INTERVIEW REGARDING

Amazon's Hemp Market

This interview was conducted by CBD Oracle via email on February 3, 2024, and is provided here for full transparency. Learn more about CBD Oracle's Editorial Policy.

FDA

The Food and Drug Administration

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA's Cannabis Product Committee (CPC) develops and implements cross-Agency strategy and policy for the regulation of cannabis products.

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CBD Oracle: We have come across many hemp products on Amazon that make unapproved medical claims such as relieving pain and anxiety or helping with sleep issues. Are these products violating FDA's guidelines? Has the agency issued any warning letters to Amazon about such products?

FDA: The FDA continues to be concerned about products that are sold online and in stores for treating or preventing diseases or conditions but that have not been reviewed for safety and effectiveness by the FDA. Selling unapproved products with unproven claims is a violation of the law, and puts patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven products also raises significant public health concerns because patients and other consumers may be influenced to use unapproved products rather than treatments with scientifically proven benefits to treat serious and even fatal diseases.

The FDA has issued warning letters to companies selling unapproved drugs containing cannabidiol (CBD), a compound found in cannabis, including to companies making unproven claims that their products can treat or prevent diseases or conditions, and a list of warning letters for CBD-related products is available on FDA's website. Aside from Epidiolex, there are no other FDA-approved drug products that contain CBD.

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), any product intended to have a therapeutic or medical use, and any product (other than a food) that is intended to affect the structure or function of the body of humans or animals, is a drug. Drugs must generally either receive premarket approval by the FDA through the new drug application (NDA) process or, for certain nonprescription drugs, meet the requirements for legal marketing without an approved drug application in section 505G of the FD&C Act. With limited exceptions not applicable to CBD and other cannabis-related products, an unapproved drug cannot be distributed or sold in interstate commerce, as they are not approved by the FDA for the diagnosis, cure, mitigation, treatment or prevention of any disease. Consumers should beware of purchasing and using any such products.

CBD also cannot lawfully be added to food. This is true for foods for humans and animals. We have issued warning letters to companies for illegally selling foods with CBD. Foods with undeclared CBD content pose a risk of unintentional or excessive CBD consumption.

The FDA has issued several warning letters to Amazon for introducing unapproved drug products and/or prohibited foods into interstate commerce. For example, the FDA issued warning letters against Amazon for the illegal sale of unapproved ophthalmic drug products as well as products labeled as energy enhancing supplements or food. Retailers, including online marketplaces, that sell and/or distribute FDA-regulated products are responsible for ensuring the products are in compliance with federal law. The FDA continues to urge stores, websites and online marketplaces, like Amazon and eBay, to protect the American public by not selling or facilitating the sale of products that violate the FD&C Act.

The agency monitors the market for the unlawful sale or distribution of cannabis and cannabis-derived products and will take action, as needed, to protect public health against companies illegally selling these products that can put consumers at risk. At the same time, the FDA recognizes the potential therapeutic opportunities that cannabis or cannabis-derived compounds could offer and acknowledges the significant interest in these possibilities. The FDA continues to believe the drug approval process represents the best way to help ensure that safe and effective new medicines, including any drugs derived from cannabis, are available to patients in need of appropriate medical therapy. The FDA is committed to supporting the development of new drugs, including cannabis and cannabis-derived drugs, through the investigational new drug (IND) and drug approval process.

For more information see the agency's webpage FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD).