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FDA CBD WARNING NEWS RELEASE

FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns: Violations include marketing unapproved new human and animal drugs, selling CBD products as dietary supplements, and adding CBD to human, animal foods

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Today, the U.S. Food and Drug Administration issued warning letters to 15 companies for illegally selling products containing cannabidiol (CBD) in ways that violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA also published a revised Consumer Update detailing safety concerns about CBD products more broadly. Based on the lack of scientific information supporting the safety of CBD in food, the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.

Today's actions come as the FDA continues to explore potential pathways for various types of CBD products to be lawfully marketed. This includes ongoing work to obtain and evaluate information to address outstanding questions related to the safety of CBD products, while maintaining the agency's rigorous public health standards. The FDA plans to provide an update on its progress regarding the agency's approach to these products in the coming weeks.

"As we work quickly to further clarify our regulatory approach for products containing cannabis and cannabis-derived compounds like CBD, we'll continue to monitor the marketplace and take action as needed against companies that violate the law in ways that raise a variety of public health concerns. In line with our mission to protect the public, foster innovation, and promote consumer confidence, this overarching approach regarding CBD is the same as the FDA would take for any other substance that we regulate," said FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D. "We remain concerned that some people wrongly think that the myriad of CBD products on the market, many of which are illegal, have been evaluated by the FDA and determined to be safe, or that trying CBD 'can't hurt.' Aside from one prescription drug approved to treat two pediatric epilepsy disorders, these products have not been approved by the FDA and we want to be clear that a number of questions remain regarding CBD's safety – including reports of products containing contaminants, such as pesticides and heavy metals – and there are real risks that need to be considered. We recognize the significant public interest in CBD and we must work together with stakeholders and industry to fill in the knowledge gaps about the science, safety and quality of many of these products."

Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. The revised Consumer Update outlines specific safety concerns related to CBD products, including potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in males. Questions also remain about cumulative use of CBD and about CBD's impacts on vulnerable populations such as children and pregnant or breastfeeding women.

CBD is marketed in a variety of product types, such as oil drops, capsules, syrups, food products such as chocolate bars and teas, and topical lotions and creams. As outlined in the warning letters issued today, these particular companies are using product webpages, online stores and social media to market CBD products in interstate commerce in ways that violate the FD&C Act, including marketing CBD products to treat diseases or for other therapeutic uses for humans and/or animals. Other violations include marketing CBD products as dietary supplements and adding CBD to human and animal foods.

The companies receiving warning letters are:

Koi CBD LLC, of Norwalk, California
Pink Collections Inc., of Beverly Hills, California
Noli Oil, of Southlake, Texas
Natural Native LLC, of Norman, Oklahoma
Whole Leaf Organics LLC, of Sherman Oaks, California
Infinite Product Company LLLP, doing business as Infinite CBD, of Lakewood, Colorado
Apex Hemp Oil LLC, of Redmond, Oregon
Bella Rose Labs, of Brooklyn, New York
Sunflora Inc., of Tampa, Florida/Your CBD Store, of Bradenton, Florida
Healthy Hemp Strategies LLC, doing business as Curapure, of Concord, California
Private I Salon LLC, of Charlotte, North Carolina
Organix Industries Inc., doing business as Plant Organix, of San Bernardino, California
Red Pill Medical Inc., of Phoenix, Arizona
Sabai Ventures Ltd., of Los Angeles, California
Daddy Burt LLC, doing business as Daddy Burt Hemp Co., of Lexington, Kentucky

The FDA has previously sent warning letters to other companies illegally selling CBD products in interstate commerce that claimed to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, or otherwise violated the FD&C Act. Some of these products were in further violation because CBD was added to food, and some of the products were also marketed as dietary supplements despite products which contain CBD not meeting the definition of a dietary supplement.

Under the FD&C Act, any product intended to treat a disease or otherwise 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. The FDA has not approved any CBD products other than one prescription human drug product to treat rare, severe forms of epilepsy. There is very limited information for other marketed CBD products, which likely differ in composition from the FDA-approved product and have not been evaluated for potential adverse effects on the body.

Unlike drugs approved by the FDA, there has been no FDA evaluation of whether these unapproved products are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs, or whether they have dangerous side effects or other safety concerns. In addition, the manufacturing process of unapproved CBD drug products has not been subject to FDA review as part of the human or animal drug approval processes. Consumers may also put off getting important medical care, such as proper diagnosis, treatment and supportive care due to unsubstantiated claims associated with CBD products. For that reason, it's important that consumers talk to a health care professional about the best way to treat diseases or conditions with existing, approved treatment options.

Additionally, some of the products outlined in the warning letters issued today raise other legal and public health concerns:

Some of the products are marketed for infants and children – a vulnerable population that may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute or excrete a substance such as CBD.

Some of the products are foods to which CBD has been added. Under the FD&C Act, it is illegal to introduce into interstate commerce any human or animal food to which certain drug ingredients, such as CBD, have been added. In addition, the FDA is not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient.

Some of the products are marketed as dietary supplements. However, CBD products cannot be dietary supplements because they do not meet the definition of a dietary supplement under the FD&C Act.

One product outlined in a warning letter to Apex Hemp Oil LLC is intended for food-producing animals. The agency remains concerned about the safety of human food products (e.g. meat, milk, and eggs) from animals that consume CBD, as there is a lack of data establishing safe CBD residue levels.

The FDA has requested responses from the companies within 15 working days stating how the companies will correct the violations. Failure to correct the violations promptly may result in legal action, including product seizure and/or injunction.

The FDA encourages human and animal health care professionals and consumers to report adverse reactions associated with these or similar products to the agency's MedWatch program.

The FDA, an agency within the U.S. Department of Health and Human Services, promotes and protects the public health by, among other things, assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.