



DIVISION OF
CORPORATION FINANCE

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

February 1, 2024

Brian S. John
Chief Executive Officer
Safety Shot, Inc.
1061 E. Indiantown Rd., Ste. 110
Jupiter, FL 33477

**Re: Safety Shot, Inc.
Post-Effective Amendment No. 5 on Form S-1
Filed January 23, 2024
File No. 333-258005**

Dear Brian S. John:

We have conducted a limited review of the post-effective amendment to your registration statement and have the following comments.

Please respond to this letter by filing a post-effective amendment and providing the requested information. If you do not believe a comment applies to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing any amendment and the information you provide in response to this letter, we may have additional comments.

Post-Effective Amendment No. 5 to Form S-1

Summary, page 3

1. We note your disclosure on page 4 that JW-500 was born out of clinical trials and that you have plans for additional clinical trials of JW-500 in the second half of 2024. We also note your disclosure on page 8 that "JW 500, JW700, and Photocil are cosmetic products and do not require clinical trials." Please revise your disclosure to reconcile this discrepancy and to clarify whether JW-500 requires FDA approval.

General

2. We note your revised disclosure and response to comment 11 and reissue the comment. Please revise your disclosure to discuss the current status of commercialization of each of your products, in particular: Photocil, JW-700, and JW-500. For example, please discuss each country where Photocil and JW-700 are currently offered, and clarify whether JW-500 is still under development and is not being offered to consumers. In this

regard, please also note:

- Your disclosure still contains statements of safety and efficacy for products that have not been approved by the FDA or similar foreign regulators. For example, on page 42 you state "[t]hese tests employed breathalyzers, providing conclusive evidence of the Safety Shot Beverage's effectiveness. While these endeavors have demonstrated the product's reliability, the Company is presently engaged in a formal double-blinded placebo-controlled clinical trial to further substantiate its findings, exemplifying a commitment to rigorous scientific validation." We remind you that safety and efficacy are determinations that are solely within the authority of the FDA or similar foreign regulators. As such, please revise your disclosure to remove any statements of safety and efficacy for any products that have not been approved by the FDA or similar foreign regulators.
3. We reissue comment 5 as it relates to the regulations applicable to your products. For Safety Shot and your other products, please further clarify the government regulations, and specifically identify the particular category you believe each falls within under the regulation of the FDA (drug, medical device, dietary supplement, food additive, etc.), revise the Government Regulation section to provide materially complete discussions of all regulations addressed on page 8, revise to eliminate disclosures throughout the document that are inconsistent with your position regarding the applicable government regulations, and disclose the regulatory category for each in your product roadmap on page 43 and in the Government Regulation section. We note the following:
- You take the position that Safety Shot is a food additive, but continue to make statements implying that Safety Shot is a drug (intended to treat, diagnose, cure, or prevent a disease) or a dietary supplement. We note, for example, the disclosure on page 42 that Safety Shot "is crafted to streamline the body's detoxification process from alcohol, employing a thoughtfully selected combination of vitamins, minerals, and nootropics to enhance rehydration and mental clarity. Noteworthy is the fact that the Safety Shot Beverage comprises 28 active ingredients, all falling under the Generally Regarded As Safe (GRAS) category." We also note the statements made in the backgrounds of Directors Boon and Gulyas, former executives with GBB Drink Lab.
 - You disclose on page 4 and elsewhere that NoStingz is an "effective barrier" and "as product contains ingredients with well established safety profiles it does not require FDA approval." You also describe it as a barrier to UVA/UVB and include it within the category of "sun screen products." On page 8 you state that it falls within the category of cosmetics. Clarify if the claims related to repelling jellyfish venom and protecting from sea lice also fall within the definition of cosmetics.
 - Revise to further clarify how SS-100 would be characterized as a drug in contrast to Safety Shot, which you characterize as a food additive. In addition, please disclose additional information to clarify the basis for your statement that SS-100 would qualify for Orphan Drug Designation to treat Acute Alcohol Poisoning. For

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example, clarify how Acute Alcohol Poisoning meets the FDA's definition of a Rare Disease. Also clarify the significance of Orphan Drug Designation. Please also revise the Government Regulation section to clarify the process for seeking FDA approval of a drug and for obtaining Orphan Drug Designation.

4. We note the recent filing pursuant to Item 7.01 of Form 8-K that included your January 17, 2024 press release regarding the lawsuit between GBB Lab, Inc. and FSD Pharma. Please revise the document, including the disclosure in Recent Developments, to disclose your relationship to GBB Labs, Inc., which is your subsidiary, as disclosed in Recital B of the asset purchase agreement filed as Exhibit 10.26. Please revise the disclosure throughout this document to clarify the references to "GBB", including to which entity you refer. Please also revise the document to identify the proceedings and disclose the nature and stage of the proceedings and relief sought. Clarify FSD Pharma's relationship with GBB Labs, Inc. or FSD Pharma, as applicable, pursuant to which the NDA was executed. Clarify the potential impact on your product and company if GBB Labs is not successful in the litigation. In addition, please revise your beneficial ownership table to disclose the 5 million shares issued to GBB Drink Labs in connection with the asset purchase agreement, as disclosed on page 7, and clarify which, if any, of your directors beneficially own those shares.

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.

Please contact Juan Grana at 202-551-6034 or Abby Adams at 202-551-6902 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Industrial Applications and
Services

cc: Arthur S. Marcus, Esq.