



What Companies Should Know Before Importing COVID-19 Safety Products into the United States

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Introduction



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TransLegal At A Glance

- International law firm and consultancy with offices in 75 countries
- In addition to handling corporate matters, TransLegal specializes in highly regulated industries, including: agriculture and organics; animal feed, additives & supplements; bioengineering; bioprospecting; chemicals; cosmetics; foods; government relations; nutritional supplements; and pharma.
- Our network of professionals includes attorneys, lobbyists, notaries and regulatory specialists.
- Some of our current projects include the registration of enzymes for food production in Vietnam, applying for approval of animal feed additives made with genetically modified ingredients in Russia and Belarus, and establishing a subsidiary of an EU-based food additive producer in Vietnam.

Wiley At A Glance

- 240 lawyers - our work is national and international in scope.
- We are “wired into Washington” - our attorneys routinely represent clients before more than 40 federal agencies.
- We practice at the intersection of the political, legal, and technical worlds with a significant number of the firm’s lawyers and public policy advisors held high-level positions in the White House, on Capitol Hill, and in federal agencies.
- We defend brand companies and products that have to meet science-based standards to stay on the market.
- Our litigation, regulatory, corporate law, and public policy skills enable us to deliver effective solutions to high stakes matters.



Today's Agenda

- COVID-19 Import Considerations
- Rules for Various Product Types
- Enforcement and Consequences of Noncompliance
- Questions

COVID-19 IMPORT CONSIDERATIONS

- Numerous Temporary Policies Are in Place to Expedite and Control Market Entry at Federal and State Levels.
- Policies May be in Place for Several Years.
- Different Rules Apply to Non-Healthcare and Healthcare Settings,
- Agencies Are Cooperating to Identify & Seize Problem Products.
- One Problem Can Hold Up Entire Shipment Even If Other Products are OK.

SEPARATE RULES, DIFFERENT AGENCIES

- U.S. approvals are based on the product's intended use and the advertising claims that are made.
- Federal agencies involved (alone or together):
 - Environmental Protection Agency (EPA)
 - Food and Drug Administration (FDA)
 - Federal Trade Commission (FTC)
 - Consumer Product Safety Commission (CPSC)
 - Customs and Border Patrol (CBP)
 - Occupational Safety and Health Administration (OSHA)
- State requirements also apply (each state is different).

Wipes and Liquid Disinfectants -- EPA

- Types of Products Regulated
- Basic Requirements:
 - Pre-market approval – registration.
 - Labeling approved by EPA.
 - Product Must Be Produced in a EPA-Registered Establishment.
 - Adverse Effects Reporting.
 - State Level Registration.
 - Special Paperwork for Importation.



Disinfectants and COVID-19

- EPA List N – For Registered Disinfectants:
 - Expedited use of certain ingredients
- **Emerging Viral Pathogen Policy** and Other Notable Policies to Increase Production and Availability of Disinfection Products.
- EPA regulates both the product and the facility where it is made:
 - Need EPA registration first (product and facility).
- State registration can take a short or long time.



Cleaning products – EPA, CPSC, OSHA

- Institutional, commercial, household:
 - Product claims limited to cleaning.
- No public health or COVID-19 claims.
- Toxic Substances Control Act (TSCA) Inventory or exemption for all ingredients.
- Federal Hazardous Substances Act (FHSA) labeling for consumer products.
- Occupational Safety and Health Administration (OSHA) requirements for workplace.



Pesticide Devices -- EPA

- Examples: Ozone generators, UV lamps and robots.
- **NOT** subject to registration/pre-market approval by EPA.
- Labeling is **NOT** reviewed or approved by EPA.
 - BUT labeling and marketing claims must NOT be “False or Misleading”.
- Device Must Be Produced in a EPA Registered Establishment.
- State Level Registration (7 states – CO, HI, IN, NM, OK, WV, WY) and DC).
- Special Paperwork for Importation.

Pesticide Devices and COVID-19

- The “**Emerging Viral Pathogen Policy**” does NOT apply to devices. No device can make claims against SARS-Cov-2 on the basis that that device has been found to be efficacious against a similar virus.
- Must have efficacy data specific to SARS-Cov-2.
- Cannot claim that the device prevents COVID-19.
 - Even if a product demonstrated reproducible efficacy against SARS-Cov-2, that is very different from claiming that the device prevents COVID-19.

Liquid Chemical Sterilants -- EPA and FDA

- Jointly regulated by EPA and FDA:
 - Claims solely for use on “non-critical” medical devices.
 - Products that make disinfectant claims.
- Exclusively regulated by FDA:
 - Liquid products that make sterilant claims and are intended for use on *critical and semi-critical* medical devices.
 - Products intended to kill microorganisms *in or on living humans*.

Summary

	Disinfectants	Devices
EPA	<p>Disinfectants and “liquid chemical sterilants” <u>not</u> intended for use on critical and semi-critical medical devices.</p> <p>Disinfectants and liquid chemical sterilants intended for use on sites that are <u>not</u> medical devices, e.g., veterinary equipment, or restaurant surfaces.</p>	Antimicrobial devices that are not medical devices are regulated by the EPA.
EPA/FDA	Liquid chemical sterilants that bear claims solely for use on non-critical medical devices are <u>jointly regulated</u> by EPA and FDA.	
FDA	Liquid chemical sterilants that are intended and labeled <u>only</u> for use on “critical or semi-critical devices.”	Medical devices are regulated by FDA.

Ventilators -- FDA

- **Enforcement Policy for Ventilators and Accessories** and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance.
- “Umbrella” **Emergency Use Authorization (EUA)** for certain ventilators, anesthesia gas machines and positive pressure breathing devices modified for use as ventilators, ventilator tubing connectors and accessories. Appendix B lists authorized products.
- FDA working directly with manufacturers to add models to the “umbrella” EUA and promptly issue 510(k)s for new and modified ventilators.
 - Most additions to this “umbrella” EUA are made within days of the request.

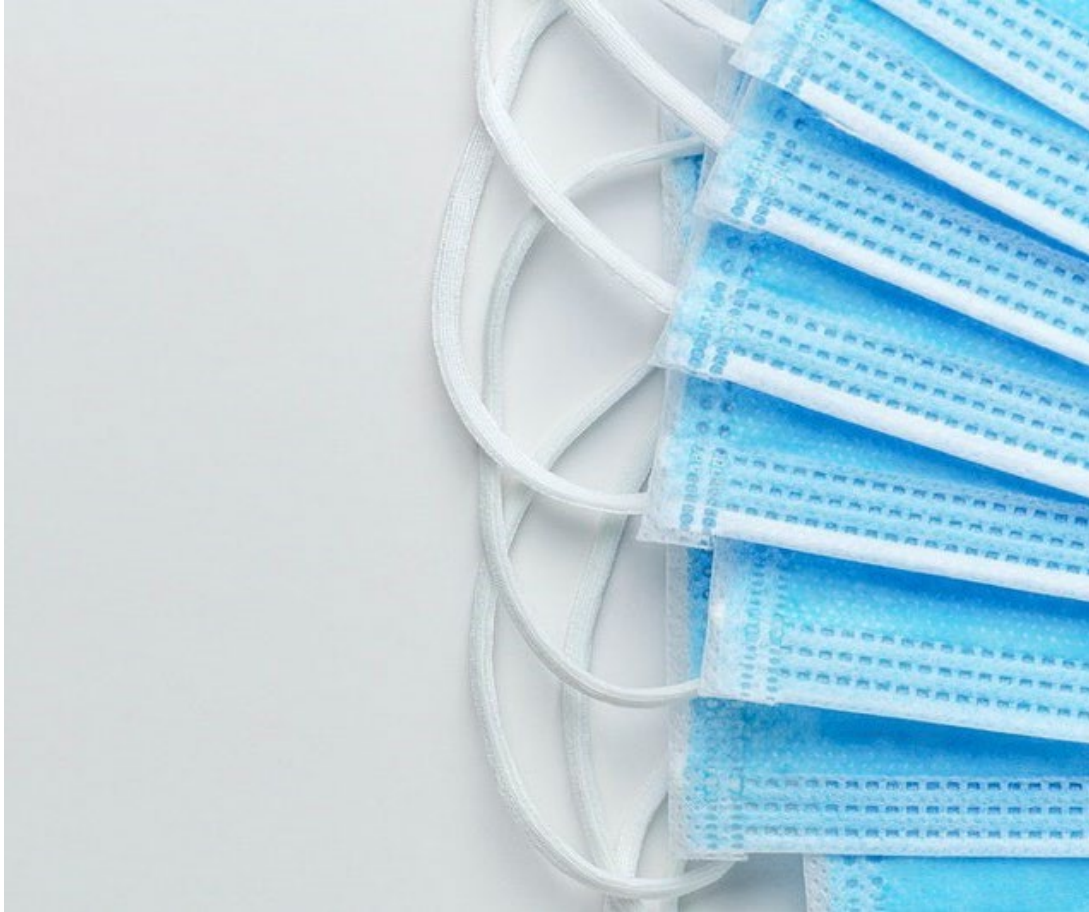


Consumer hand sanitizers -- FDA



- Antiseptic rub products for use by consumers without water.
- Considered an Over-the-Counter (OTC) drug.
- **FDA Temporary Policy** allows for WHO formula ONLY, still must register, no need to comply with cGMPs.
- FDA requirements continue to apply for other formulas, including cGMPs.
- Separately regulated:
 - Consumer antiseptic wash products for use with water and rinsed off after use, including hand washes and body washes.
 - Health care, first aid, food industry antiseptics.

Masks – FDA and OSHA



- Rules vary depending on health care, employment, consumer markets.
- State ration rules and priority rules may apply.
- NIOSH certification required for N95s.

ENFORCEMENT AND CONSEQUENCES OF NONCOMPLIANCE

- Understanding the rules is important – not doing this means:
 - Enforcement Actions
 - Monetary Fines
 - Product Seizures/No Market
 - Warning Letters, etc. that are made public
- Agencies policing COVID-19 safety products include –
 - EPA
 - FDA
 - FTC
 - CBP

EPA Approach

- EPA is paying close attention to false and misleading claims, unregistered pesticide claims, potential for injury to consumers.
- Working with CBP to seize illegal products imported through international channels such as LAX and SFO.
 - 7,800 illegal products confiscated
- Third-Party Platforms:
 - Conference call between EPA, retailers, and third-party platforms.
 - EPA “advisory letters” issued to third-party platforms to “immediately take these illegal products off of their websites.”

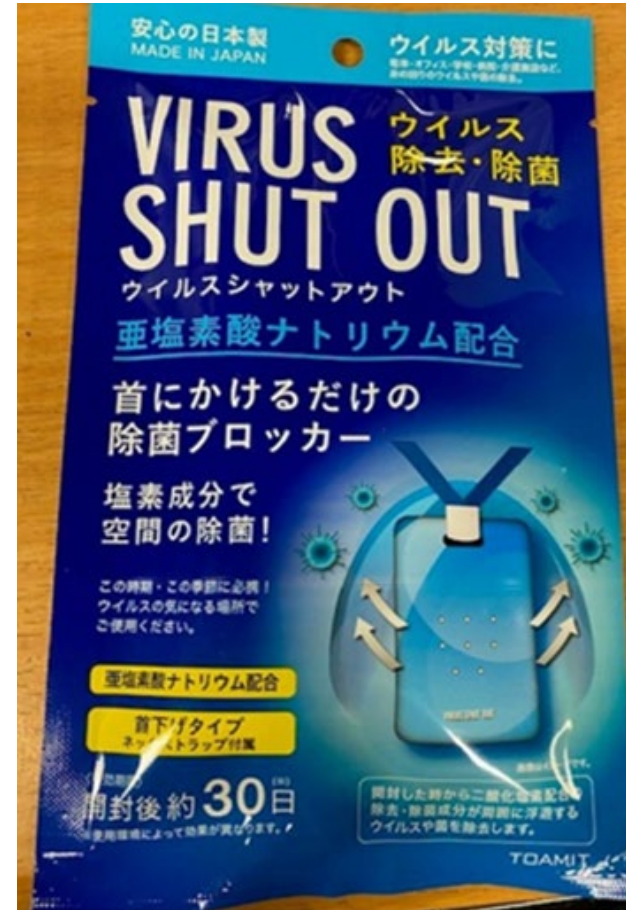
Enforcement Example

- Medline Industries
 - Micro-Kill 70 Isopropyl Alcohol/Disinfectant Wipes:
 - The wipes ensure “[e]ffective disinfection of hard-to-kill microorganisms on hard, non-porous surfaces.”
 - Sold and distributed for 2 years.
 - Consent Agreement and Final Order:
 - **Civil penalty: \$4,930,000**



COVID-19 Enforcement Example

- Example: “Virus Shut Out”
 - Georgia resident recently arrested and charged for allegedly importing, selling, and mailing an unregistered pesticide.
 - If prosecuted and found guilty, the individual faces prison sentence and criminal penalties.



FDA Approach

- Coronavirus (COVID-19) Update: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products
 - July 27, 2020 Press Release.
 - Agency Urges Consumers, Health Care Professionals Not to Use Certain Products, Citing Serious Adverse Events and Death.
 - List of 75 products.
- Import Alert 66-78
 - August 3, 2020.
 - "Detention Without Physical Examination of Drugs, Based Upon Analytic Test Results" (DWPE).
 - Red List.
- Warning letters issued to Eskbiochem S.A. de C.V. and others.
 - Products with undeclared methanol and misleading claims –including incorrectly stating that FDA approved these products.

FTC Regulation of Advertising/Marketing

What is a covered advertisement?

- Advertising = all types of communication to third parties in connection with products.
- Goes beyond traditional advertising to include:
 - Social Media
 - Sponsored Media Content and Representations by Influencers
 - Websites and Materials on Third-Party Retail Sites
 - Labeling and Packaging
 - Press Releases and Technical Bulletins
 - Sales Talks and Oral Representations by Sales Force



FTC Enforcement

- Warning letters to companies making claims to treat or prevent coronavirus / COVID-19 telling them to cease making claims and respond in 48 hours.
 - Products include those claimed to be effective for cleaning (e.g., copper products, facial brush, air purifiers) in addition to supplements.
- Example: Letter to Face Vital LLC, offering sonic silicone facial brush for claims such as:
 - “Face Vital Sonic Silicone Facial Brush, Fight off Coronavirus.”
 - “Take this lightweight brush with you, keep your hands and face clean everywhere you go – protect yourself from the coronavirus.”
 - FTC: Not supported by competent or reliable scientific evidence.



Summary of Recommendations

- Know who your U.S. customers will be for your product. Study the claims you intend to make.
 - Needed to identify the regulatory rules that apply.
- Understand the rules before sending “high visibility” COVID-19 safety products to the U.S. to avoid stopped shipments at the border.
- See if you can use the Temporary Policies despite their limitations.
 - It can take months or years to qualify a product if you can’t use the Temporary Policies.
- Respect the “safe harbor” rules of these Temporary Policies to avoid strict enforcement and possible fines.
- Speak to an expert – it’s complicated!

Thank you for listening. Any questions?



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