Welcome to Today's Webinar

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Cleaning UP from 2020: Guidance for Disinfectant, Germ and Virus Killing Claims

WEBINAR

July 29, 2020

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Overview

- The regulatory landscape: Who regulates what – EPA, FDA and FTC jurisdiction and requirements
- What can you say and when can you say it
- Potential liability and enforcement considerations
- What to do if you receive a warning letter or other enforcement action

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Overview

- “Coronavirus” = “SARS-CoV-2” = the strain of coronavirus associated with COVID-19
- Products that claim to disinfect, sanitize or otherwise fight germs, including bacteria and viruses
- Jurisdiction: EPA, FDA … both
  - EPA: FIFRA/pesticides; general purpose disinfectants
    - Except if used on or in the human body
  - FDA: Hand sanitizers
    - Critical/semi-critical medical devices

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EPA and FIFRA

- Federal Insecticide Fungicide and Rodenticide Act:
  - “Pesticides” = products that claim to kill, inhibit, prevent or otherwise mitigate any “pest”
  - “Pest” = broadly defined to include viruses, bacteria, fungi, and other microbes
- Pesticide products must meet certain EPA requirements
  - Registration: Product and establishment
  - Labelling, packaging
  - Reporting and record-keeping

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EPA Registration

- All products making “public health” claims must be registered
  - Exemptions for “treated articles” … but claims strictly limited to protection of the article itself
  - Data- and time-intensive process
  - Application requires detailed information on product chemistry, production process, ingredient sources, toxicity and efficacy; proposed product label claims and directions for use
    - Application preparation ~4-8 weeks in general not including time to conduct any necessary toxicity or efficacy testing
  - EPA review period (and fees) varies … expect a minimum of 6-9 months but can be much longer

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EPA Registration

- Registration is *product and company specific*
  - If Company A has a product registered with EPA, Company B still needs its own registration, even if the formula and process are exactly the same
    - Though can obtain relatively quicker review of substantially similar products
- EPA review to determine that the product is safe to use (as directed) and works as claimed

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Demonstrating Efficacy

- Heart of the registration process and basis for the product label and marketing claims
  - EPA will review efficacy data to determine if it supports proposed claims
  - Testing conducted using high quality EPA-approved protocols following “good laboratory practices” (GLP)
  - Terms like “disinfectant”, “sterilizer”, “sanitizer” each have specific meanings and data requirements to support use of the term
    - Disinfectant: Destroy or irreversibly inactivate infectious fungi and bacteria but not necessarily their spores; must achieve 99.9999% microbial load reduction in 10 minutes
    - Sanitizer: Reduce, but not necessarily eliminate, microorganisms (99.9% reduction in 5 minutes)
    - Sterilizer: Eliminate microbes and their spores (99.9999% reduction)

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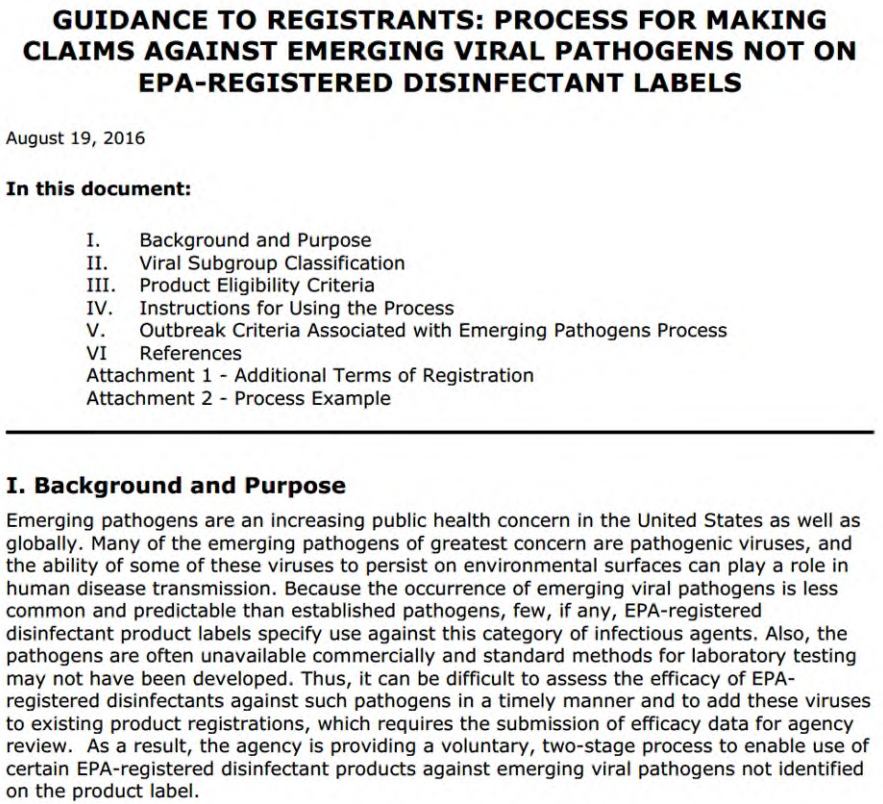
Demonstrating Efficacy

- Can only make specific claims of efficacy against organisms for which you have test data
- Dilemma for “coronavirus” … “emerging pathogen” that we have not seen (or tested against) before
- EPA “Emerging Pathogens Policy”
  - Process to enable claims against new virus



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

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.

EPA Emerging Pathogens Policy

- *Emerging Viral Pathogens Guidance for Antimicrobial Pesticides* (2016)
  - Two-stage process by which companies holding current EPA registrations for certain disinfectant products can *temporarily* promote those products for use against "emerging pathogens"
    - Stage 1: If meet criteria, registrant requests a label amendment adding to their registration a statement of effectiveness against emerging viral pathogens
      - Ideally done prior to an outbreak… though EPA is working under the policy to approve new amendment requests/registrations
    - Stage 2: When CDC declares emergency with an emerging pathogen, registrants may then communicate to the health care community and public that their product may be used against the new pathogen

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EPA Emerging Pathogen Policy

- Registrants with a "pre-qualified emerging viral pathogen designation" can include a statement regarding efficacy against the emerging pathogen "in technical literature distributed to health care facilities, physicians, nurses, public health officials, non-label-related websites, consumer information services, and social media sites“
  - May not make the claim on product labeling

EPA Emerging Pathogen Policy

- EPA/CDC: Spaulding Classification model tiers microorganisms in accordance with the level of resistance to being killed (inactivated) by typical disinfectant products
  - Three viral subgroups: Policy assumes that if data show efficacy against a virus in the same or higher tier, then presumed effective against similar type of virus

Small, Non-Enveloped Viruses (<50 nm): These small, non-enveloped viruses can be highly resistant to inactivation by disinfection. Despite the lack of a lipid envelope, these organisms have a very resistant protein capsid. The following are viral families in the small non-enveloped subgroup: (1) Picornaviridae, (2) Parvoviridae, (3) Caliciviridae, (4) Astroviridae, and (5) Polyomaviridae.

Large, Non-Enveloped Viruses: Compared to small, non-enveloped viruses, these viruses are less resistant to inactivation by disinfection. Although they have a resistant protein capsid, their larger size (50-100nm) makes them more vulnerable than their smaller viral counterparts. The following are viral families in the large non-enveloped subgroup: (1) Adenoviridae, (2) Reoviridae, and (3) Papillomaviridae.

Enveloped Viruses: Enveloped viruses are the least resistant to inactivation by disinfection. The structure of these viruses includes a lipid envelope, which is easily compromised by most disinfectants. Once the lipid envelope is damaged, the integrity of the virus is compromised, thereby neutralizing its infectivity. The following are viral families in the enveloped subgroup: (1) Arenaviridae, (2) Bornaviridae, (3) Bunyaviridae, (4) Coronaviridae, (5) Filoviridae, (6) Flaviviridae, (7) Hepadnaviridae, (8) Herpesviridae, (9) Orthomyxoviridae, (10) Paramyxoviridae, (11) Poxviridae, (12) Retroviridae, (13) Rhabdoviridae, and (14) Togaviriedae.

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EPA “List N”

- List of disinfectants that the agency believes to be effective against SARS-CoV-2
  - https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19
  - Currently ~468 entries
  - Only includes surface disinfectant products (e.g., sprays and aerosols).
    - Not include pesticide “devices” (UV light systems, ozone generators) or FDA-regulated products (hand sanitizers, body wipes)

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Practical Considerations

- What to look for:
  - Registered with EPA?
    - EPA Registration # and EPA Establishment #
    - Labeled with the % of the active and other ingredients
    - Directions for Use, Storage and Disposal information, and caution or warning statements
  - Is it on List N?
    - But … remember that the list is not complete and does not include devices
  - Does the label claim effectiveness against similar or harder to kill viruses … SARS/MERS/Influenza?

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Practical Considerations

- Be careful with products sold over the internet
  - Many lack an EPA Reg. #
  - Illegal or ineffective pesticides pose a safety risk not only from the chemicals in the product but from the false sense of security they may provide
- If you are a company and want to use a disinfectants in your store/operations:
  - Some pesticides must be applied by a professional applicator, but most consumer pesticides can be used at your facility
  - *Follow the Directions for Use* (particularly in terms of contact time and dose)
  - Be careful what you say to your customers/employees
    - Even the best disinfectants cannot guarantee protection against infections

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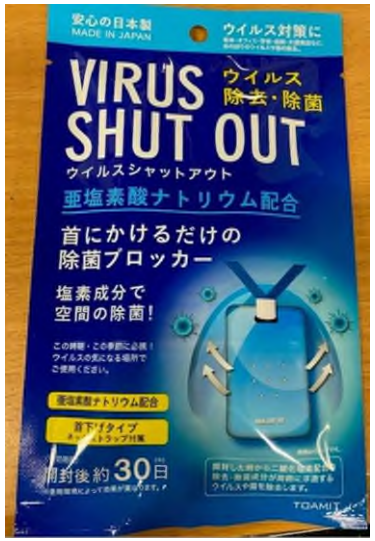
EPA Enforcement

- Highly active and heavily focused on coronavirus claims
- Several high profile actions have been taken against the sale and import of unregistered products with anti-viral claims
  - Working with Customs
- Criminal actions involving illegal import and sale of anti-viral products



EPA Enforcement

- EPA closely monitoring on-line marketing platforms
  - Working with Amazon, eBay, and others to identify and address illegal pesticide sales

“Unscrupulous dealers are using their platforms to sell illegal disinfectant products… [EPA] takes our responsibility to protect Americans from fraudulent surface disinfectants seriously."

- EPA Administrator Andrew Wheeler

“Unregistered disinfectants can put consumers at risk, as they may be ineffective against the virus that causes COVID-19 …. EPA is working hard to stop the sale of these illegal products."

- Susan Bodine, OECA

“EPA is vigorously investigating fraudulent disinfectant sales to the public via online marketplaces."

- John Busterud, EPA Region 9 Administrator

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Thank You

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Overview

- The FDA’s jurisdiction over antimicrobial and disinfecting claims
- The FTC’s role in antimicrobial and disinfecting claims
- How the NAD handles these claims
- Key takeaways

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EPA and FDA Memorandum of Understanding

- EPA and FDA have a Memorandum of Understanding regarding regulation of certain products.
- MOU addresses two main types of liquid chemical germicides:
  - 1. Sterilants - chemical germicides used to reprocess reusable critical (introduced into the body, must be sterile) and semicritical devices (introduced into mucous membrane, do not have to be sterile)
  - 2. General purpose disinfectants - chemical germicides used to reprocess noncritical devices and medical equipment surfaces.

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Regulatory Responsibilities

- FDA will be primarily responsible for the premarket review of safety and efficacy requirements for liquid chemical germicides that are sterilants intended for use on critical or semicritical devices.
- If a liquid chemical sterilant product has subordinate claims such as tuberculocidal or virucidal, these claims also will be regulated by FDA.
- EPA will be primarily responsible for premarket review of liquid chemical germicides that are general purpose disinfectants intended for use on devices other than critical or semicritical devices. Examples of noncritical devices are wheel chairs, medical beds, stands, certain operating room surfaces, medical lamps, dental units, and stethoscopes.

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FDA Premarket Notification and EPA Registration

- FDA marketing clearance through the section 510(k) process or approval through the premarket approval process of sterilants will satisfy certain requirements for registration under FIFRA Section 3.
- EPA registration of liquid chemical germicides that are used as disinfectants for devices, except sterilants, will satisfy the criteria necessary to establish substantial equivalence as defined in 21 U.S.C. §360c(i)(1)(A). For this category of liquid chemical germicides, submission by the manufacturer to FDA of a copy of the EPA correspondence granting registration will satisfy FDA's requirement for a premarket notification under 21 U.S.C. §360(k). Upon receipt of this information from the manufacturer of a liquid chemical germicide in this category, FDA will issue an order finding the product substantially equivalent to a predicate device that does not require premarket approval.

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FDA's Enforcement Policy Update - Application

- In March 2020, FDA issued an Enforcement Policy Update for Sterilizers, Disinfectant Devices, and Air Purifiers
  - Sterilizers for use in a health care facility are medical devices that are regulated by FDA and are intended to render medical devices sterile (i.e., free from viable microorganisms). Sterilizers vary in both construction (ranging from small table-top sterilizers to large sterilizers intended for large loads) and modality (e.g., steam, ethylene oxide, vaporized hydrogen peroxide, etc.).
  - Disinfectant devices can kill most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfectant devices commonly used in health care settings include chemical/physical disinfectant devices and ultraviolet (UV) disinfectant devices.

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FDA's Enforcement Policy Update – Application (cont'd)

- FDA considers chemical/physical disinfectant devices to encompass chemical disinfectant solutions used to disinfect medical devices, as well as medical washer disinfectors or automated endoscope reprocessors (AERs) that utilize chemical disinfectant solutions or physical (e.g., thermal) processes to reprocess medical devices.
- UV disinfecting devices are devices that use UVA or UVC light to produce a germicidal effect. They are intended to augment disinfection of health care environmental surfaces after manual cleaning has been performed.
- Air purifying devices are intended for medical purposes to kill pathogens/microorganisms in the air by exposure to UV radiation or remove them through filtration.

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FDA's Updated Enforcement Policy - Substance

- FDA does not intend to object to limited modifications to the indications or functionality of FDA-cleared or FDA-approved sterilizers, disinfectant devices and air purifiers pertaining to a device's virucidal effectiveness against SARSCoV-2, without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency:
  - Prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.8112 or submission of a Premarket Approval Application (PMA) Supplement under section 515 of the FD&C Act and 21 CFR 814.3913
  - Registration and Listing requirements in 21 CFR 807,
  - and Unique Device Identification requirements in 21 CFR 830 and 21 CFR 801.20.
  - As an example, this would apply to a manufacturer that previously received 510(k) clearance for a steam sterilizer that is intended for sterilization of medical devices in health care settings, where the manufacturer would like to include a statement in the labeling that the device is effective in killing SARS-CoV-2 when used in accordance with the validated sterilization processes identified in the labeling

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FDA's Updated Enforcement Policy - Substance

- For devices that do not have FDA clearance or approval, FDA's updated enforcement policy would allow marketing provided that the manufacturer can demonstrate compliance with specified consensus standards (ANSI, AAMI, AOAC, etc.)
- Labeling requirements also apply
- https://www.fda.gov/media/136533/download

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Hand Sanitizer - FDA's Updated Enforcement Policy

- The CDC has recommended practicing good hand hygiene as a measure to fight COVID-19. They suggest alcohol-based hand sanitizer that contains at least 60% alcohol when soap and water are not regularly available. Because of this, demand for hand sanitizer has increased.
- FDA updated its enforcement policy to allow for increased hand sanitizer production.
- https://www.fda.gov/media/136289/download
- Updated policy relaxes standards per the tentative final monograph for antiseptic hand sanitizers until the FDA declares that the policy is not longer in effect.
- Formula, labeling, registration, listing requirements still apply.

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Prefense FDA Warning Letter

WARNING LETTER

Prefense LLC

MARCS-CMS 605488 — APRIL 23, 2020

- "We hate to say it, but coronavirus is in the U.S. and close to home in Chicago. Nasty stuff but that's why the best defense is Prefense!" [from a January 24, 2020 post on your Twitter webpage at https://twitter.com/prefense]
- "Coronavirus now a global emergency! . . . Be safe out there – the best defense is Prefense hand sanitizer – up to 24 hour protection from one application – it works when it dries!" [from a January 30, 2020 post on your Twitter webpage at https://twitter.com/prefense]

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Prefense FDA Warning Letter (cont'd)

Your Prefense Hand Sanitizers do not conform to the 1994 TFM, as further amended by the 2016 Consumer Antiseptic Rub proposed rule and the 2015 Health Care Antiseptic proposed rule, nor any other TFM or final rule, and do not meet the conditions under section 505G(a)(3) of the FD&C Act, as added by the CARES Act, for marketing without an approved application under section 505. First, we note that your products are labeled with Amosilq (benzalkonium chloride/silica complex) as the active ingredient. Amosilq was not a proposed active ingredient in the rulemaking for topical antiseptic drug products. Second, even if benzalkonium chloride were considered the active ingredient in Prefense Hand Sanitizers, the labeling for your products does not conform to the relevant labeling conditions in the 1994 TFM and its subsequent amendments.[5]

Specifically, your labeling claims suggesting that Prefense Hand Sanitizers are effective in preventing infection or disease from specific pathogens such as "staph, strep, E.coli, drug resistant MRSA, Wuhan COVID-19 Coronavirus and more" go beyond merely describing the general intended use of a topical antiseptic as set forth in the 1994 TFM. Additionally, your labeling claims suggesting that Prefense Hand Sanitizers provide up to 24 hours of efficacy against serious-disease related pathogens including the

- Active ingredient not allowed per updated enforcement policy, label does not comply with 1994 TFM
- Specific disease prevention claims
- 24-hr efficacy claim was problematic

Eskbiochem FDA Warning Letter

WARNING LETTER

Eskbiochem SA de CV

MARCS-CMS 608690 — JULY 23, 2020

Adulteration Under Section 501(d)(2) [21 U.S.C. 351(d)(2))] and 501(a)(2)(B) [21 U.S.C. 351(a)(2)(B)]

ClearCare Nogerm ADVANCED HAND SANITIZER, a drug product labeled as manufactured at your facility, is labeled to contain 75% volume/volume (v/v) of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the product contained an average of 39% ethanol and 28% methanol v/v. Additionally, the drug product LAVAR GEL HAND SANITIZER, also labeled as manufactured at your facility, is labeled to contain 70% v/v of the active ingredient ethyl alcohol (ethanol). However, FDA laboratory testing of batches of this product detained at the border found that the product contained 0% ethanol and 83% methanol v/v. Therefore, these hand sanitizer drug products are adulterated under section 501(d)(2) of the FD&C Act in that the active ingredient of ethanol was substituted wholly or in part with methanol, a dangerous chemical when in contact with human skin or ingested.

- Letter begins by noting that FDA tested the products (does not reference inspection)
- Active ingredient not allowed
- FDA issued public warning not to use products, demanded that Eskbiochem provide responsive information

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Hand Sanitizer False Advertising Litigation

LAW360

Defending Against A Wave Of Hand Sanitizer Class Actions

While Purell's labeling does not specifically represent that it is effective at preventing COVID-19, there is no doubt that the COVID-19 pandemic lurks in the background of these lawsuits. For example, the Gonzalez complaint notes that the "recent outbreak of the fatal Coronavirus has prompted increased demand for the Products" and that "[a]ccording to some reports, defendant has promoted the Products as a viable means of preventing transmission of Coronavirus."

Likewise, the Miller complaint notes in passing that the "recent outbreak of the coronavirus has greatly increased demand for the Product." And the COVID-19 pandemic may also have prompted plaintiffs to begin filing similar lawsuits against other manufacturers of hand sanitizer, such as Vi-Jon Inc. (the manufacturer of Germ-X) and Target.[4] As the COVID-19 pandemic continues to spread, it is inevitable that plaintiffs will continue to file these lawsuits against hand sanitizer manufacturers around the country.

- Common claims: "Kills 99.9% of germs" or similar
- How is the reasonable consumer likely to understand this claim, particularly in the context of a pandemic?
- Consider disclosures to limit claims interpretation

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The Federal Trade Commission's Role

Deception

- A material statement or omission that is likely to mislead the reasonable consumer.
  - A reasonable consumer takeaway is about a 20
  - Material – likely to influence a purchasing decis
  - Many states use "unthinking consumer" standar

Unfairness

- Substantial injury
- Consumers could not have avoided
- Not outweighed by counter-veiling benefits

Advertising: Basic Principles

- Advertising must be truthful and not misleading.
- Claims, both express and implied, must be substantiated ***before*** they are made.
- Advertisements cannot be unfair (cause harm not outweighed by overall benefit to competition.
- Qualifying information about the attributes or use of products or services must be disclosed whenever required to avoid misleading consumers.

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Health Claims: "Competent and Reliable Scientific Evidence"

unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Provision, "competent and reliable scientific evidence" means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons and are generally accepted in the profession to yield accurate and reliable results.

Translation: Evidence sufficient in terms of quality and quantity such that experts in the field would say that it's enough to substantiate the claim.

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FTC Enforcement on UV Disinfection Claims (2015)

Your Health Is Your Biggest Asset

Life today is a constant struggle against stressors, both internal and external. Between hectic schedules, pressures at home and at work, and environmental factors such as viruses and bacteria, it's vital that we do all we can to protect our health and well being.

Zadro Health Solutions proudly manufactures the latest and most innovative products designed to help promote a healthy and active lifestyle and make life easier.

UV Disinfection Scanners

Help protect against harmful germs, viruses, and bacteria with patented UV Disinfecting Technology.

Our specially designed Disinfecting Wands have been proven to eliminate 99.9% of targeted germs and viruses* on surfaces and in water in as little as 10 seconds.

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The FTC and FDA Have Issued Dozens of Warning Letters

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FTC AND FDA WARNING LETTERS

The Federal Trade Commission and U.S. Food and Drug Administration (FDA) have sent warning letters to companies allegedly selling unapproved products that may violate federal law by making deceptive or scientifically unsupported claims about their ability to treat or cure coronavirus (COVID-19). See press release.

COMPANY	DATE
Curativa Bay Corporation (248.79 KB)	6/25/2020
North Isle Wellness Center (234.49 KB)	6/19/2020
Project 1600 Inc. (246.83 KB)	6/18/2020
Out of the Box Remedies (248.05 KB)	6/10/2020
Organic Beauty Recipes (244.96 KB)	6/8/2020
Dr Sherrill Sellman (125.81 KB)	6/1/2020
StayWell Products LLC (248.74 KB)	5/28/2020

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Vaniman Manufacturing Co. Warning Letter

This is to advise you that FTC staff has reviewed your website at www.vaniman.com on April 27, 2020. We have determined that you are unlawfully advertising that certain products prevent Coronavirus Disease 2019 (COVID-19).

An example of a Coronavirus prevention claim on your website includes:

- "**Which HEPA air purifiers can filter out the COVID-19 virus?** No air purifier will capture the virus with 100% certainty – but HEPA air purifier like our **Pure Breeze** system and even our smaller **Vanguard Gold Mobile** can **greatly** help to reduce the spread AND capture the Covid virus in your home or workplace." [https://www.vaniman.com/do-hepa-air-purifiers-filter-out-the-covid-19-virus/]

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Out of the Box Warning Letter

- "Coronavirus Terminator . . . 'I have suggested that people put iodine into a nebulizer for aerosol treatment for transdermal effect into the lung tissues in the case of lung cancer, emphysema, asthma, and tuberculosis. . . So effective is iodine that aerosols can be effective in sterilizing a room at levels not even detectable by humans.' . . . To which I would add viruses of any type, including mutated viruses and corona COVID-19. Adding Lugol's iodine to 'Ciggy Juice' ramps up the application of antiviral iodine to sensitive lung tissue. . . . More information on this wonderful product can be found on my blog at www.outoftheboxremedies.net" [from your websites https://www.outoftheboxremedies.com/#!/Coronavirus-Terminator-vaping-pen-100-ml-iodine-solution/p/180279268/category=0 and https://outsidetheboxremedies.yolasite.com/]

- "Coronavirus Terminator Refill (100 ml, 3.4 oz) . . . The Coronavirus Terminator Refill contains Lugol's iodine, a known antiviral. This antiviral, antibacterial medicine is ideal for killing any alien microbes in the lungs." [from your websites https://www.outoftheboxremedies.com/#!/Coronavirus-Terminator-Refill-100-ml-3-4-oz/p/183746255/category=0 and https://outsidetheboxremedies.yolasite.com/]

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How is the NAD handling these claims?

- NAD has issued several opinions over the last decade involving antimicrobial claims on various products, everything from cat litter to garbage bags to textiles.
- Where products feature antimicrobial claims, NAD is likely to find that a reasonable consumer may understand that there is a benefit to the user.
- Carefully consider not just the intended claims but all claims reasonably conveyed.

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Key Takeaways

- This area is changing quickly. Stay apprised of regulatory changes.
- Figure out how the product is regulated and what claims can be made based on the product regulatory status.
- EPA registration or FDA clearance may be required for sale but may not be enough for advertising claims substantiation. Ask yourself – what claims are conveyed to the reasonable consumer (not just what claims are intended).
- Substantiation bar is fairly high in terms of substantiating a benefit to the user where antimicrobial/disinfection-type claims are made.
- Disclosures – clear, conspicuous, and in close proximity.
- Watch for enforcement from the regulatory agencies, NAD, and class actions.

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QUESTIONS?

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