Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Key Regulatory Concerns For Cos. Making COVID-19 Products

By **Cheryl Falvey, John Fuson and Mariam Sarwar** (September 22, 2020, 4:15 PM EDT)

Cheryl Falvey

John Fuson

Mariam Sarwar

In the wake of the COVID-19 pandemic, product manufacturers and distributors — many of whom have pivoted to create personal protective equipment for the first time — are now faced with a veritable morass of guidelines and requirements to navigate, from a variety of governmental agencies.

Recent enforcement actions by federal agencies have only highlighted the importance of understanding exactly how a product must be produced, advertised, labeled and sold. This raises the important question: Who is the regulator, and what is the rule?

As companies navigate the alphabet soup of federal agencies supervising COVID-19 product distribution, the biggest takeaway to keep in mind is that how a product is advertised for sale plays a critical role in how it is regulated and by which agency. A product's regulatory profile can determine whether there are specific product labeling or manufacturing registration requirements.

This article outlines a few of the major players involved in regulating products designed to mitigate or prevent COVID-19 — specifically, the U.S. Food and Drug Administration, the U.S. Consumer Product Safety Commission, the Federal Trade Commission and the U.S. Environmental Protection Agency — and discusses high-level considerations for entities who find themselves caught up in the regulatory alphabet soup.

Food and Drug Administration

The FDA — which has played perhaps the largest role in regulating products designed to mitigate or prevent COVID-19 — oversees the regulation of drugs and medical devices. Due to the overwhelming need for medical countermeasures against COVID-19, the agency has relaxed its usually stringent product approval process for drugs and medical devices designed to help mitigate, prevent or treat the virus, and has instead issued minimal product requirements in a series of emergency use authorizations, or EUAs.

Products within the scope of EUAs will not be subject to an FDA enforcement action, even if such products are not formally FDA-approved. However, several important considerations bear mentioning.

First, EUA protections are not boundless. EUAs only protect entities from liability in the form of an FDA enforcement action, and do not provide protection from a product liability action in any form. Certain states have issued varying levels of tort immunity for sellers of PPE, but many have yet to implement such protections.

Second, EUA protections are not indefinite. EUAs generally only last for the duration of the pandemic — and thus product manufacturers and distributors must be prepared to pull their products from the market whenever the pandemic is deemed over.

Third, EUA protections are subject to their own set of conditions. Though products authorized by an EUA may not need to undergo specific FDA premarket review, they still must adhere to requirements listed within the applicable EUA.

For example, EUAs tend to require specific types of labeling and disclosures. To avoid liability, mask sellers must ensure that they adhere to labeling requirements, such as the mandate that nonsurgical masks specify that they are "for use when FDA-cleared masks are not available."

Producers of nonsurgical masks who give in to the temptation of asserting that their product is of medical quality, or provides a certain level of filtration, run the risk of incurring an FDA warning letter or enforcement action. Similar labeling requirements are found in EUAs for other types of masks, face shields and gloves.

Hand sanitizers, a major commodity during the pandemic, are now regulated under two regimes: (1) the temporary final monograph, which requires testing to meet specified germ kill rates under detailed testing procedures, or (2) the FDA's temporary policies, which do not require verification testing as long as the products are made using the World Health Organization's formula. Whether produced under the monograph or a temporary policy, labeling is a top concern for hand sanitizer manufacturers.

If a hand sanitizer manufacturer makes a claim that goes beyond what the monograph allows (i.e., saying it prevents a particular disease), the FDA may issue a warning letter to that company asserting that it advertised an unapproved drug. In fact, earlier this year, the FDA issued a warning letter to the manufacturer of Purell for asserting the unsubstantiated claim that its hand sanitizers could prevent or reduce the spread of illnesses such as MRSA, norovirus, influenza and Ebola.

Consumer Product Safety Commission

The FDA and the CPSC have concurrent jurisdiction over cloth masks intended for consumer use, and cloth masks must meet CPSC flammability requirements. Most cloth masks that comply with FDA regulations will likely also meet the CPSC's flammability requirements for wearing apparel, which do not have an exclusion for masks.

Masks primarily for children must comply with the CPSC's 100-parts-per-million lead limit. If the children's mask is made of cotton, it may be exempt from testing and certification.

In addition to meeting CPSC lead limits, all children's products need tracking labels for traceability of their components, and technically, children's masks would be no exception.

Federal Trade Commission

The FTC regulates unfair or deceptive trade acts and practices, such as misleading methods of inducing consumers into making product purchases. The FTC is empowered to bring administrative or judicial enforcement actions against violators, typically seeking restitution or disgorgement for alleged violations or civil penalties.

To avoid such liability, all product claims must have substantiation for any meanings that a reasonable consumer would glean from the claim. This includes both express claims — e.g., an ad directly stating that "ABC mouthwash prevents colds" — as well as implied claims — e.g., an ad stating that "ABC mouthwash kills the germs that cause colds," implying that the product will prevent colds. All health claims require "competent and reliable scientific evidence."

With an overwhelming number of companies selling products containing medical claims related to COVID-19, the FTC has been issuing hundreds of warning letters. For example, the agency promptly issued a warning letter to the manufacturer of ultraviolet lights that were alleged to kill airborne coronavirus, requiring the company to alert the FTC of the specific actions it had taken to address the agency's concerns within 48 hours.

Moreover, the FTC and the FDA have recently announced a cooperative program that will scrutinize companies making coronavirus claims — meaning that more such letters are bound to follow for other companies making unsubstantiated assertions.

Environmental Protection Agency

The EPA also plays a role in regulating COVID-19 countermeasures. Under federal law, bacteria, viruses and other microbes in the environment are considered a type of pest, and, accordingly, products intended to kill, destroy or otherwise mitigate pests are regulated by the agency as pesticides or pest control devices.

This means that the EPA must specifically approve claims for effectiveness against SARS-CoV-2, and has created a list of products that are allowed to state that they may be used against COVID-19.[1] Otherwise, whether a claim is pesticidal or nonpesticidal in nature is assessed by the agency on a case-by-case basis.

Product claims are considered to be pesticidal if they are synonymous with "preventing, destroying, repelling, or mitigating any pest." Advertising implying that a product has antimicrobial properties may be considered a pesticidal claim. If so, the product in question must be registered in order to retain the claim and be able to be lawfully sold or distributed in the U.S.

Other factors that may imply an intended use for antimicrobial effect include whether the product is similar in composition to products registered under the Federal Insecticide, Fungicide and Rodenticide Act that make antimicrobial claims, and whether the product contains an ingredient at levels for which there is no functional reason other than pesticidal activity.

Again, labeling can be determinative of whether a product is EPA-regulated. For example, a bleach product consisting of 5.25% sodium hypochlorite would likely require registration if the label states that bacteria will be killed at certain doses. However, an identical bleach would likely not need to be

registered if the labeling only claims to whiten, bleach or clean laundry, and does not contain an explicit or implicit antimicrobial claim.

Summary

A central concern for the FDA, the FTC and the EPA is whether a product makes COVID-19-related health claims. Those health claims are under a microscope now — and in certain circumstances, may not be permitted without prior regulatory action or approval.

Product manufacturers and distributors should thus heed caution when labeling and advertising their products. If any product does purport to prevent or kill the virus, entities must ensure, and be prepared to validate, that their claims are substantiated by competent and reliable evidence.

Cheryl Falvey and John Fuson are partners, and Mariam Sarwar is an associate, at Crowell & Moring LLP.

[1] The list is accessible at https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2.