IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mark: “GREEN SOUL”

Docket No. GO-3887

Serial No. 88244601

Examining Attorney:
Elle Marino

Applicant:
International Products Group, LLC

Applicant's Response to Office Action

I. Background

Applicant filed the present application “Green SOUL” on or about December 28, 2018 for the following goods: “Shampoo; Conditioner; Scalp Treatment Products; Hair Oil; Hair Styling Products; Facial Cleansers; Facial Moisturizers; Facial Treatments, such as Serums And Spot Treatments; Acne Relief Creams And Mask; Night Cream; Facial Masks; Anti-Inflammation Skin Treatments; Sore Muscle Relief; Sore Muscle Bath Soak; Relaxing Bath Soak; Massage Oil; Moisturizing Oil; Body Moisturizer - Creams And Lotions; Sore Foot Relief; Arthritis Relief Cream Or Ointment; Essential Oil Blends For Aromatherapy; all of the foregoing being derived from natural ingredients including legal hemp and not including any controlled substances; and, Shampoo; Conditioner; Scalp Treatment Products; Hair Oil; Hair Styling Products; Facial Cleansers; Facial Moisturizers; Facial Treatments, such as

Serums And Spot Treatments; Acne Relief Creams And Mask; Night Cream; Facial Masks; Anti-Inflammation Skin Treatments; Sore Muscle Relief; Sore Muscle Bath Soak; Relaxing Bath Soak; Massage Oil; Moisturizing Oil; Body Moisturizer - Creams And Lotions; Sore Foot Relief; Arthritis Relief Cream Or Ointment; Essential Oil Blends For Aromatherapy, all of the foregoing not including hemp-based ingredients nor any controlled substances" (collectively, the "Goods").

On August 30, 2019, the Examining Attorney issued an Office Action preliminarily rejecting the Mark's registration on the following grounds: (1) that the Applicant does not have a bona fide intent to legally use the mark in commerce, under the Controlled Substances Act ("CSA"); (2) that the Applicant does not have a bona fide intent to legally use the Mark in commerce under the Food, Drug, and Cosmetics Act ("FDCA"); (3) that an identification amendment is required which may incurred additional class requirements; and (4) that a disclaimer of "Green" is required. Additionally, the Examining Attorney requested additional information.

For the following reasons, Applicant respectfully contends that the Examining Attorney's concerns are unfounded under federal law, and the Mark's registration should be approved:

II. Law & Argument

A. The Goods are legal under the CSA.

The Examining Attorney rejected the Application, as applied to the goods of "Shampoo; Conditioner; Scalp Treatment Products; Hair Oil; Hair Styling Products; Facial Cleansers; Facial Moisturizers; Facial Treatments, such as Serums And Spot Treatments; Acne Relief Creams And Mask; Night Cream; Facial Masks; Anti-Inflammation Skin Treatments; Sore Muscle Relief; Sore Muscle Bath Soak; Relaxing Bath Soak; Massage Oil; Moisturizing Oil; Body Moisturizer - Creams And Lotions; Sore Foot Relief; Arthritis Relief Cream Or Ointment; Essential Oil Blends For Aromatherapy; all of the foregoing being derived from natural ingredients including legal hemp and not including any controlled substances", on the basis that such subset of the Goods are illegal under the CSA and thus that it would be a "legal impossibility" for Applicant to lawfully use the Mark in commerce.

One of the Examining Attorney's assertions is that the Applicant did not have a valid basis for filing an application because, as of the date of the Application's filing, "[t]he goods and/or services identified did not potentially comply with applicable federal laws until that date". However, Applicant would like to respectfully point out that the timeline on this assertion does not

support it, and thus Applicant is confused by this statement and unsure how to best respond. As the Examining Attorney notes, the CSA was amended to remove hemp from the legal definition of Marijuana on December 20, 2018. Applicant filed its intent-to-use application on December 28, 2018 — eight full days after this amendment took effect. The 2018 Farm Bill passed the senate on June 28, 2018 and Congressed finally approved this legislation after a joint conference committee by December 12, 2018, at the time with a wide expectation that the President would sign such a bill into law. Thus, at all times Applicant had a good faith, bona fide intent to use this Mark (applied for on an intent-to-use basis) legally in commerce by complying with all federal laws, either in effect or presumed to be in effect prior to launching and using the Mark in commerce.

As the Examining Attorney concedes, "to the extent the applicant's goods will be derived from cannabis plants that meet the current statutory definition of hemp, the goods may presently be lawful." This is, indeed the case. As intended to be used, Applicant's Goods which contain hemp products will be "solely derived from hemp with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3 percent on a dry weight basis." As such, the Applicant's intended use is, indeed, lawful

under the CSA. Taken with the amendment of goods, below, Applicant respectfully requests that the Examining Attorney withdraw the rejection on this basis and approve the Mark for publication, as it is entitled to under all applicable laws.

B. The Goods are legal under the FDCA.

As an additional rejection on the basis of Applicant not having a bona fide intent to legally use the Mark in commerce, the Examining Attorney rejected the following goods on the basis that they are illegal under the FDCA: "Scalp Treatment Products; Facial Treatments, such as Serums And Spot Treatments; Acne Relief Creams And Mask; Anti-Inflammation Skin Treatments; Sore Muscle Relief; Sore Muscle Bath Soak; Sore Foot Relief; Arthritis Relief Cream Or Ointment; all of the foregoing being derived from natural ingredients including legal hemp and not including any controlled substances."

For the reasons set forth herein, Applicant respectfully contends that the Examining Attorney was mistaken in stating that "[t]he application identifies items or activities that involve a *per se* violation of federal law."

1. Legal standards.

The Examining Attorney's FDCA rejection appears to hinge upon the presumption that the Goods are a "drug" requiring FDA approval or otherwise illegal under the FDCA. However, in the wake of the Farm Bill (2018)'s amendment to the definition of Marijuana, much confusion as ensued. Given this widespread confusion, the FDA has further clarified the applicability of the FDCA on various hemp (and specifically CBD) products.

Specifically, the FDA has advised that it is illegal to sell foods which contain THC or CBD, and that it is illegal to sell THC or CBD products as dietary supplements. However, the FDA has advised that "cosmetic products" are not subject to premarket approval by the FDA and thus that cosmetic products containing cannabis and cannabis-derived ingredients is not a violation of the FDCA.

In short, the FDA has decided that THC and CBD products are not included within the dietary supplement definition of Section 201(ff)(3)(B) of the FDCA. As such, "if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the

existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement." *See the FDA's web page titled "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)", as accessed by undersigned counsel on February 28, 2020, available at https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#cosmetics, a true and accurate copy of which is attached as "Exhibit A".*

Similarly, the FDA has advised that foods containing THC or CBD remain illegal to sell without FDA approval, stating that "[u]nder section 301(ll) of the FD&C Act [21 U.S.C. § 331(ll)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public." *See Exhibit A, at point #10.*

Of particular relevance to the present Application, the FDA has advised that cosmetics containing cannabis-derived ingredients may be *legal* to sell under the FDCA. *See Exhibit A, at point 13.* Under §201(i) of the FDA, a

cosmetic is defined as "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles…" Under the FDCA, "cosmetic products and ingredients are not subject to premarket approval by FDA, except for most color additives. Certain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients". *Id.*

Nonetheless, cosmetics containing cannabis ingredients may remain illegal under the FDCA if — *and only if* — any ingredient "causes the product to be adulterated or misbranded in any way". *Id.* As to this point, the FDA advises that "[a] cosmetic generally is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling, or under such conditions of use as are customary or usual (section 601(a) of the FD&C Act [21 U.S.C. § 361(a)])." *Id.*

The FDA further has advised that a cosmetic product may be classified as a "drug" (and thus illegal to enter into interstate commerce under federal

law) under the FDCA but only if such cosmetic product "is intended to affect the structure or function of the body, or to diagnose, cure, mitigate, treat or prevent a disease." *Id.* For its part, the FDCA defines the term "drug" as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." FD&C Act, sec. 201(g)(1).

2. The Goods are legal under the FDCA as "cosmetic" products.

In the present case, the Goods are cosmetic in nature and are not drugs, and thus are not subject to premarket FDA approval under the FDCA. Therefore, the Goods can legally travel through interstate commerce under the FDCA and all applicable laws.

The Goods highlighted by the Examining Attorney under this advisory, namely, "Scalp Treatment Products; Facial Treatments, such as Serums And Spot Treatments; Acne Relief Creams And Mask; Anti-Inflammation Skin Treatments; Sore Muscle Relief; Sore Muscle Bath Soak; Sore Foot Relief; Arthritis Relief Cream Or Ointment; all of the foregoing being derived from natural ingredients including legal hemp and not including any controlled substances" are cosmetic products under §201(i) of the FDCA insofar as

each of these goods are intended to be "rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body … for cleansing, beautifying, or promotion attractiveness or altering the appearance".

Additionally, none of the goods highlighted by the Examining Attorney within this advisory meet the FDCA's definition of a "drug", because none of those goods are intended to affected the "structure or function of the body", nor are any such goods intended to "diagnose, cure, mitigate, treat, or prevent *disease*". For reference, the FDA defines "disease" as being limited to "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." *See Regulations on Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body*, 65 FED. REG. 1009 (proposed Jan. 06, 2000).

Because all of the identified Goods, including those highlighted by the Examining Attorney under this advisory, are cosmetic products and are not drugs in that they are not intended to diagnose, cure, mitigate, treat, or

prevent any *disease* nor to affect the structure or function of the body, the Goods are able to legally travel through interstate commerce under the FDCA and all other applicable laws. As such, Applicant respectfully requests that the Examining Attorney withdrawal this preliminary rejection and approve the Mark for publication, as it is entitled to by law.

C. Identification amendment.

Applicant hereby amends the Application to read as follows:

> International Class 003: *Shampoo; hair conditioner; non-medicated scalp treatment products, namely, non-medicated scalp treatment cream; hair oil; hair styling preparations; facial cleansers; facial moisturizers; non-medicated facial treatments, namely, skin serums; night cream; facial masks; relaxing non-medicated body soak for the bath; massage oil; moisturizing body oil; body moisturizer in the nature of creams and lotions; essential oils for aromatherapy; epsom-salt based score muscle bath soak; epsom-salt based cream for sore foot relief; all of the foregoing containing cannabis derived solely from hemp with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis; and then, all of the following goods not including hemp-based ingredients nor any controlled substances; Shampoo; hair conditioner; non-medicated scalp treatment products, namely, non-medicated scalp treatment cream; hair oil; hair styling preparations; facial cleansers; facial moisturizers; non-medicated facial treatments, namely, skin serums; night cream; facial masks; relaxing non-medicated body soak for the bath; massage oil; moisturizing body oil; body moisturizer in the nature of creams and lotions; essential oils for aromatherapy; epsom-salt based score muscle bath soak; epsom-salt based cream for sore foot relief;*

D. Disclaimer of "Green" apart from the Mark as shown.

No claim is made to the exclusive right to use "GREEN" apart from the mark as shown.

E. Applicant's responses to the Examining Attorney's requests for information.

1. Do or will applicant's identified goods include any oils, extracts, ingredients or derivatives from the plant Cannabis sativa L (also known as cannabis, marijuana or hemp)? If yes, please specify all the goods and what they contain.

   Answer: Yes. The goods will contain cannabis derived solely from hemp with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis.

2. If the answer to Question 1 is "yes," does the hemp used or to be used in applicant's goods contain more than 0.3 percent delta-9 tetrahydrocannabinol (THC) on a dry weight basis?

   Answer: No.

3. If applicant has any documentation relative to the THC content of the oils, extracts or derivatives used or to be used in the goods, please submit them with the response.

   Answer: As Applicant is still in the development phase of the Goods contemplated by this Intent to Use application, no such documentation currently exists. However, Applicant is happy to supplement this response as the proper documentation (such as certificate of authenticity) may come into existence.

4. If applicant's goods do or will contain oils, extracts, ingredients or derivatives from the plant Cannabis sativa L which has more than 0.3 percent delta-9 tetrahydrocannabinol on a dry weight basis, identify the part or parts of the plant used in obtaining the oils, extracts, ingredients or derivatives.

Answer: Applicant expects that the legal oils, extracts, ingredients, or derivatives from the plant Cannabis sativa L will come from the plant's stalk, stems, leaves, and flowers of the hemp plant.

5. If the "hemp" is grown in the United States of America, was the hemp used in the goods obtained from an authorized grower or supplier of industrial hemp from a hemp growing pilot program set up under the 2014 Farm Bill?

   Answer: To the extent that Applicant is currently in the development phase, Applicant expects that all hemp to be used in the goods will be obtained from an an authorized grower or supplier of industrial hemp from a hemp growing pilot program set up under the 2014 Farm Bill and/or an authorized grower or supplier of industrial hemp from a hemp growing program authorized by the 2018 Farm Bill, and/or an authorized grower or supplier of industrial hemp from a hemp growing program authorized by federal law.

6. Do or will the goods include cannabidiol (CBD)?

   Answer: Yes.

7. If so, will there be more than a trace amount of CBD in the goods, e.g., more than 50 parts per million (PPM)?

   Answer: Applicant currently does not have the knowledge to answer this question in full. However, at the highest end, Applicant expects that CBD content in its most potent products will not exceed 200 mg per .3 mL of carrier oil, in accordance with federal laws and presumed industry best practices.

8. Do or will applicant's identified goods include CBD which is derived from, oils, extracts or ingredients from plants other than Cannabis sativa L?

   Answer: No.

9. Is applicant currently seeking FDA approval of the marketing of its Class 005 goods identified in the application?

   Answer: Applicant is not presently applying for any goods within class 5, as none of its goods are intended to be medicinal in nature. Thus, no FDA approval is required and therefore not sought.

10. If the answer to Question 9 is yes, please provide a copy of such application.

    Answer: N/A

11. Upon information and belief, do applicant's goods comply with the Controlled Substances Act?

    Answer: Yes.

12. Upon information and belief, do applicant's goods comply with the Food, Drug and Cosmetic Act?

    Answer: Yes.

III. Conclusion

For the reasons set forth herein, Applicant respectfully requests that the Examining Attorney withdraw the initial rejections and approve this Mark for publication, as it is entitled to under law. Specifically, the Goods are federally legal under both the CSA and FDCA, to the extent that they contain cannabis derived solely from hemp with a delta-9 tetrahydrocannabinol (THC) concentration of not more than 0.3 percent on a dry weight basis, and are "cosmetics" and not "drugs" as defined by the FDA.

Dated: February 28, 2020.

Respectfully Submitted,

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