



DIVISION OF
CORPORATION FINANCE

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

December 6, 2019

Ray Grimm
Chief Executive Officer and Director
New You, Inc.
3246 Grey Hawk Court
Carlsbad, California 92010

Re: New You, Inc.
Registration Statement on Form S-1
Filed November 7, 2019
File No. 333-234577

Dear Mr. Grimm:

We have reviewed your registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by amending your registration statement and providing the requested information. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Form S-1 filed November 7, 2019

Cover Page

1. We note your disclosure that the selling stockholders will sell their shares at prices determined by market prices or in negotiated transactions. We also note that your common stock is currently quoted on the OTC Pink. Please note that being quoted on the OTC Pink does not satisfy the requirement that there be an established public trading market, with respect to secondary at-the-market offerings, for purposes of identifying the offering price on the prospectus cover page as required by Item 501(b)(3) of Regulation S-K. Therefore, please revise to reflect the fixed price at which the shares will be offered.

Business Overview, page 5

2. We note that your summary only discusses the positive aspects of the company and the offering. The prospectus summary should provide a brief, but balanced, description of the key aspects of the company as of the latest practicable date. Please revise the summary to also discuss any negative aspects of the Company's experience, strategy, and prospects, and any risks or obstacles you face. For instance, please highlight that you have no patents or trademarks, that you purchase your inventory from a related party, that your officers, directors and other affiliates control a majority of your common stock.
3. Please revise to clarify the basis for your statement that the business opportunities afforded your customers and Brand Partners allows them "to make a difference in both the world and their personal lives."
4. Please revise the Summary section to provide greater detail regarding the nature of your products. Also disclose the net losses for the last year and six-month period, and the expected need for raising additional capital within the near future.

Change in Control and Transition to the New You Business, page 5

5. Please expand this section to provide a description of the history and development of New You LLC prior to its acquisition by you in January 2019.

Risk Factors, page 6

6. Please include a risk factor that discusses at length the current concerns of the FDA regarding products that contain cannabis or cannabis-derived compounds, including CBD. We note in particular that the FDA has deemed marketing food containing CBD or labeling it as a dietary supplement to be illegal. Also disclose any material risks relating to state or foreign regulations on your business. In addition, consider disclosing the risks relating to your multi-level marketing business model.

If we fail to protect our intellectual property . . . , page 7

7. Please revise to disclose here that you have no trademarks or patents.

Our insurance coverage may be inadequate to cover all significant risk exposures, page 9

8. Please revise to clarify the nature of the liabilities that are unique to your products.

Our officers and directors have significant control over stockholder matters . . . , page 9

9. You state here that your officers and directors own 90.13% of outstanding common shares, while your beneficial ownership table on page 23 shows that officers and directors hold 43.81%. Please revise to reconcile these disclosures.

Selling Stockholders, page 12

10. Given the nature of the offering and its size relative to the number of shares outstanding held by non-affiliates, it appears that the selling stockholders may be acting as conduits for the company in an indirect primary offering. Please revise to identify the selling stockholders as underwriters. In the alternative, provide an analysis of why you believe this is not an indirect primary offering, taking into consideration each of the factors identified in Securities Act Rules Compliance and Disclosure Interpretations 612.09, as well as any other factors you deem relevant.

Description of Business, page 16

11. Please revise to explain the terms “Canna-active,” “phytocannabinoid-rich hemp,” “MCT,” “hops-extracted beta-cayophyllene,” and others.
12. Please clarify the references to "bulk CBD, CBG, CBD, full-spectrum and broad-spectrum cannabinoid extracts and emulsions" and explain how those several ingredients are used in your products. Be sure to distinguish clearly between CBD and CBG.
13. We note you describe your business as the development and marketing of CBD products; however, it appears that you purchase your products from a supplier and resell them through a multi-level marketing model where you earn commission on product sales. In addition, we note that the products you describe on pages 16-17 are trademarked, but you state on page 17 that you hold no patents or trademarks. Please clarify your role in the development of CBD products. If you are not currently involved in product development and your business only involves the distribution of the products you purchase from your suppliers, revise to make this clear. If you are involved in product development, please expand to describe your product candidates, their current stage of development and their regulatory status.
14. You describe your CBD products as intended to provide certain therapeutic benefits, stating, for example, that they provide “wellness benefits of USA-grown cannabinoids” and “an energy boost,” that they “promote fast and steady weight loss naturally,” that they “help” your customers with “appetite, glycemic and mood control” and are designed to remove bloating and relieve constipation, among other claims. Products that are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or any function of the body are considered drugs under the Federal Food, Drug and Cosmetic Act and subject to FDA approval. Please revise to describe the regulatory status of these products, or revise to avoid unsubstantiated therapeutic claims.
15. Please revise to remove references to safety and efficacy throughout your filing, such as the description of the “Release” product. Determinations as to a drug’s safety and efficacy are solely within the purview of the FDA or other regulatory body.

16. Please revise the description of your products and the products offered by your supplier to avoid referring to any CBD products as supplements, which implies that these products supplement diet or nutrition. For guidance, please refer to Question 9 of the FDA's Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers (available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>).
17. Please clarify where your Brand Partners and your markets are located. In this respect, we note the reference on page 10 to "distributors in foreign markets" and on page 17 to your being subject to "numerous federal, state, local, and foreign laws and regulations." In particular, disclose which foreign countries your products are sold in.

Regulatory Requirements, page 17

18. Please provide a more robust discussion of the material laws and regulations to which your business is subject. Revise to avoid all suggestion that because hemp and hemp-based products are no longer included in Schedule 1 of the Controlled Substances Act, such products are "100% legal." As an example, please disclose the effect of the United States Food and Drug Administration's regulation on your business, including any requirement for FDA approval of your products before you can market them, the nature and duration of the FDA approval process, the status of your products in this approval process, regulation of the manufacturing and labelling of your products, post-market reporting and record keeping, and regulation of advertising and promotion, including regulation of your statements of efficacy. Also include the sanctions for non-compliance with FDA regulation.
19. It appears that certain of your product offerings are food or beverages that contain CBD or that are intended to be added to food and beverages. Please provide us the basis for your belief that your products can be sold without prior FDA approval as stated on page 17. For guidance, please refer to Question 10 of the FDA's Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers (available at <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>).

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 18

20. Please revise to disclose the specific reasons for the significant increase in revenues during the interim period 2019, including the specific products that contributed to the increase. Refer to the requirements of Item 303(a)(3) of Regulation S-K.

Known Trends and Uncertainties Expected to Have a Material Impact on Revenues, page 19

21. You state on page 19 that you expect to continue to see high retention rates of your Brand Partners. Please revise to quantify your retention rates. Please also reconcile your

disclosure with your statement at the bottom of page 9 that you have a high rate of attrition among your distributors.

Directors and Executive Officers, page 21

22. Please revise to avoid promotional language throughout this section. We note, merely as examples, the following words and phrases:

- "vision" and "leadership"
- "unmatched"
- "unique formula for success"
- "seasoned professional"

Delete or provide a clear basis for such claims as your statements that Ray Grimm's work has "benefited the physical and financial health of thousands," or that Greg Montoya's marketing systems have "collectively helped generate approximately \$374 million" in sales.

23. Please revise to ensure that you have disclosed the principal occupations and employment over the last five years of each of your directors and executive officers named here. Include the name and the principal business of any corporation or other organization in which such occupation or employment were carried out.

Certain Relationships and Related Party Transactions, page 24

24. Please revise to describe the basis on which Carlsbad Naturals LLC is a related party.
25. Please revise to provide the amount of each of the transactions described in paragraph 2, not only a net amount.
26. Please provide disclosure pursuant to Item 404(d) of Regulation S-K with respect to the transactions with CBD Naturals, LLC as discussed in Note 6 to your financial statements on page F-9.

Condensed Consolidated Financial Statements

NOTE 1 - Organization and Significant Policies

Recent Developments, page F-5

27. Please explain to us how you determined the amount of the reverse recapitalization adjustment included on page F-3. In Note 2 on page F-16 you also indicate that these entities were related parties prior to the reverse recapitalization. Tell us whether there was common control between these entities prior to the transaction.

Use of Estimates, page F-5

28. You indicated that one of your significant estimates includes the valuation of stock-based compensation. Please revise to include an accounting policy for stock-based compensation and to disclose how you determined the fair value of any stock-based compensation issued during the periods of the financial statements.

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Revenue Recognition, page F-6

29. We reference your various products on pages 16 and 17. Please explain to us how you considered the guidance in ASC 606-10-50-5 and 55-89 through 55-91 related to disaggregation of revenues and in ASC 280-10-50-40 related to information about products and services.

3. Notes Payable, page F-29

30. We note the settlement of notes payable prior to transfer in control was treated as a debt extinguishment resulting in a gain of \$409,443 in the year ended December 31, 2018. Please explain to us how you determined the amount of the gain.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Jenn Do at 202-551-3743 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Greg Dundas at 202-551-3436 or Mary Beth Breslin at 202-551-3625 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Joe Laxague