



Steven W. Troxler
Commissioner

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Anita MacMullan
Director

Month day, 2019

Name
Firm Name
Street Address
City, State

To whom it may concern:

It has come to our attention that (___ firm name ___) is (manufacturing/selling) products that contain CBD at (___ firm location ___).

Please be advised of the following regarding CBD products in the marketplace:

- It is a prohibited act under section 301(II) of the FD&C Act [21 U.S.C. 331(II)] to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. 355] or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.
- CBD is the active ingredient in the approved drug product Epidiolex, a drug product that has been approved under section 505 of the federal Food, Drug & Cosmetic Act ("FD&C Act"). Substantial clinical investigations have been instituted for CBD and the existence of such investigations have been made public.
- Since CBD is the active ingredient in the approved drug product Epidiolex, it is currently excluded from being a dietary supplement under section 201(ff)(3)(B)(i) and (ii) of the FD&C Act.
- CBD products marketed with claims to prevent, mitigate, diagnose, treat or cure serious diseases (aka "health claims") indicate that the products are intended for use as drugs under the FD&C Act [21 U.S.C. 321(g)(1)]. Section 201(p) of the FD&C Act [21 U.S.C. 321(p)] specifies that new drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA. CBD in products other than the approved drug Epidiolex and which makes health claims would be a new drug that cannot legally be introduced into interstate commerce.
- North Carolina has routinely adopted by reference the federal Food, Drug & Cosmetic Act and implementing regulations. The violation of these federal laws and regulations would equally be a violation of state laws and regulations.

Once you place products into the marketplace, you have a responsibility to comply with all federal and state laws. Failure to comply could result in legal action being taken against you, including without limitation, embargo, seizure and injunction.

Sincerely,

Anita MacMullan
Director
Food and Drug Protection Division

cc: Joe Reardon, Assistant Commissioner for Consumer Protection
FDA/ATL-DO

N.C. Department of Agriculture & Consumer Services



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FOR IMMEDIATE RELEASE
FRIDAY, FEB. 8, 2019

CONTACT: *Joe Reardon, assistant commissioner*
NCDA&CS
919-707-3011

Regulators notify industry regarding CBD products in the marketplace

RALEIGH – The N.C. Department of Agriculture and Consumer Services is sending out letters next week to manufacturers and retailers who sell products containing CBD oil, detailing what is legal to sell in North Carolina.

“Under federal Food and Drug Administration laws, CBD is considered a drug,” said Joe Reardon, NCDA&CS assistant commissioner of consumer protection. “North Carolina state laws mirror federal laws. This means that CBD cannot legally be added to any human food or animal feed that is for sale.”

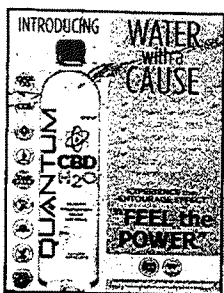
The product can also not make health claims, including statements that the product may prevent, treat or cure any disease. Failure to comply could result in embargo or seizure of products.

“We are taking an educate before regulate stance with industry,” Reardon said. “We know they may not be aware of the state laws regarding the addition of a drug to a food product. However, we reserve the right to be more assertive, as other states have been, if we need to be in the future. Our main concern is consumer health and safety with any product that falls under our regulatory authority.

“We also urge consumers to be smart shoppers and ask questions before choosing to purchase any tincture that contains CBD or hemp extract. Find out how the product is manufactured, if the company has purity standards and what the potency may be,” he said.

Industry with questions about the regulation of CBD can call the Food and Drug Protection Division, 919-733-7366.

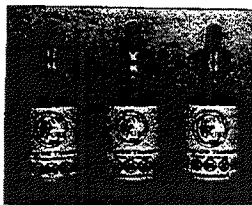
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MISSION STATEMENT

Our mantra is simple. We stand behind every claim, product label, and CBD delivery system that will help you live a more pain free life, while enhancing a healthy lifestyle and reducing your anxiety, stress and reliance on painkillers, toxic medications, and over-the-counter pills that contain harsh chemicals with unwanted side effects; **All with a 100% (THC) FREE Guarantee!**

We will always partner and collaborate with the highest grade CBD Hemp growers, and coupled with the industry's most efficient proprietary filtration process, we will never skimp on quality that is being put into your body.

FOR MORE INFORMATION CONTACT:

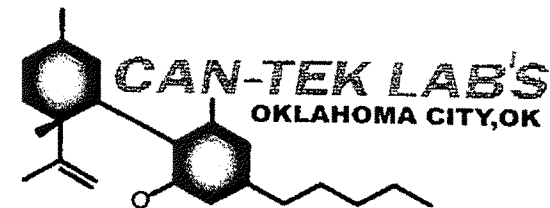


Angier Family Pharmacy

Angier Pharmacy

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- Chemical and solvent FREE
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