SafeFoodTeam

Hazards and Claims

Omar A. Oyarzabal, Ph.D.
Safe Food Team, LLC
South Burlington

Food or Dietary Supplement?

- Food ingredients from hemp are limited, and will probably be for some time
- The use of hemp-derived ingredients in dietary supplement formulations is increasing
- Two different regulatory landscapes, yet based on old regulations that target prevention of:
  - Adulteration
  - Misbranding

A Careful Choice of Words on Labels

- Most product from seeds are finding a niche in the food and dietary supplement market
  - Dehulled hemp seed, seed oil
- **Hemp-infused** edibles are more complicated
  - Prove that practices include safety measures
  - Unique hazards: *Clostridium botulinum*
- Are the products really infusions?

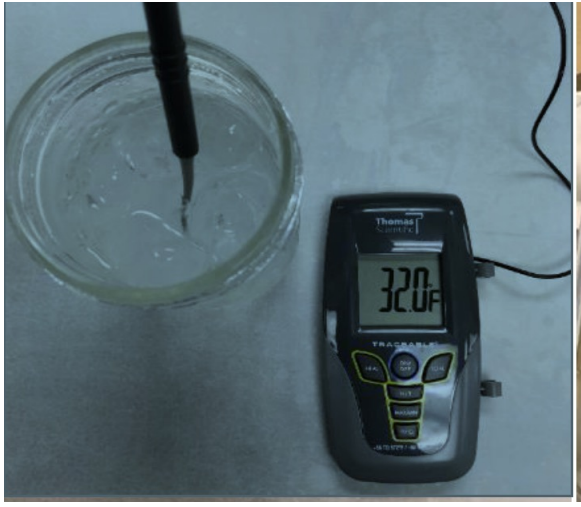
These Are Infusions

Clostridium botulinum

Shelf-Stable Products

- Infused oils, butters, tinctures, etc.
- Evaluation of the formulation and process (*C. botulinum*)

Water activity / Temperature



pH / Temperature

Packaging and Labeling

- Product packaging and labeling are heavily regulated areas of the cannabis industry
  - Safety and Claims!
- A complicated scenario because some states allows for “intra-state” sales of these products
- How will food products be labeled?
- What will be the guidelines from FDA?

Safety

Summitt Labs Issues Voluntary Nationwide Recall of KORE ORGANIC Watermelon CBD Oil Due to High Lead Results

COMPANY ANNOUNCEMENT

Summitt Labs Issues Voluntary Nationwide Recall of KORE ORGANIC Watermelon CBD Oil Due to High Lead Results

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Read Announcement | View Product Photos

Share | Tweet | Linkedin | Email | Print

More Recalls, Market Withdrawals, & Safety Alerts

Recalls, Market Withdrawals, & Safety Alerts

Recall Resources

Enforcement Reports

Industry Guidance For Recalls

Major Product Recalls

Archive for Recalls, Market Withdrawals & Safety Alerts

Summary

Company Announcement Date:	July 28, 2020
FDA Publish Date:	July 28, 2020
Product Type:	Drugs
Reason for Announcement:	Contains lead
Company Name:	Summitt Labs
Brand Name:	KORE ORGANIC
Product Description:	Watermelon CBD oil tincture

Company Announcement

UPDATED 7-28-20 TO CORRECT LOT# & BATCH# – Tampa, Florida; Summitt Labs is voluntarily recalling **Lot #730 Batch #K018** of KORE ORGANIC Watermelon CBD Oil Tincture, 30 ml bottle, 15mg 450x to the consumer level. The Florida Department of Agriculture and Consumer Services tested a random sample and found the product to

Content current as of:
07/28/2020

Regulated Product(s)
Drugs

Follow FDA
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@FDArecalls
Recent Recalled Product Photos on FDA's Flickr Photostream

Safety

Federal officials seize adulterated dietary supplements from Life Rising Corporation due to poor manufacturing practices

FDA NEWS RELEASE

Federal officials seize adulterated dietary supplements from Life Rising Corporation due to poor manufacturing practices

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More Press Announcements

Press Announcements

For Immediate Release: June 14, 2019

At the request of the U.S. Food and Drug Administration, U.S. Marshals seized more than 300,000 containers of dietary supplements, including tablets, capsules, and teas from Life Rising Corporation. The seized goods, which were held by Life Rising or manufactured in the company's facility located in Willowbrook, Ill., consisted of more than 500 products bearing brand names Life Rising, Holicare, or HopeStream, and are valued at approximately $3.5 million. The U.S. District Court for the Northern District of Illinois determined there was probable cause that the company prepared, packed, and/or held dietary supplements under conditions that do not conform to the dietary supplement current good manufacturing practice (CGMP) requirements.

"This seizure underscores the agency's commitment to taking aggressive action when manufacturers distribute adulterated dietary supplements that have the potential to put consumers at risk," said Melinda K. Plaisier, the FDA's Associate Commissioner for Regulatory Affairs. "The FDA has a variety of enforcement tools at its disposal, and when products don't comply with FDA regulations, we will not hesitate to take appropriate action."

The FDA inspection at Life Rising found that its dietary supplements were prepared, packed, and/or held under conditions that violated CGMP regulations. Among other observed deficiencies, the company failed to establish product specifications for the identity, purity, strength, and composition of each finished batch of dietary supplement,

Content current as of:
06/14/2019

Regulated Product(s)
Dietary Supplements

Topic(s)
Criminal Acts & Fraud

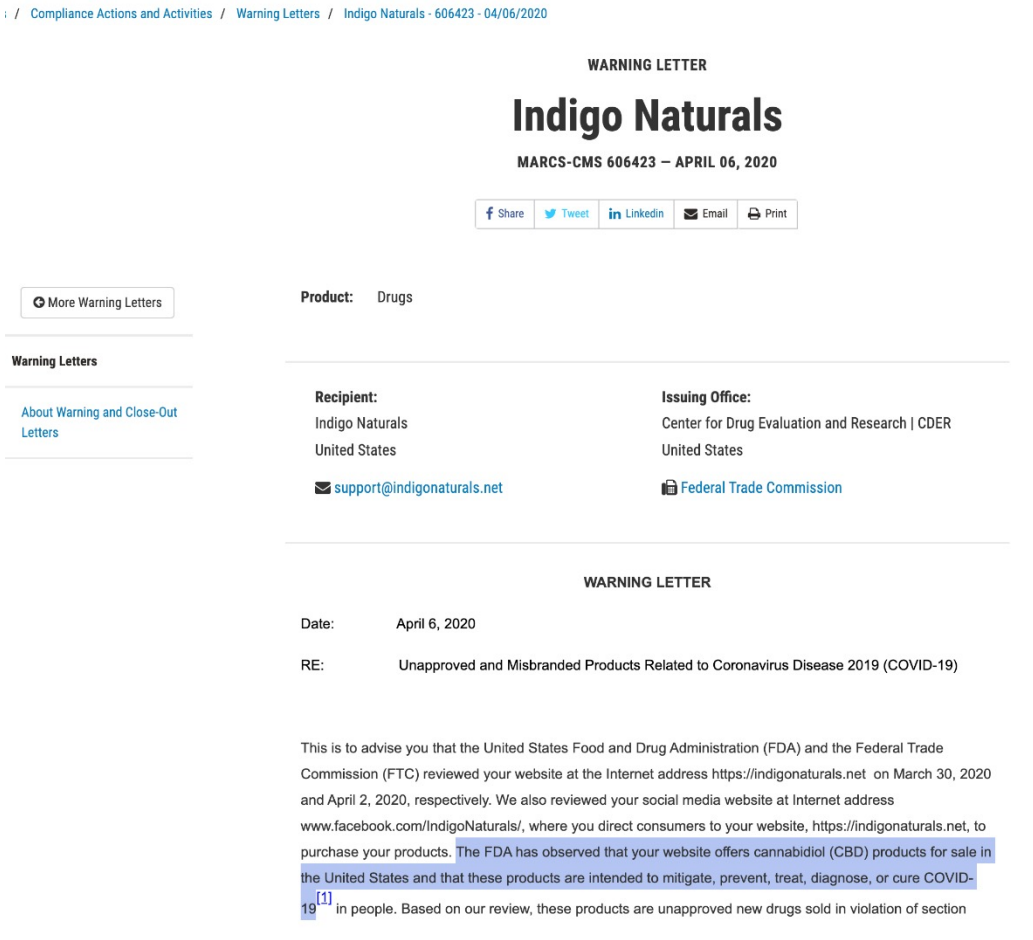
Follow FDA
Follow @US_FDA
Follow FDA
Follow @FDAmedia

“Misleading” Claims

- Moving into “clean labels”
- Remove “questionable” statements or claims from labels
- Consult, wait

Consequences of “Misleading” Claims

…The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19



Compliance Actions and Activities / Warning Letters / Indigo Naturals - 606423 - 04/06/2020

WARNING LETTER

Indigo Naturals

MARCS-CMS 606423 – APRIL 06, 2020

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More Warning Letters

Warning Letters

About Warning and Close-Out Letters

Product: Drugs

Recipient:
Indigo Naturals
United States
support@indigonaturals.net

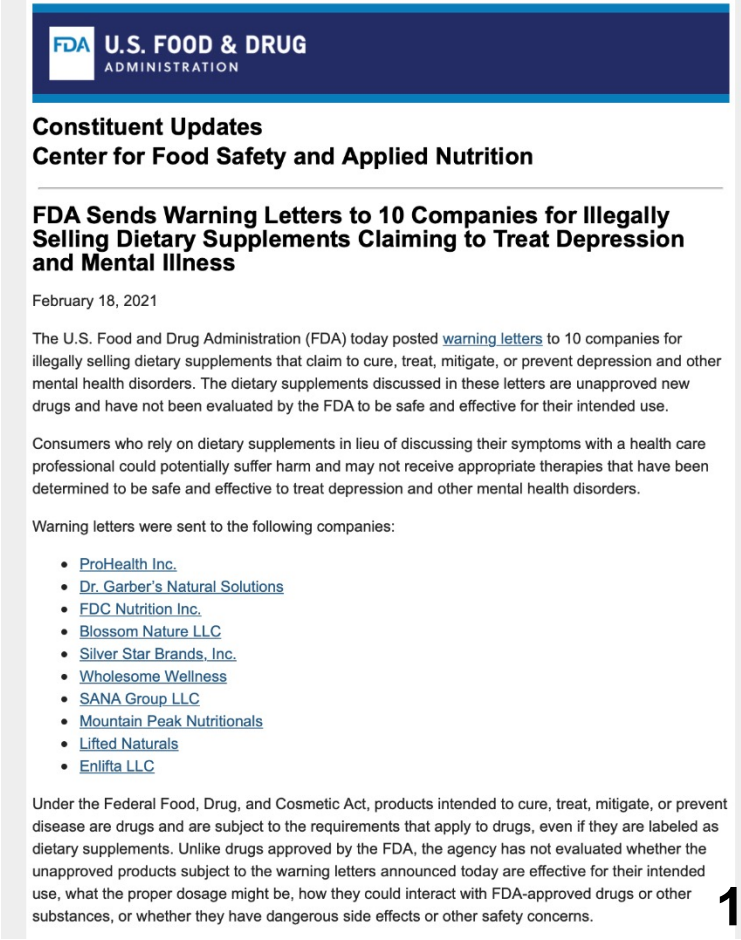
Issuing Office:
Center for Drug Evaluation and Research | CDER
United States
Federal Trade Commission

WARNING LETTER

Date: April 6, 2020

RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19)

This is to advise you that the United States Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) reviewed your website at the Internet address https://indigonaturals.net on March 30, 2020 and April 2, 2020, respectively. We also reviewed your social media website at Internet address www.facebook.com/IndigoNaturals/, where you direct consumers to your website, https://indigonaturals.net, to purchase your products. The FDA has observed that your website offers cannabidiol (CBD) products for sale in the United States and that these products are intended to mitigate, prevent, treat, diagnose, or cure COVID-19[1] in people. Based on our review, these products are unapproved new drugs sold in violation of section



FDA U.S. FOOD & DRUG ADMINISTRATION

Constituent Updates
Center for Food Safety and Applied Nutrition

FDA Sends Warning Letters to 10 Companies for Illegally Selling Dietary Supplements Claiming to Treat Depression and Mental Illness

February 18, 2021

The U.S. Food and Drug Administration (FDA) today posted warning letters to 10 companies for illegally selling dietary supplements that claim to cure, treat, mitigate, or prevent depression and other mental health disorders. The dietary supplements discussed in these letters are unapproved new drugs and have not been evaluated by the FDA to be safe and effective for their intended use.

Consumers who rely on dietary supplements in lieu of discussing their symptoms with a health care professional could potentially suffer harm and may not receive appropriate therapies that have been determined to be safe and effective to treat depression and other mental health disorders.

Warning letters were sent to the following companies:

- ProHealth Inc.
- Dr. Garber’s Natural Solutions
- FDC Nutrition Inc.
- Blossom Nature LLC
- Silver Star Brands, Inc.
- Wholesome Wellness
- SANA Group LLC
- Mountain Peak Nutritionals
- Lifted Naturals
- Enlifta LLC

Under the Federal Food, Drug, and Cosmetic Act, products intended to cure, treat, mitigate, or prevent disease are drugs and are subject to the requirements that apply to drugs, even if they are labeled as dietary supplements. Unlike drugs approved by the FDA, the agency has not evaluated whether the unapproved products subject to the warning letters announced today are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs or other substances, or whether they have dangerous side effects or other safety concerns.

Testing Needs

- Driven by states
  - Usually related to microbial loads of dried biomass, pesticides residues and heavy metal levels
- Driven by assessing potency of products
  - Extraction (making isolates), storage, etc.
- Driven by product formulations and processing conditions
  - Safety, pathogens, microbial loads (indicators of process control)
- Stringent set of requirements for laboratory certifications
  - ISO 17025 accredited