPA does not regulate drugs or medical devices.
- It is unlawful to sell a pesticide that is not registered with US EPA.
- EPA reviews the label in the registration process. It is unlawful to distribute a product that is “misbranded,” *i.e.*, whose labeling is “**false and misleading.**”
- Changes to the label require EPA approval (*i.e.*, an “amendment”) and the sale of a product whose amended labeling has not been approved is unlawful.

Product needs for EPA and producers and retailers of pesticide products

- Disinfectants: hard-surface and multiple-surface (floor and countertop) disinfectant cleaners; disinfectant wipes and sponges; aerosol cleaner/disinfectants
- “Treated Articles”: Products treated with pesticides to protect and preserve the articles (sponges, wipes, cleaner/detergents, aerosol cleaners, computer keyboards, mice and other peripherals)



Antimicrobials with “public health” claims (claims for control of microorganisms that pose a threat to human health):

- Sanitizers: controls some, not all, bacteria; used on food contact surfaces
- Disinfectants: destroys or inactivates bacteria, fungi and viruses in inanimate environment; bathroom and kitchen cleaners, wipes and cloths and sponges that apply disinfectant products effective to destroy or inactivate staph, salmonella in residential, commercial, institutional and other sites.
- Hospital disinfectants: effective against staph, salmonella and pseudomonis aeruginosa and use in hospitals, clinics, dental offices, other health care offices
- Sterilants, fungicides, water purifiers, tuberculocides, virucides.

Emerging or new EPA policies for claims of effectiveness against COVID-19



Environmental Topics

Laws & Regulations

About EPA

CON

Coronavirus (COVID-19)

This is an emerging, rapidly evolving situation and the [Centers for Disease Control and Prevention](#) will provide updated information as it becomes available, in addition to updated guidance. This website provides key EPA resources on the coronavirus disease (COVID-19).

NEW [Read Joint Guidance from CDC and EPA on Cleaning and Disinfecting.](#)

Information on Disinfectants



Information on Drinking Water and Wastewater



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People™

Coronavirus Disease 2019 (COVID-19)

CDC > Coronavirus Disease 2019 (COVID-19) > Prevent Getting Sick > Cleaning Your Home

Coronavirus Disease 2019 (COVID-19)

Symptoms

Testing

Prevent Getting Sick

How It Spreads

Protect Yourself

Cloth Face Covers

Cleaning Your Home

Cleaning and Disinfection for Households

Interim Recommendations for U.S. Households with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19)

Other Languages | Print Page

Summary of Recent Changes

Revisions were made on 3/26/2020 to reflect the following:

- Updated links to EPA-registered disinfectant list
- Added guidance for disinfection of electronics
- Updated core disinfection/cleaning guidance



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Using disinfectants to control the COVID-19 virus

Topic Fact Sheet

This guidance is for the public and professionals to control the COVID-19 virus on surfaces. The coronavirus named "SARS-CoV-2" is the cause of "COVID-19" in people.

This information applies to sprays, **surface wipes**, and other liquids. You may see them called "**antimicrobials**", "disinfectants", or "biocides" on product labels.

Antimicrobial Products List

There are currently no EPA-registered disinfectants that specifically include the SARS-CoV-2 virus on the product label. Refer to the following list from the U.S. Environmental Protection Agency for products that control the virus:

List N: Disinfectants for Use Against SARS-CoV-2

<https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against->



Related Topics:

- PDF version
- Consejos para protecciones y eficacia de desinfectantes
- Antimicrobials
- Antimicrobials Fact Sheet
- Minimizing Pesticide Risks
- Reading Pesticide Labels
- COVID-19 Resources

What are pests?

- Learn about a pest
- Identify a pest
- Control a pest

All products on this list meet EPA's criteria for use against SARS-CoV-2, the virus that causes COVID-19.

The screenshot shows the EPA website header with navigation links for Environmental Topics, Laws & Regulations, and About EPA. Below the header, there is a search bar and social media sharing options. The main heading of the page is "How does EPA know that the products on List N work on SARS-CoV-2?". The text explains that while surface disinfectant products on List N have not been tested specifically against SARS-CoV-2, EPA expects them to kill the virus because they:

- Demonstrate efficacy (e.g. effectiveness) against a harder-to-kill virus; or
- Demonstrate efficacy against another type of human coronavirus similar to SARS-CoV-2.

It also states that all surface disinfectants on List N can be used to kill viruses on surfaces such as counters and doorknobs. Finally, it notes that because SARS-CoV-2 is a new virus, this pathogen is not readily available for use in commercial laboratory testing to see if a certain disinfectant product is effective at killing the virus.

List N: Disinfectants for Use Against SARS-CoV-2

All products on this list meet [EPA's criteria](#) for use against SARS-CoV-2, the virus that causes COVID-19.

Finding a Product

To find a product, enter **the first two sets of its EPA registration number** into the search bar below. You can find this number by looking for the EPA Reg. No. on the product label.

For example, if EPA Reg. No. 12345-12 is on List N, you can buy EPA Reg. No. 12345-12-2567 and know you're getting an equivalent product.

[Search by EPA registration number](#)

Using Other Products

If you can't find a product on this list to use against SARS-CoV-2, look at a different product's label to confirm it has an EPA registration number and that human coronavirus is listed as a target pathogen.

Follow the Label

When using an EPA-registered disinfectant, **follow the label directions** for safe, effective use. Make sure to follow the contact time, which is the amount of time the surface should be visibly wet, listed in the table below. [Read our infographic on how to use these products.](#)

These products are for use on surfaces, NOT humans.

Other COVID-19 Resources

- [EPA's Coronavirus Site](#)
- [CDC's Coronavirus Disease 2019 Site](#)
- [CDC's Cleaning and Disinfection Recommendations for COVID-19](#)
- [NPIC's COVID-19 Virus Factsheet](#)

“Process for making claims against emerging viral pathogens not on EPA-registered disinfectant labels.”

GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS

August 19, 2016

In this document:

- I. Background and Purpose**
- II. Viral Subgroup Classification**
- III. Product Eligibility Criteria**
- IV. Instructions for Using the Process**
- V. Outbreak Criteria Associated with Emerging Pathogens Process**
- VI. References**
- Attachment 1 - Additional Terms of Registration**
- Attachment 2 - Process Example**

I. Background and Purpose

Emerging pathogens are an increasing public health concern in the United States as well as globally. Many of the emerging pathogens of greatest concern are pathogenic viruses, and the ability of some of these viruses to persist on environmental surfaces can play a role in human disease transmission. Because the occurrence of emerging viral pathogens is less common and predictable than established pathogens, few, if any, EPA-registered disinfectant product labels specify use against this category of infectious agents. Also, the pathogens are often unavailable commercially and standard methods for laboratory testing may not have been developed. Thus, it can be difficult to assess the efficacy of EPA-registered disinfectants against such pathogens in a timely manner and to add these viruses to existing product registrations, which requires the submission of efficacy data for agency review. As a result, the agency is providing a voluntary, two-stage process to enable use of certain EPA-registered disinfectant products against emerging viral pathogens not identified on the product label.

1) In the first stage, which may be performed prior to any outbreak, registrants with an eligible disinfectant product may submit a request for label amendment regarding the

- EPA reviews the supporting information and determines if the claim is acceptable. Once approved, a company can make certain **off-label claims** as specified in that guidance in the event of an outbreak such as SARS-CoV-2. For instance, the preapproved company can include certain statements about expected efficacy on:
 - technical literature distributed to health care facilities, physicians, nurses, and public health officials;
 - non-label-related websites;
 - consumer information services; and
 - social media sites.
- EPA's emerging viral pathogen guidance was triggered for SARS-CoV-2 on Jan. 29, 2020. This type of human coronavirus is an enveloped virus, meaning it is one of the easiest types of viruses to kill. Products with human coronavirus claims but not the emerging viral pathogen claim cannot make the same marketing claims in these materials listed above.

FDA and FTC standards and enforcement



Does silver cure COVID-19?

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A Close Look At What's Not Being Said About The Coronavirus (Day 1)

Pastor Jim and the panel discuss the shocking news about the coronavirus.

Guests: Doctor Sherrill Sellman, Zach Drew, Derek Gilbert, Sharon Gilbert

What about herbs?



A sonic silicone facial brush?



Not according to science

Not according to the FTC

Not according to the FDA

- Approximately **68** letters have been issued by FTC and FDA – jointly or individually – based on improper claims.
 - 38 jointly issued letters
- Companies required to respond within 48-hours
- Targeting companies promoting various products with claims to *prevent, diagnose, treat, mitigate, or cure* COVID-19

Danger: Don't Drink Miracle Mineral Solution or Similar Products

The FDA warns you not to drink sodium chlorite products such as Miracle Mineral Solution. These products can make you sick.

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Letters address wide range of products/treatments:

- Joint letters - Products included dietary supplements, essential oils, tea, silver-containing products, homeopathic products, CBD products
- FTC letters - Products included general therapy products, vitamins and supplements, IV therapy and related products, ozone therapy, stem cell therapy, air purifier
- FDA letters - Products included drugs, homeopathic drugs, dietary supplements, hand sanitizer, essential oils



FDA and FTC Joint Letters

Date	Company	Agency	Product Type
3/6/2020	Jim Bakker Show	FDA & FTC	Silver Products
3/6/2020	Herbal Amy LLC	FDA & FTC	"Coronavirus Protocol" - Tea, cell protection, immune system, herbal
3/6/2020	Vivify Holistic Clinic	FDA & FTC	Tea
3/6/2020	GuruNanda, LLC	FDA & FTC	Essential Oils
3/6/2020	Xephyr, LLC dba N-Ergetics	FDA & FTC	Silver Products
3/6/2020	Quinessence Aromatherapy Ltd.	FDA & FTC	Essential Oils
3/6/2020	Colloidal Vitality LLC/Vital Silver	FDA & FTC	Essential Oils, Silver Products
3/26/2020	Corona-cure.com	FDA & FTC	Nasal Spray
3/26/2020	Carahealth	FDA & FTC	Herbal products
3/30/2020	Halosense, Inc.	FDA & FTC	Salt Therapy
3/30/2020	JRB Enterprise Group Inc. DBA Anti Aging Bed	FDA & FTC	Silver Products
3/30/2020	Bioactive C60/FullerLifeC60 LLC	FDA & FTC	Antioxidant
3/31/2020	Neuro XPF	FDA & FTC	CBD Products
4/1/2020	Homeomart Indibuy	FDA & FTC	Homeopathic Products

Date	Company	Agency	Product Type
4/1/2020	Gaia's Whole Healing Essentials, LLC	FDA & FTC	Silver Products
4/1/2020	Health Mastery Systems DBA Pure Plant Essentials	FDA & FTC	Essential Oils
4/6/2020	Ananda, LLC DBA Ananda Apothecary	FDA & FTC	Essential Oils
4/6/2020	Cathay Natural, LLC	FDA & FTC	Herbal Products
4/6/2020	Native Roots Hemp	FDA & FTC	CBD Products
4/6/2020	Indigo Naturals	FDA & FTC	CBD Products
4/7/2020	CBD Online Store	FDA & FTC	CBD Products
4/7/2020	Savvy Holistic Health dba Holistic Healthy Pet	FDA & FTC	Immune Support
4/8/2020	Genesis 2 Church	FDA & FTC	Mineral Solution
4/9/2020	Free Speech Systems LLC d.b.a. Infowars.com	FDA & FTC	Silver Products (gargle, toothpaste, wound dressing gel)
4/9/2020	Earthley Wellness dba Modern Alternative Mama LLC	FDA & FTC	Herbal Products
4/10/2020	Herbs of Kedem	FDA & FTC	Herbal Products (throat spray, disinfectant spray, and supplements)
4/13/2020	Gaia Arise Farms Apothecary	FDA & FTC	Herbal Products
4/13/2020	The GBS dba Alpha Arogya India Pvt Ltd	FDA & FTC	Ayurvedic Products

Date	Company	Agency	Product Type
4/15/2020	The Art Of Cure	FDA & FTC	Homeopathic Products
4/16/2020	Nova Botanix LTD DBA CanaBD	FDA & FTC	CBD Products
4/21/2020	Copper Touch, LLC	FDA & FTC	Hand Sanitizer
4/21/2020	DrJockers.com, LLC	FDA & FTC	Dietary Supplements, Herbal Products
4/27/2020	Santiste Labs LLC	FDA & FTC	Essential Oils, CBD Products
4/27/2020	Hopewell Essential Oils	FDA & FTC	Essential Oils
5/4/2020	Honey Colony LLC	FDA & FTC	Vitamins; Silver Products
5/4/2020	Dr. Dhole's Sushanti Homeopathy Clinic	FDA & FTC	Homeopathic
5/6/2020	GlutaGenic	FDA & FTC	Viral protection kits (including suppositories, antimicrobial nasal spray, and other items)
5/6/2020	Alive By Nature, Inc.	FDA & FTC	Sublingual gel products

Date	Company	Agency	Product Type
3/26/2020	MedQuick Labs, LLC	FTC	IV Therapy
4/3/2020	LightAir International AB	FTC	Air Purifier
4/3/2020	Bioenergy Wellness Miami	FTC	Antiviral
4/3/2020	Resurgence Medical Spa, LLC	FTC	Vitamins
4/7/2020	Rocky Mountain IV Medics	FTC	Vitamins; IV Therapy
4/7/2020	New Performance Nutrition	FTC	Immune Support
4/7/2020	PuraTHRIVE LLC,	FTC	Vitamins
4/8/2020	Vita Activate	FTC	Immune Support
4/8/2020	Suki Distribution Pte. Ltd.	FTC	Antiviral
4/8/2020	Face Vital LLC	FTC	Cosmetic
4/17/2020	Stemedix, Inc	FTC	Stem Cell Therapy
4/17/2020	Center for Regenerative Cell Medicine	FTC	Stem Cell Therapy
4/17/2020	TRLYHEAL Pty. Ltd.	FTC	Ozone Therapy
4/17/2020	American Medical Aesthetics	FTC	Ozone Therapy; Stem Cell Therapy

Date	Company	Agency	Product Type
4/17/2020	Merge Medical Center	FTC	IV Therapy; Vitamins; Silver Products
4/17/2020	AwareMed	FTC	IV Therapy
4/17/2020	Jiva Med Spa	FTC	Immune Support; Essential Oils
4/24/2020	doTERRA International, LLC	FTC	Essential Oils
4/24/2020	Pruvit Ventures, Inc.	FTC	Essential Oils
4/24/2020	Total Life Changes, LLC	FTC	Vitamins
4/24/2020	Tranont	FTC	Immune Support
4/24/2020	Modere, Inc.	FTC	Immune Support
4/24/2020	Arbonne International, LLC	FTC	immune Support
4/24/2020	Zurvita, Inc.	FTC	Immune Support; Vitamins; Herbal Products

Date	Company	Agency	Product Type
3/30/2020	Unitedpharmacies.md	FDA	Drugs
4/6/2020	Alternative Health Experts LLC DBA Immunization Alternatives	FDA	Dietary Supplements; Homeopathic Drugs
4/8/2020	NRP Organics Ltd	FDA	Dietary Supplements
4/14/2020	Earth Angel Oils	FDA	Essential Oils
4/22/2020	Antroids.com	FDA	Drugs
4/22/2020	Foxroids.com	FDA	Drugs
4/23/2020	Prefense LLC	FDA	Hand Sanitizer

It is unlawful under the FTC Act, 15 U.S.C. 41 *et seq.*, to advertise that a product can prevent, treat, or cure human disease unless you possess

competent and reliable scientific evidence

including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made.

The bottom line, marketers cannot make unsubstantiated claims that their products/therapies can treat or cure COVID-19

Cannot make or exaggerate those claims through:

- product name
- website name
- metatags
- or other means

without rigorous scientific evidence sufficient to substantiate the claims.

Andrew Smith, Director of FTC Bureau of Consumer Protection

“We’re seeing these false claims for all sorts of products, but anyone who makes them simply has no proof and is likely just after your money.”



“It’s shameful to take advantage of people by claiming that a product prevents, treats, or cures COVID-19[.]”

“Currently there is no scientific evidence that these products or services can treat or cure coronavirus.”

- Unapproved new drugs sold in violation of 21 U.S.C. § 355(a)
- Misbranded drugs under 21 U.S.C. § 352
- In relevant part, the FDCA defines “drug” to mean . . . articles *intended for use* in the ***diagnosis, cure, mitigation, treatment, or prevention*** of disease in man or other animals . . . and . . . articles (other than food) *intended* to affect the structure or any function of the body of man or other animals 21 U.S.C. § 321(g).
- Evidence of intended use:
 - Company retail websites
 - Company-sponsored blogs
 - Social media websites including Twitter, Facebook, Instagram, LinkedIn, YouTube

“There’s no proof that any product will prevent or treat COVID-19 . . . Let’s be clear: companies making these claims can look forward to an FTC lawsuit like this one.” – *Andrew Smith, Director of FTC Bureau of Consumer Protection*

“Americans expect and deserve proven medical treatments and today’s action is a forceful reminder that the FDA will use its legal authorities to quickly stop those who have proven to continuously threaten the health of the American public. . . . We will continue to aggressively pursue those that place the public health at risk and hold bad actors accountable.” – *Stephen M. Hahn, M.D., FDA Commissioner*

“The FDA will continue to help ensure those who place profits above the public health during the COVID-19 pandemic are stopped. . . . We are fully committed to working with the Department of Justice to take appropriate action against those jeopardizing the health of Americans by offering and distributing products with unproven claims to prevent or treat COVID-19.” *Judy McMeekin, Pharm.D., Associate Commissioner for Regulatory Affairs, FDA*

- *U.S. v. My Doctor Suggests LLC (d/b/a My Health Supplier), GP Silver LLC, and Gordon Pedersen*, Case No. 2:20-cv-00279 (D. Utah 2020)
- *FTC v. Marc Ching, individually and d/b/a Whole Leaf Organics*, Case No. 2:20-cv-3775 (C.D. Cal. 2020)
- *U.S. v. Genesis II Church of Health and Healing*, Case No. 1:20-cv-21601 (S.D. Fl. 2020)
- *U.S. v. Marschall*, Case No. MJ20-5097 (W.D. Wash.)
- State AG's - Little FTC Acts
- Class Actions



The FDA and FTC are *encouraging anyone* aware of suspected fraudulent COVID-19 medical products – including any claiming to treat, cure, prevent, mitigate, or diagnose – to report to the FDA/FTC.





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