Steven W. Troxler
Commissioner

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

Anita MacMullan
Director

February 18, 2019

Letter to Industry regarding the manufacture and sale of products that contain CBD

NCDA&CS is sharing the following information with industry regarding the manufacture and sale of products that contain CBD. Please be advised of the following regarding CBD products in the marketplace:

- It is a prohibited act under section 301(ll) of the FD&C Act [21 U.S.C. 331(ll)] 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 /s/
Director, Food and Drug Protection Division

cc: Joe Reardon, Assistant Commissioner for Consumer Protection
Alexander M. "Sandy" Stewart, Assistant Commissioner

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NORTH CAROLINA DEPARTMENT OF AGRICULTURE & CONSUMER SERVICES
FOOD & DRUG PROTECTION DIVISION

Name and Title of Individual: [redacted]	Date: 5/07/19	
Firm Name: [redacted]	HOUR	10:00 a.m.
Number & Street [redacted]		p.m.
City & State [redacted]	Zip Code:	

Notice of inspection is hereby given pursuant to Article 12, §106-140 of North Carolina Food, Drug and Cosmetic.

Signature (NC Department of Agriculture Employee(s):	Title (NC Department of Agriculture Employee (s)
Jennifer A. Bridges	Food Regulatory Specialist

Article 12, §106-140 of the North Carolina Food, Drug and Cosmetic Act is quoted below:

§106-140. (a) For the purposes of enforcement of this Article, the Commissioner or any of his authorized agents, are authorized upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge, (1) To enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed, or packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold such foods, drugs, devices or cosmetics in commerce; and (2) To inspect at reasonable times and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished or unfinished materials, containers and labeling therein, and to obtain samples necessary to the endorsement of this Article. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device or cosmetic is manufactured, processed, analyzed, packed or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether any food, drug, device or cosmetic which is adulterated or misbranded within the meaning of this Article or which may not be manufactured, introduced into commerce or sold or offered for sale by reason of any provision of this Article, has been or is being manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Article. No inspection authorized by the preceding sentence shall extend to a. Financial data, b. Sales data other than shipment data, c. Personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Article), d. Pricing data, and e. Research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under lawful regulations issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of the federal act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of the federal act). Such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to such classes of persons as the Board may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health. (3) To have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof: Provided, that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Article by reason of their receipt, carriage, holding, or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers. (b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent-in-charge a report in writing setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device or cosmetic in such establishment: (1) Consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) Has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. (c) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any salable product samples in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall offer reasonable payment for any such product samples. (d). It shall be the duty of the Commissioner of Agriculture to make or cause to be made examination of samples secured under the provisions of this section to determine whether or not any provision of this Article is being violated.

NORTH CAROLINA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES
FOOD AND DRUG PROTECTION DIVISION

Name of Individual to Whom Report Issued TO: [redacted]	Date of Inspection: 5/07/19	C.F. Number:
Title of Individual: Store Associate	Type of Establishment Inspected: [redacted]	
Firm Name: [redacted]	Name of Firm, Branch or Unit Inspected: [redacted]	
Street Address: [redacted]	Street Address of Premises Inspected: [redacted]	
City and State: [redacted]	City and State: [redacted]	

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During an Inspection of Your Firm (I) (We) observed:

The purpose of this inspection is to determine if the operation is offering for sale any of the following products.

- food products labeled to contain CBD
- CBD products labeled as a dietary supplement
- CBD products that bear medical or drug claims on the packaging or or accompanying material or,
- dried or fresh floral material Represented to be a "Smokeable" product.

The following CBD products were observed for retail sale during this CBD survey inspection:

[redacted]

Signed By: Amanda Caudell Title: Inspector: Jennifer A. Budgi

FORM #04-FDPD-002