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;
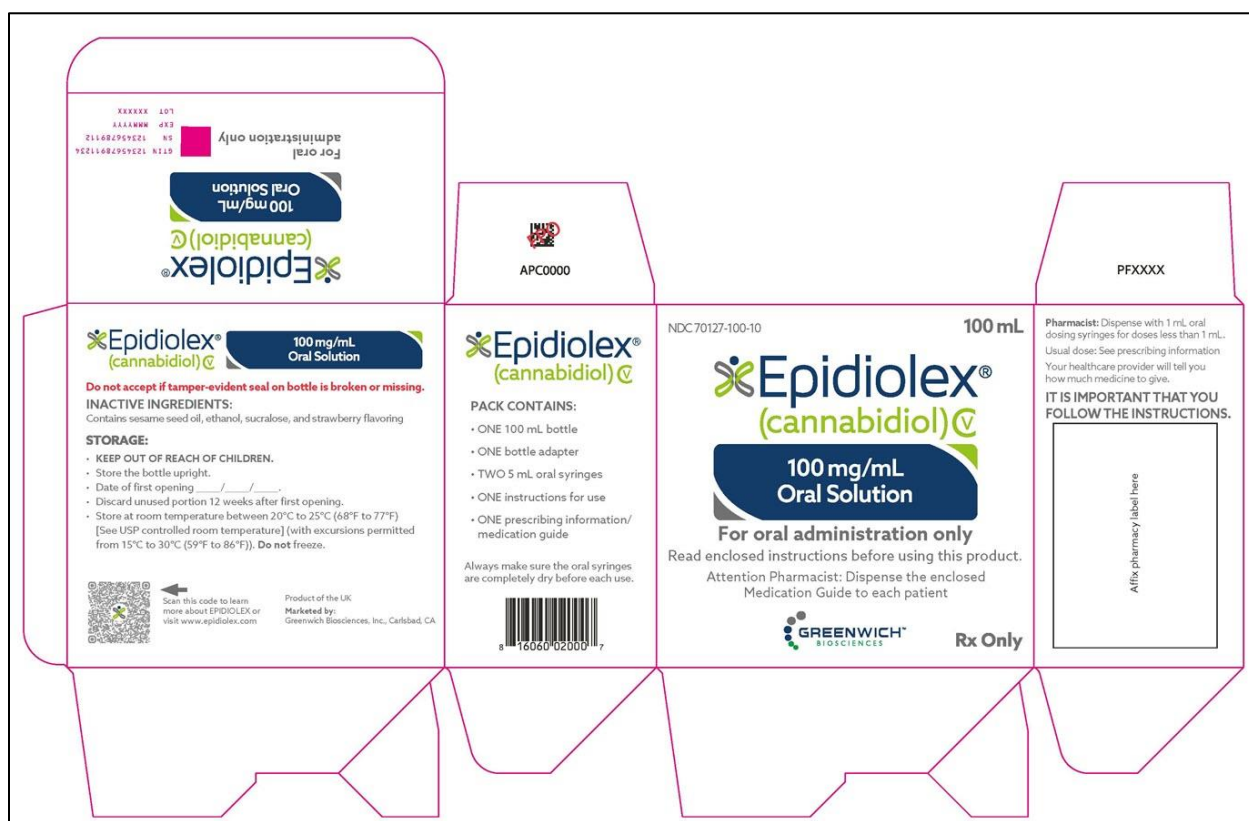*Public Hearing; Request for Comments*

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.

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.

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

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.

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

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.

Have any questions? ✉ info@buycbdoilonline.com

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20 Count | 20 mg each

CBD GUMMY BEARS – 400mg

★★★★★

NEW LIFE HEMP –
Gummy Bears 400mg

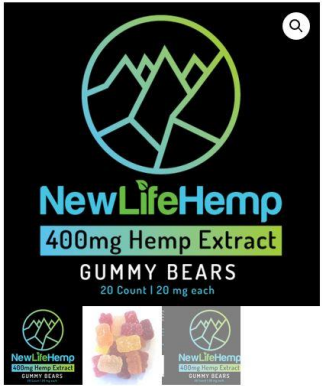Start your day right with these delicious, vegan CBD Gummy Bears. These gummies are made with all natural, non-gmo hemp oil extrat. New Life Hemp's CBD Gummy Bears are made in America and contain zero THC. Each CBD Gummy Bear has 20 MG of CBD. Each bottle contains 5 delicious flavors of gummies: Orange,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

$29.99

[1 ⬍] [Add to cart]

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 extrat. 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.

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.

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%

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

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.