

Blog Post

Dose of Caution Needed When Making Coronavirus Drug Claims

April 17, 2020

Just like the dose makes the poison, the claim makes the drug.

With a pandemic well underway, some marketers are offering products that they claim will treat or prevent COVID-19, the disease caused by the novel coronavirus. Without federal approval, however, anyone making claims about unapproved drugs risks inviting a federal enforcement action. As a result, marketers should exercise great caution when making coronavirus-related claims about their products.

Any product intended to be introduced into, or applied onto, the body that claims to diagnose, cure, mitigate, treat, or prevent disease is a drug, and drugs must be approved by the U.S. Food and Drug Administration (FDA) as safe and effective for their intended uses. This is true whether the product is ingested, injected, or otherwise applied to the body. This is also true even if the product is herbal, “natural,” or made from essential oils.

Pandemic or not, until a manufacturer or distributor receives FDA approval, marketers may not legally make unapproved drug claims about a product offered for sale to consumers in the United States. Those who do make offending claims – whether via the Internet, product packaging, print

Related Work

Government Affairs
and Public Policy
Healthcare
Healthcare Licensure
and Compliance
Pharmacy, Drugs, and
Medical Devices

Related Offices

Tallahassee

Health Law Rx

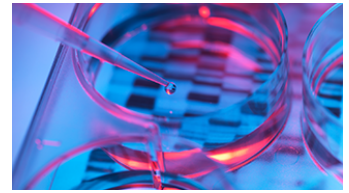
Akerman Perspectives
on the Latest
Developments in
Healthcare Law

[Visit this Akerman blog](#)

Coronavirus Resource Center

[Visit the Resource
Center](#)

advertisements, or any other manner – may draw the ire of the FDA.



The FDA has already been working for weeks to reign in the proliferation of unapproved drug claims. Through April 14, 2020, the FDA has issued 31 warning letters – the usual first step in an FDA enforcement action – demanding that alleged violators cease selling products related to COVID-19. The products boasted claims such as the following:

- “If you have COVID-19: Take [Product name] and 6 to start... For children, follow the same instructions as above and cut the amounts in half.”
- “Our instant protection nasal spray is designed to protect your vulnerable nasal passages from infection by the 2019 Novel Coronavirus specifically and other viruses in general”
- “Will you get Coronavirus?... 6 steps for protection from the Coronavirus... Build up your immunity with foods rich in antioxidants and bioactive protection such as [Product name]”
- “Coronavirus 2019... Treatment Has A Home Remedy. This Chinese Wuhan Flu Pneumonia has a non-traditional remedy that has successfully killed coronaviruses from the flu virus to pandemic diseases, in vitro, for over 100 years... Protect your immune system try [Product name]”

Full copies of FDA’s warning letters may be viewed [here](#). Members of the public may report suspected violations to FDA [here](#). Anyone wishing to make product claims related to coronavirus or COVID-19 should first seek the advice of counsel.

This information is intended to inform firm clients and friends about legal developments, including recent decisions of various courts and administrative bodies. Nothing in this Practice Update should be construed as legal advice or a legal

opinion, and readers should not act upon the information contained in this Practice Update without seeking the advice of legal counsel. Prior results do not guarantee a similar outcome.