



AMERICAN
EPILEPSY
SOCIETY

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Supplemental Appendix C: *CBD Label Examples*

American Epilepsy Society (AES)

**Written Comments to Norman E. “Ned” Sharpless, MD
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration (FDA)
Department of Health and Human Services (HHS)**

on Docket ID# FDA-2019-N-1482

***Scientific Data and Information about
Products Containing Cannabis or Cannabis-Derived Compounds;
Public Hearing; Request for Comments***

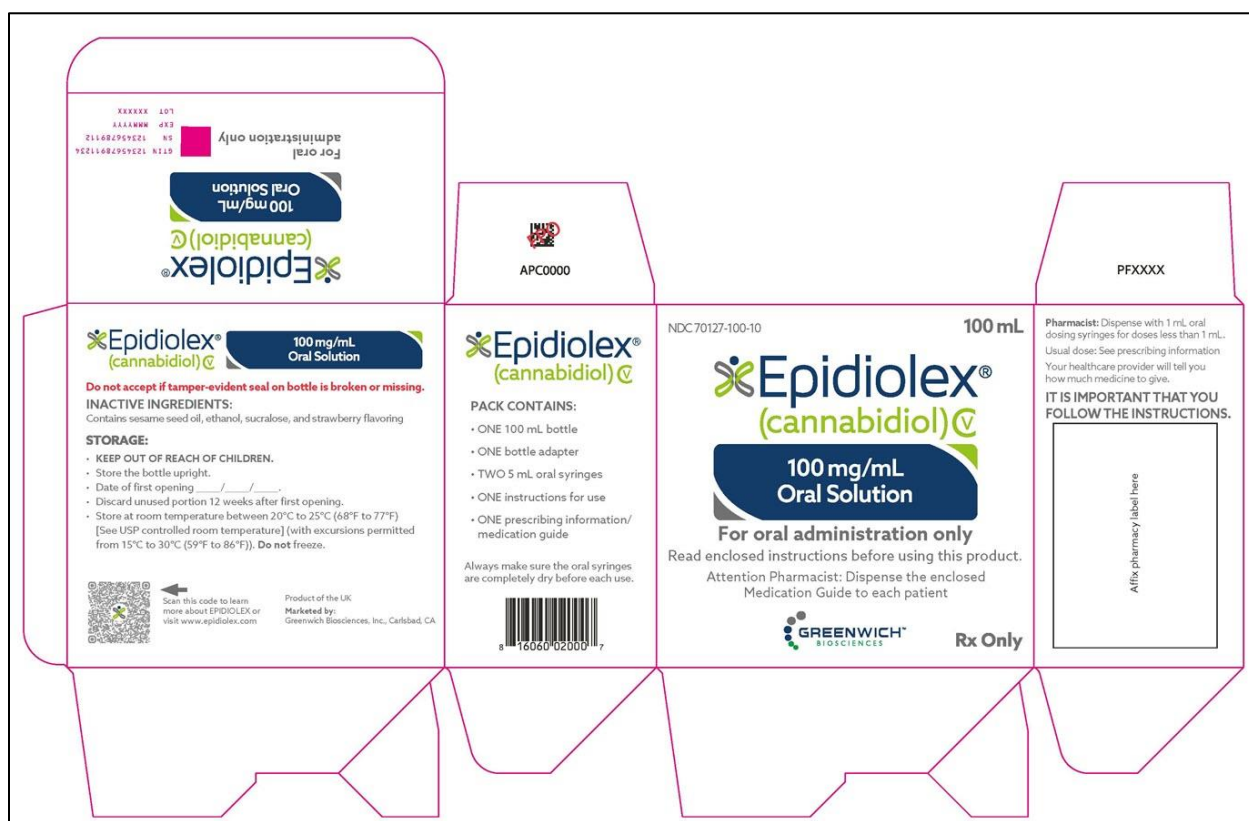
Submitted on: July 16, 2019

Appendix C: CBD Label Examples

Examples of unclear and inaccurate cannabidiol (CBD) labeling on products currently in the marketplace are numerous. Overarching labeling concerns include tremendous variability in dosage, omission of key information about product ingredients and/or dosage, and lack of warnings about potential adverse events and drug interactions.

A label from the FDA-approved drug, Epidiolex[®], follows as a point of reference and contrast to subsequent label examples that highlight a range of issues with CBD products currently in the marketplace.

I. FDA Approved Drug – Label for Epidiolex



II. Label Examples Highlighting a Variety of Issues with Dosage Accuracy and Clarity

Label Example A. From a state approved product in Iowa, this label lacks “per capsule” CBD dose labeling. Consumers must be able to calculate per capsule dosage to know that product contains 20 mg CBD per capsule; at a glance, consumers might assume the dosage is 600 mg per capsule.



Label Example B. Difficult to translate serving size to milligrams. Provides hemp oil content per serving but not CBD or other cannabinoid dosage.

Suggested Use: Use up to a full dropper, twice a day. As a dietary supplement, place 20 drops under the tongue, hold for 60 seconds, then swallow.

Storage: In order to preserve freshness, store away from excessive heat, light, and humidity.

Warning: If pregnant or nursing, consult your physician before using this or any other supplement.

KEEP OUT OF THE REACH OF CHILDREN

HempWorx products are made from industrial hemp plants. Cannabidiol (CBD), a constituent that naturally occurs in industrial Hemp, is just one of over 85 cannabinoids that is identified in the hemp plant. Our oil is CO2 extracted resulting in a solvent free, pure extract.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

Manufactured For:
MyDailyChoice, Inc.
 8840 West Russell Road,
 Suite 240 Las Vegas, NV 89148

HEMPWORX

500

**Full Spectrum Hemp Oil
Peppermint Flavor**

DIETARY SUPPLEMENT
1 oz / 30 ml

Supplement Facts
 Serving Size: 0.6ml
 (approx. 20 Drops)
 Servings Per Container: 50

	Amount Per Serving	% Daily
Calories	9	
Calories from Fat	9	
Total Fat	1g	
Phytocannabinoid Hemp Oil	10mg	**

*Percent Daily Values are based on 2,000 calorie diet.
**Daily Value not established.

Ingredients: Pressed Hemp (seed) oil, CBD-rich Whole Hemp Extract, Natural Peppermint Flavor

Shake well before use

Label Example C. Suggested use is 30-40 drops, TID or QID, but serving size is 1mL (20 drops). Concentration only for hemp extract, no CBD information.



CHARLOTTE'S WEB
HEMP EXTRACT
IN MCT | 500
mint chocolate flavor
DIETARY SUPPLEMENT
1 FL. OZ. (30mL)

Suggested Use: Take 30 to 40 drops, three to four times daily or as directed by a health care provider.

Supplement Facts
Serving Size: 1/4 teaspoon (1mL)
Servings Per Container: 30

	Amount Per Serving	% Daily Value
Calories	8	
Calories from Fat	8	
Total Fat	1g	2%*
Hemp Extract (aerial parts)	28mg	**

* Percent Daily Values are based on a 2,000 calorie diet.
** Daily Value not established.

Other Ingredients: Coconut Oil Medium Chain Triglycerides – Fractionated Coconut Oil, Sunflower Seed Oil, Organic Natural Flavors.

Manufactured by:
CW Botanicals™
A Stanley Brothers Company
Boulder, CO 80301
844-274-5347

BATCH#:
For more information on this product and others visit www.CWBotanicals.com

*A portion of proceeds will be donated to the Realm of Caring Foundation.
www.theroc.us*





Label Example D. Only a total CBD amount is provided, no concentration or suggested dose.

CBD (cannabidiol) **300mg CBD**
DROPS Made from organically grown cannabis
CBD (cannabidiol)


Active Ingredients: CBD 300 mg
Total Cannabinoids 300 mg

Recommend Use:
Shake before use. Place dropper under the tongue and hold for 60 seconds before swallowing. Refrigerate after opening.

This statement has not been evaluated by the FDA. Pregnant women and lactating mothers should not use this product. Always consult a medical doctor before modifying your diet or using any new product. This product is not intended to diagnose, treat, cure, or prevent any disease.

Batch# 273KB31941

Keep out of reach of children.
For Medical use only
Not for resale



Label Example E. Per serving and container cannabinoid content are presented as “4.2+ mg” and “500+ mg” respectively. Lacks information about specific cannabinoids. Suggests oral or topical administration but lacks information about absorption and related effective dosage.

SUGGESTED USAGE: As a dietary supplement, take one or more servings daily orally, or as advised by healthcare professional.

May also apply a few drops topically to skin and rub in thoroughly.



BODY AS DOCTOR™
by Wayne Garland

Hemp Oil Extract
500+mg Cannabinoids

Natural Flavor

Supplement Facts
Serving Size: 15 drops (0.5mL)
Servings per Container: about 120

	Amount Per Serving	% DV
Hemp extract blended with organic, cold pressed virgin hemp seed oil	0.5mL	†

† Daily Value (DV) not established

*These statements have not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent disease.

Manufactured for:
Body as Doctor • 805 Excalibur Street, Lafayette, CO 80026
(877) 975-9080 • www.BodyasDoctor.com



CONTAGIOUS HEALTH

Dietary Supplement
Vegan Formula

2 fl oz
(60 mL)



Please Recycle

4.2+mg cannabinoids per serving

Batch #



8 94034 91150 6

Label Example F. Neither dose nor concentration of CBD in milligrams is clearly labeled. Spelling errors.



7 12392 22802 2

QUALITY DECARBOXYLATED CBD OIL

Made in U.S.A.

3RD-PARTY LAB TESTED

Distributed by: MHR, LLC
616-863-2222 • Jenison, MI 49428

Cannabidiol (CBD) is a natural constituent of industrial hemp oil. This product is not intended to diagnose, treat, cure or prevent any disease.

HIGH CBD HEMP OIL

HEMP OIL SUPPLEMENT

GOLD LABEL

1 gram: 24-27% CBD



3g


CBD CONTENT:

720mg - 810mg

CBD content varies by batch.
Minimum CBD Content: 720mg

Label Example G. Online Product Information for Gummy Bear product displays total package CBD content prominently but presents per serving size (1 gummy) dosage much less prominently. Conflates supplement and food label information. Presents no warnings related to potential adverse events or overdose and no “Keep out of reach of children” warning.

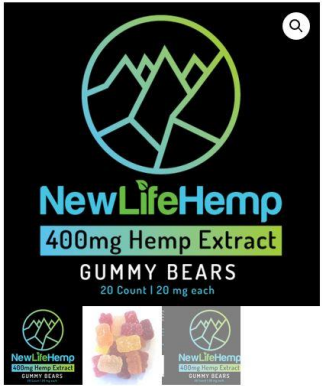
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New Life Hemp
400mg Hemp Extract
GUMMY BEARS
20 Count | 20 mg each

CBD GUMMY BEARS – 400mg

★★★★★

NEW LIFE HEMP – Gummy Bears 400mg

Start your day off right with these delicious, vegan CBD Gummy Bears. These gummies are made with all natural, non-gmo hemp oil extract. New Life Hemp's CBD Gummy Bears are made in America and contain zero THC. Each CBD Gummy Bear has 20 MG of CBD. Each bottle contains 5 delicious flavors of gummies: Orange, Lemon, Strawberry, Grapefruit and Tropical.

\$29.99

1

SKU: NLHG-400 Category: CBD Edibles

Description **Reviews (13)**

NEW LIFE HEMP – Gummy Bears 400mg

Start your day off right with these delicious, vegan CBD Gummy Bears. These gummies are made with all natural, non-gmo hemp oil extract. New Life Hemp's CBD Gummy Bears are made in America and contain zero THC. Each CBD Gummy Bear has 20 MG of CBD. Each bottle contains 5 delicious flavors of gummies: Orange, Lemon, Strawberry, Grapefruit and Tropical.

SUPPLEMENT FACTS

Serving Size: 1 Gummy
Serving Per Container: 20

Amount/Serving	%DV*
Calories 10	
Total Fat	0g 0%
Saturated Fat	0g 0%
Trans Fat	0g 0%

Total Carbohydrate	5g	5%
Dietary Fiber	0g	0%
Sugars	2g	0%
Includes 0g Added Sugars	0g	0%
Protein	0g	0%
*CBD	20mg	per gummy

***Percent Daily Values (DV) are based on a 2,000 calorie diet**

† Daily Value not established

Other Ingredients: Non GMO Hemp Extract, organic evaporated cane juice, organic corn syrup, organic white grape juice concentrate, pectin sodium citrate, citric acid, ascorbic acid, natural flavors, colors added (including anatto, tumeric, grape juice concentrate, red fruit juice concentrate). Packaged in the same facility as peanuts, tree nuts, wheat, soy, and milk.

Usage: Enjoy one or two gummy bears in the morning or throughout the day, chewing thoroughly.

Label Example H. A CBD “Dietary Supplement” product with relatively good labeling, although lacks a batch number.

SUPPLEMENT FACTS

Serving Size: 20 Drops (1/3 Dropper)
Servings per Container: 30

	Amount per Serving	% Daily Value
Cannabidiol (CBD) Hemp Derived	20mg	*

* Daily Value not established

Other Ingredients: Extra Virgin Olive Oil


GMO
FREE


GLUTEN
FREE


VEGAN

Manufactured by:
Procana Laboratories
Support@Procana.com
www.Procana.com





CBD Complete[®]
Extra Strength

600 mg CBD

DIETARY SUPPLEMENT
1 FLUID OZ (30ml)

Procana CBD Complete[®] offers pure isolated CBD derived from hemp. Available in an Extra Strength dose to help balance the Endocannabinoid System.

Consult your physician before taking Procana. Store in a cool, dry place.

Procana has not been approved by the FDA to treat, cure, or prevent any illness or disease.

To continue our medical research, please share your experience at:
Procana.com/survey



Label Example I. A CBD/THC “Medicinal Cannabis” product of the same brand (below) contains somewhat ambiguous information about relative CBD:THC ratios (prominently displays 2:1, but per serving inset states 5 mg CBD and 3 mg THC).

Both products from this brand contain warnings, although they vary between products. Each product invites consumers to a survey for “medical research,” but links lead to web forms that invite product reviews/testimonials prompted by a list of indications for product use.



GOVERNMENT WARNING:
THIS PRODUCT CONTAINS CANNABIS, A SCHEDULE 1 CONTROLLED SUBSTANCE. KEEP OUT OF REACH OF CHILDREN AND ANIMALS. CANNABIS PRODUCTS MAY BE POSSESSED OR CONSUMED BY PERSONS 21 YEARS OF AGE OR OLDER UNLESS THE PERSON IS A QUALIFIED PATIENT. THE INTOXICATING EFFECTS OF CANNABIS PRODUCTS MAY BE DELAYED UP TO 2 HOURS. CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSULT YOUR PHYSICIAN BEFORE TAKING PROCANA. CONSUMPTION OF CANNABIS PRODUCTS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE MACHINERY. PLEASE USE EXTREME CAUTION.



8 mg | CBD/THC 2:1
Medicinal Softgels

MEDICINAL CANNABIS

Serving Size 1 Softgel
Servings per Container 20

	Amount per Serving	% Daily Value
(CBD) Cannabidiol	5 mg	*
(THC) Tetrahydrocannabinol	3 mg	*

* Daily Value not established
Other Ingredients: Grapeseed Oil, Softgel Capsule (Gelatin, Glycerin, Purified Water).



Distributed by **Procana of California**
Support@Procana.com
www.Procana.com

20 Softgels

ACTUAL
SIZE

***PLEASE LEAVE A SURVEY TO FURTHER MEDICAL RESEARCH!**

www.Procana.com/Survey