IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Nestlé Skin Health S.A.	
Serial No.:	87015660	In Pyo Lee Examining Attorney
Filed:	April 27, 2016	Law Office 114
Mark:	Cetaphil	
Our Ref:	102.0757	

RESPONSE TO OFFICE ACTION

Box RESPONSES
NO FEE
Commissioner for Trademarks
P.O. Box 1451
Alexandria, Virginia 22313-1451

This responds to the Office Action dated September 11, 2017.

In that Office Action, the Examining Attorney accepted the Statement of Use and Applicant's specimens for Class 3, but refused acceptance of the Statement of Use and Applicant's specimens for Class 5.

In support of his refusal, the Examining Attorney writes:

> Registration is refused because the specimen does not show the applied-for mark in use in commerce in connection with any of the goods specified in International Class 005 in the statement of use. Trademark Act Sections 1 and 45, 15 U.S.C. §§1051, 1127; 37 C.F.R. §§2.34(a)(1)(iv), 2.56(a); *In re Graystone Consulting Assocs., Inc.*, 115 USPQ2d 2035, 2037-38 (TTAB 2015); *In re Chengdu AOBI Info. Tech. Co.*, 111 USPQ2d 2080, 2081-82 (TTAB 2011); TMEP §§904, 904.07(a), 1301.04(d), (g)(i). Specifically, the specimen comprises photographs of applicant's moisturizer, make-up remover, and facial washes, all of which appear to be non-medicated goods classified in International Class 003. Hence, the specimen is satisfactory for the identified goods in International Class 003. However, the goods featured in the specimen do not appear to comprise pharmaceutical products and preparations for use in dermatology, medicated sunscreen, or

> dietary and nutritional supplements for human purposes. Several goods featured in the specimen do feature phrases that may reasonably be understood and/or imply that the goods are pharmaceutical in nature, including "clinically proven," "dermatologist tested," and "eczema calming." However, as the attached screen-shots show, these phrases do not necessarily identify pharmaceutical goods or preparations.

Applicant respectfully disagrees with the Examining Attorney's refusal and, for the reasons that follow, Applicant requests that the Examining Attorney reconsider and withdraw his refusal.

The Examining Attorney Has Focused on Applicant's Marketing Claims

The Examining Attorney's refusal gives significant attention to Applicant's marketing claims to the exclusion of consideration of the products/specimens themselves. The Examining Attorney places significance on the marketing claims of "clinically proven," "dermatologist tested," and "eczema calming." However, he ignores the nature of the *products themselves*. Applicant's marketing claims do not necessarily bear on the nature of the product. Insofar as a medicated product *may not be* "clinically proven" or "dermatologist tested," it is equally true that a non-medicated product *may be* "clinically proven" or "dermatologist tested". Consideration of the products themselves makes clear that Applicant's Class 5 specimens are acceptable.

Moreover, the TTAB's primary reviewing court has previously found that a single product may have dual uses as both a cosmetic and a pharmaceutical preparation where the specimens do not contradict the dual classification. *Jean Patou, Inc. v. Theon, Inc.,* 9 F.3d 971, 975 29 USPQ2d 1771, 1774 (Fed. Cir. 1993). The FDA's rules are consistent with the Board's position. 21 C.F.R. §§ 201(g) and (i) (FD&CA); 21 C.F.R. § 509 (FD&CA).

The Examining Attorney concedes that "[s]everal goods featured in the specimen do feature phrases that may reasonably be understood … that the goods are pharmaceutical in nature". However, there is nothing that "contradict[s] the dual classification". The only thing that seems to contradict a dual classification is the Examining Attorney's subjective conclusion. Indeed, after reciting facts that *support* acceptance of Applicant's specimens in Class 5, the Examining Attorney rejects the specimens despite the absence of any facts or evidence that "contradict[s] the dual classification".

Insofar as there is no evidence that "contradict[s] the dual classification" and the Examining Attorney concedes that "[s]everal goods featured in the specimen do feature phrases that may reasonably be understood … that the goods are pharmaceutical in nature," his refusal should be withdrawn.

Applicant's "Redness Relieving Facial Moisturizer with Sunscreen"

With regard to Applicant's "Redness Relieving Facial Moisturizer with Sunscreen," this product contains dipotassium glycyrrhizinate and the sunscreen "active ingredients" titanium dioxide and zinc oxide. *See* **EXHIBIT A**. Dipotassium glycyrrhizinate is a skin conditioning agent with anti-allergic and anti-inflammatory properties. It can inhibit the leucotriene and reduce histamine. It has been widely used in dermatological **medicines** in topical applications. *See* **EXHIBIT B**.

Moreover, to the extent that the reduction of inflamed or red skin *beautifies* and *promotes attractiveness*, it is a drug. *Supra* at 6. *See* **EXHIBIT C**.

Therefore, Applicant's "Redness Relieving Facial Moisturizer with Sunscreen" is a topical dermatological medicine.

Products containing sunscreen/SPF are considered "medicated" by the FDA

Sunscreens, typically a lotion, spray, gel or other topical product, absorb or reflect some of the sun's ultraviolet (UV) radiation on the skin exposed to sunlight. Sunscreen ingredients help to prevent sunburn and may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun.

Consequently, a product that includes the term "sunscreen" or "SPF" in its labeling or in any other way represents or suggests that it is intended to prevent, mitigate or treat the effects of solar radiation comes within the definition of a drug according to the U.S. Food and Drug Administration (FDA).

The regulatory requirements for "drugs" are more extensive than the requirements applicable to cosmetics. For example, the FD&C Act requires that drug manufacturers register every year with the FDA and update their lists of all manufactured drugs twice annually. Additionally, drugs must be manufactured in accordance with current Good Manufacturing Practice guidelines. According to the FDA, "[a]s an FDA-regulated product, sunscreens must pass certain tests before they are sold." *See* **EXHIBIT D**.

Per FDA regulations:

- Manufacturers of sunscreens have to be registered drug establishments with the FDA and comply with cGMP regulations for drug manufacturing;
- Labeling for products claiming any SPF has to comply with labeling requirements for OTC drugs, including Drug Facts format labeling;

- The final product containing SPF has to be listed with the FDA's NDC database (National Drug Code Directory) by the manufacturer or the distributor;
- The product has to have efficacy testing on the formula to show that it delivers the SPF that the label claims. Additional tests are warranted if the manufacturer wants to make broad spectrum protection claims;
- Safety testing to prove that the product is safe, usually a repeated insult patch test (RIPT) on human volunteer subjects needs to be done; and
- Stability testing will have to be conducted, including periodic assays of the active ingredients, to show that the active ingredients do not deteriorate over time.

Therefore, the FDA treats sunscreens as drugs and exercises regulatory oversight over sunscreens. In other words, sunscreens are considered over-the-counter drug products, according to the FDA.

Further, sunscreen products must contain so-called "active ingredients" that absorb or block UV rays. Insofar as sunscreens and products containing SPF ingredients may reduce the chance of premature skin aging, skin cancer, and other harmful effects due to the sun, they are medical in nature or drugs. These may be properly classified in Class 5. **EXHIBIT E**.

To the extent that all of Applicant's Class 5 specimens show products with sunscreen or SPF, they are properly in Class 5.

Other Relevant FDA Regulations

FDA regulations require certain ingredients, called "Active Ingredients," be identified on the label first and identify the established name of the drug ingredient(s) and the quantity, kind and proportion of any alcohol, when a cosmetic product is also an OTC drug product. 21 U.S.C. § 502(e)(1)(A).

Further, "[w]here a cosmetic product is also an over-the-counter drug product, the declaration shall declare the active drug ingredients as set forth in 201.66(c)(2) and (d) of this chapter, and the declaration shall declare the cosmetic ingredients as set forth in 201.66(c)(8) and (d) of this chapter." 21 C.F.R. § 701.3. Also *see* https://www.fda.gov/cosmetics/labeling/regulations/ucm126444.htm#clgl7.

Applicant's "Redness Relieving Facial Moisturizer with Sunscreen" contains the active ingredients titanium dioxide and zinc oxide. **EXHIBIT F** (the ingredient listing for Applicant's previously submitted specimen, "Redness Relieving Facial Moisturizer with Sunscreen").

Applicant's "Daily Facial Moisturizer" includes two "active ingredients": avobenzone and octocrylene. **EXHIBIT G** (the ingredient listing for Applicant's previously submitted specimen, "Daily Facial Moisturizer").

By virtue of listing these ingredients separately and first under the heading "Active Ingredients" and the quantity, these products are "cosmetic product[s] [that are] also [] over-the-counter drug product[s]".

According to the FDA's "Cosmetic Labeling Guide":

> **When is a cosmetic also a drug?**
>
> A cosmetic is *also* a drug when it is intended to ***cleanse***, ***beautify*** or ***promote attractiveness*** as well as treat or prevent disease or otherwise affect the structure or any function of the human body (emphasis added).

21 C.F.R. §§ 201(g) and (i) (FD&CA); 21 C.F.R. § 509 (FD&CA). *See* **EXHIBIT H**.

Here, Applicant's various products, at least: 1) cleanse, 2) beautify (through moisturization or reduction of redness), 3) promote attractiveness (through moisturization or reduction of redness), 4) treat disease (by treating the symptoms of redness or dermatitis) and/or 5) prevent sunburn, overexposure to the sun and may prevent skin cancer.

Per the FDA, a cosmetic is also a drug if it, among other things, is "intended for use in the ... cure, mitigation, treatment, or prevention of disease ... and ... intended to affect the structure or any function of the body ...." 21 C.F.R. §§ 201(g). A calming eczema lotion "mitigates" the symptoms of eczema. It also contains ingredients that promotes the organization and aggregation of keratinous protein chains of the *stratum corneum* and generates a pool of hydro-soluble molecules which composes the Natural Moisturizing Factor (NMF). Clearly, the product is "intended to affect the structure or any function of the body".

Moreover, it is important to note that the standard of the FDA is not that the product actually accomplishes the stated goals. Rather, the product must simply be *intended* to cleanse, beautify or promote attractiveness.

Here, Applicant's various products are intended to: control acne, control oil, treat the symptoms of eczema, provide protection from the sun, cleanse, beautify and/or promote attractiveness. Therefore, they may be classified as cosmetics or drugs, or both. TMEP § 1401.07.

The Board confirms the FDA's position:

> Under petitioner's theory, a product classified as a "cosmetic" could not also be classified as "therapeutic." But, TMEP § 1401.07 recognizes that a product may have a plurality of uses, such that it may be classified in two, or more, classes. *See also*, *In re International Salt Co.*, 166 USPQ 215, 216 (TTAB 1970) (holding same goods capable of classification in more than one class where specimen of use does not negate other uses).
>
> Further, our primary reviewing court has previously found that a single product may have dual uses as both a cosmetic and a pharmaceutical preparation, where there is testimony to support such use, and the specimens do not contradict the dual classification. *Jean Patou, Inc. v. Theon, Inc.*, 9 F.3d 971, 975 29 USPQ2d 1771, 1774 (Fed. Cir. 1993).

Thomas Sköld v. Galderma Laboratories, Inc., Cancellation No. 92052897 (November 8, 2012); *see* **EXHIBIT I** at 8.

Here, Applicant has provided ample evidence that Applicant's products "may have dual uses as both a cosmetic and a pharmaceutical preparation".

For these reasons, Applicant's specimens are sufficient to establish actual use in Class 5.

Classification is Not Mutually Exclusive

The Examining Attorney's analysis seems to treat the relevant products as binary. In other words, a product must be classified in Class 3 *or* Class 5, but not both. This analysis contradicts the clear precedent of the U.S. Patent & Trademark Office, the TTAB and the FDA's position.

The Board recently determined in addressing a section of the TMEP that states, "many goods are commonly understood to move in a particular channel of trade or have particular attributes.... For example, "skin lotion" usually refers to a cosmetic product - one that is not medicated. For that reason, it can be classified in Class 3 without further specification. However, a skin lotion that is medicated should be classified in Class 5, and the identification should indicate that the product is medicated in order to justify its classification in Class 5 rather than in the more commonly understood and assigned Class 3. TMEP § 1401.03(5) (rev. Oct. 2012):

> Under petitioner's theory, a product classified as a "cosmetic" could not also be classified as "therapeutic." But, TMEP § 1401.07 recognizes that a product may have a plurality of uses, such that it may be classified in two, or more, classes. *See also*, *In re International Salt Co.*, 166 USPQ 215, 216 (TTAB 1970) (holding same goods capable of classification in more than one class where specimen of use does not negate other uses).

> Further, our primary reviewing court has previously found that a single product may have dual uses as both a cosmetic and a pharmaceutical preparation, where there is testimony to support such use, and the specimens do not contradict the dual classification. *Jean Patou, Inc. v. Theon, Inc.*, 9 F.3d 971, 975 29 USPQ2d 1771, 1774 (Fed. Cir. 1993).

Sköld, Cancellation No. 92052897 at 8 (November 8, 2012); *see* **EXHIBIT I** at 8.

Accordingly, the Board has specifically rejected the binary review adopted by the Examining Attorney. Additionally, the FDA recognizes that the product categories "drug" and "cosmetic" are not mutually exclusive. 21 C.F.R. §§ 201(g) & (i) (FD&CA); 21 C.F.R. § 509 (FD&CA).

Therefore, it is entirely possible for Applicant's products to perform the dual function in Classes 3 and 5. In this case, the specimens of use for one class does not negate use in the other class. *In re International Salt Co.* at 216. Indeed, the same products and same specimens are acceptable for both Classes 3 and 5.

The concepts of dual classification, and drug versus cosmetic is important to the analysis and crucial to Applicant's business because nearly all of Applicant's products are subject to FDA regulatory oversight – as a cosmetic, a drug and/or a medical device.

To take an outrageous hypothetical: Let us assume a company markets 100 gallons of water. The company packages 50 gallons in water in bottles and labels them as "Refreshing Water". The company packages the second 50 gallons in bottles and labels them as "Super Duper Organic Hair Tonic – Regrows hair in 60 days with daily use". The product sold as "Refreshing Water" is not subject to FDA oversight at all. By contrast, even though the ingredients/products are exactly the same, the FDA will consider the "Super Duper Organic Hair Tonic" as a drug, and can exercise regulatory oversight over the product. In all likelihood, the FDA would order a recall or removal of "Super Duper Organic Hair Tonic" from the market.

Extending that hypothetical to a more real-world situation: Let us assume a company makes 100 gallons of facial lotion with sunscreen ingredients that provide an SPF of 15. The company packages 50 gallons in bottles and labels them as "Facial Moisturizer". The company packages the second 50 gallons in bottles and labels them as "Facial Moisturizer with SPF 15". The product sold as "Facial Moisturizer" is subject to FDA oversight *only as a cosmetic*. By contrast, even though the ingredients/products are exactly the same and both contain sunscreen ingredient, under FDA rules, the "Facial Moisturizer with SPF 15" is a drug, and the FDA can exercise regulatory oversight over the product *as a drug*, including labeling requirements and efficacy regulation. *See* **EXHIBIT J**.

The above hypotheticals illustrate how products may be both Class 3 cosmetics *and* Class 5 drugs. Moreover, it illustrates how an owner/applicant's *intent* may affect the analysis.

Because Applicant's products contain sunscreen ingredients and are marketed as sunscreens with an SPF rating, they are drugs, subject to regulation by the FDA. *See* **EXHIBIT J**.

Returning to the Examining Attorney's discussion of Applicant's marketing claims of "clinically proven," "dermatologist tested," and "eczema calming," insofar as these phrases demonstrate Applicant's intent for the product to be a drug and these phrases "may reasonably be understood and/or imply that the goods are pharmaceutical in nature" (to use the Examining Attorney's words), Applicant's intent should control.

Applicant's anti-redness treatments and Applicant's products containing SPF must be accepted in Class 5.

For this reason, the Examining Attorney should withdraw his refusal and accept Applicant's specimens in Class 5.

U.S. Patent & Trademark Office has accepted specimens for nearly identical products in connection with NSH's Registration No. 0754929

Applicant directs the Examining Attorney's attention to Applicant's existing Registration No. 0754929, which covers only goods in Class 5. The complete prosecution history (as available from the U.S. Patent & Trademark Office's TSDR system) is attached as **EXHIBIT K**. **Exhibit L** contains only the past specimens filed by Applicant, all of which have previously been accepted by the U.S. Patent & Trademark Office as valid specimens for Class 5 products.

The U.S. Patent & Trademark Office accepted the specimens shown in **EXHIBIT L**, without any objection, which comprise:

- **CETAPHIL** Lotion Fat-Free;
- **CETAPHIL** Daily Face Moisturizer SPF 15;
- **CETAPHIL** Daily Skin Cleanser;
- **CETAPHIL** Moisturizing Cream (for dry, sensitive skin); and
- An image of Applicant's product range, shown below:

In submitting its Class 5 specimens in connection with the instant application, Applicant relied on the U.S. Patent & Trademark Office prior treatment of its **CETAPHIL** mark and the specimens that the U.S. Patent & Trademark Office has consistently accepted in Class 5 – from 1962 until the present.

The Examining Attorney's refusal contravenes the U.S. Patent & Trademark Office's treatment of Applicant's mark and its Class 5 specimens for the past 55 years.

While Applicant is mindful that Examining Attorneys are not bound by the decisions of other Examining Attorneys, Applicant submits that the long history of the U.S. Patent & Trademark Office's treatment should be given some deference.

More importantly, Applicant submits that the U.S. Patent & Trademark Office's prior treatment of its **CETAPHIL** mark in Class 5 reflects a correct analysis of Applicant's products, one that the Examining Attorney here should follow.

Finally, in light of the expansive definition of "drug" by the FDA, the FDA and the Board's unambiguous position that the same product may have dual purposes in Classes 3 and 5, the fact that Applicant's products contain medicinal ingredients, and Applicant's marketing phrases, Applicant is entitled to leeway and deference as to in which Class 5 its products properly fall. Further, in light of such deference, the Examining Attorney should not supplant Applicant's assessment with his own, especially in the absence of any evidence to support that position.

CONCLUSION

Applicant has responded to all issues raised by the Examining Attorney. Specifically, Applicant's arguments and evidence show:

1. TMEP § 1401.07 and the Board recognize that a product may have a plurality of uses, such that it may be classified in two, or more, classes. *See also*, *In re International Salt Co.*, 166 USPQ 215, 216 (TTAB 1970) (holding same goods capable of classification in more than one class where specimen of use does not negate other uses), and Applicant's goods fall into such a category;

2. The FDA recognizes that a cosmetic is *also* a drug when it is intended to *cleanse*, *beautify* or *promote attractiveness* as well as treat or prevent disease or otherwise affect the structure or any function of the human body;
3. The U.S. Patent & Trademark Office has accepted Applicant's essentially identical specimens for essentially identical goods in connection with Applicant's existing Registration No. 0754929, which covers only goods in Class 5;
4. Applicant's "Redness Relieving Facial Moisturizer with Sunscreen" contains dipotassium glycyrrhizinate and is, therefore, considered a Class 5 product;
5. Applicant's "Redness Relieving Facial Moisturizer with Sunscreen" contains titanium dioxide and zinc oxide and is, therefore, considered a Class 5 product;
6. Applicant's "Daily Facial Moisturizer" contains avobenzone and octocrylene and is, therefore, considered a Class 5 product;
7. Any of Applicant's products claiming an SPF are considered Class 5 drugs;
8. It is usually the intent (as shown through marketing) of the owner that determines whether a product is a cosmetic or a drug – or both; and
9. The FDA's expansive definition of "drug" to include products intended to cleanse, beautify or promote attractiveness coupled with Applicant's claims and Applicant's medicated and "active" ingredients[1] is sufficient to establish that Applicant's products are proper in Class 5.

Accordingly, Applicant respectfully requests that the Examining Attorney withdraw his refusal, accept Applicant's Statement of Use and specimens for Class 5, and forward the application for issuance of a certificate of registration.

If a telephone conference will advance the prosecution of the subject application, the Examining Attorney is invited to call the undersigned at 917.779.9967.

Respectfully submitted,

/g mathew lombard/
G. Mathew Lombard
Attorney for Applicant, NYS Bar Member
September 15, 2017

[1] Including at least: dipotassium glycyrrhizinate, avobenzone, octocrylene, titanium dioxide and zinx oxide.