

MCKEE, VOORHEES & SEASE, PLC

CASSIE J. EDGAR
PATENT & REGULATORY ATTORNEY

From: Cassie J. Edgar
Chair, Regulatory Law Practice Group
McKee, Voorhees & Sease, PLC

To: Donald D. Ashley
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
via e-mail to COVID-19-Task-Force-CDER@fda.hhs.gov

Date: 4/24/2020

Re: Warning Letter Dated 4/23/2020

Dear Mr. Ashley:

In response to the FDA's warning letter issued April 23, 2020, Prefense acknowledges FDA's concerns regarding COVID-19 efficacy claims, conformance with relevant OTC monograph guidelines for hand sanitizer, and time-specific extended efficacy claims. Prefense wishes to address and resolve these issues as quickly as possible and therefore is responding within the requested 48-hour response window on corrective actions taken in the past 48 hours and future actions planned.

COVID-19 Efficacy Claims

Prefense is fully aligned with FDA's comments that the hand sanitizer product line should not be marketed as a product intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people. Prefense has not intended to make any claims of efficacy against COVID-19, and the specific website and social media references which were pointed out by the FDA to have implied an intended use for this purpose under 21 CFR 201.128 have been removed.

In addition, Prefense also does not permit any distributors, including those that were listed on the website, to make any claims of efficacy against COVID-19. In fact, to prevent such statements a memo was sent to all distributors on March 12, 2020 titled "COVID-19 / Coronavirus Prefense Product Talking Points: What We Can and Can't Say" (attached as Appendix A). In this memo, direction was given that "It is vitally important that everyone associated with Prefense LLC communicates accurate, up-to-date, consistent, and legally allowable information about our products. This is always true, but it is especially important in this critical time as people across the world are dealing with COVID-19 (coronavirus)." Further, distributors were told "Your cooperation in maintaining consistent and accurate communications is appreciated and expected. Failure to do so could result in legal or regulatory ramifications for all of us and may also result in revocation of your rights to distribute Prefense products in the future. Compliance is not optional as we move forward — it is necessary and critical in order for us to maintain our mission — and for our customers who rely on us and deserve and expect no less."

This guidance memo is being updated to ensure compliance in light of this FDA warning letter, and the updated guidelines will be communicated to all distributors before May 1st.

Based on the FDA letter dated April 23rd pointing out specific statements made on distributor websites, follow-up was conducted by the VP of Sales and the CEO who thoroughly reviewed each site. The links and names of these distributors have been removed from prefense.com until such time as all distributors clearly comply.

Compliance with OTC topical antiseptic product labeling requirements

Prefense also acknowledges FDA's statements regarding compliance with the tentative final monograph (TFM) entitled "Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products," Proposed Rule, 59FR 31402 (June 17, 1994) (1994 TFM), as further amended by the "Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 81 FR 42912 (June 30, 2016) and "Safety and Effectiveness of Health Care Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph; Reopening of Administrative Record," Proposed Rule, 80 FR 25166 (May 1, 2015), as well as "Safety and Effectiveness of Consumer Antiseptic Rubs; Topical Antimicrobial Drug Products for Over-the-Counter Human Use", Final Rule, 84 FR 14847 (April 12, 2019). The currently listed active ingredient was incorporating a trade name by referencing "Amosilq"; however for clarity and to address the FDA's concerns, Prefense is initiating discussion with label designers to amend product labels and clarify that the active ingredient is benzalkonium chloride, without any reference to this trade name.

In addition, any reference to specific classes of pathogens as listed on page 4 of FDA's letter will not be included on the label, listed on the Prefense website/social media, or permitted to be used by distributors on their websites/social media.

Time-Specific Extended Efficacy Claims

The FDA, on page 4, raises concerns that statements of long lasting efficacy do not conform to the 1994 TFM or any of the amendments; and states that the FDA is not aware of any studies in the published literature to support a determination that Prefense Hand Sanitizers are GRASE for a time-specific efficacy claim.

Prefense is currently compiling their own and third party published data sets regarding benzalkonium chloride and extended efficacy; and will submit such data including studies conducted under ASTM guidelines to FDA upon request.

In addition, at least 12 other benzalkonium chloride products currently on the market are making similar claims (listed in Appendix B). These include, for example, a CVS product which states that it "kills 99.99% of germs for up to 24 hours" (<https://www.cvs.com/shop/cvs-health-advanced-antiseptic-hand-sanitizer-foam-1-7-oz-prodid-1030538>); a product which is actually titled "All Day" and claims that it "kills 99.99% of germs but then stays active on the surface of your skin to protect you for up to 24 hours through 10 handwashes!" (<https://www.alldayprotect.com/shop/hand-pocket-pen>) and a product with the name "GermFree24" which states that it provides "up to 24 hours of protection against harmful

germs” (<https://escbrands.com/product/germfree24-hand-sanitizer-foam-1-7-oz-4-pack/>). Prefense respectfully requests acknowledgement that such extended efficacy claims are pervasive and well known related to benzalkonium chloride, and as such are supportive a determination that products with this active ingredient are GRASE for such a time-specific efficacy claim.

Summary

Prefense never intended for hand sanitizer products to be marketed as a product intended to mitigate, prevent, treat, diagnose, or cure COVID-19 in people and will continue to monitor any distributor materials to ensure compliance with appropriate guidelines. Revisions to the label clarifying the active ingredient are being initiated in order to ensure compliance with labeling guidelines under the relevant OTC monograph guidelines. Prefense is committed to regulatory compliance, consistent with the company’s mission to be a trusted source of safe alcohol-free products for consumers and will continue to work with the FDA to ensure appropriate guidelines are followed, and look forward to fully and expeditiously resolving this issue.

Respectfully,



Cassie J. Edgar
On behalf of Prefense LLC

Cassie J. Edgar
Member
Patent Attorney and Chair Regulatory Law Practice Group

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APPENDIX A



LEGAL MEMORANDUM IMPORTANCE LEVEL -HIGH

From: John E. Patchett, JD
Secretary and Member
Prefense LLC

A handwritten signature in blue ink, appearing to read "John E. Patchett".

To: Prefense Distributors, Wholesalers, Retailers, Sales

Date: March 2020

Re: COVID-19 / Coronavirus
Prefense Product Talking Points
What We Can and Can't Say

To Whom it May Concern:

It is vitally important that everyone associated with Prefense LLC communicates accurate, up-to-date, consistent, and legally allowable information about our products. This is always true, but it is especially important in this critical time as people across the world are dealing with COVID-19 (coronavirus).

As a broad-spectrum antimicrobial sanitizer, Prefense has been shown to be very effective against a wide variety of pathogens (bacteria, viruses, and other microorganisms). However no testing has yet been concluded that specifically demonstrates its effectiveness against COVID-19. Prior testing of our active ingredient does prove its effectiveness against similar viruses — so there is good reason to infer it is likely effective vs. the coronavirus. But we cannot currently state that affirmatively or determinatively. So do not do so until further notice. You can refer to those studies and materials we have previously provided.

I have attached an updated version of Prefense "Talking Points" — which is a short summary of what is allowed. This can be used to maintain consistency in your various communications and interactions with customers and clients. No edits or additional claims of any kind are allowed without advance written approval from Prefense LLC. Any marketing materials and communications are subject to advance approval of Prefense LLC. You may also use information from our website that goes into more detail as necessary and helpful.

We are trying to fast-track additional production in order to meet all of our needs - and to help protect the health of the public. Inviting heightened scrutiny from governments and regulators due to inaccurate or possibly exaggerated claims about what Prefense does (or doesn't do) would be burdensome, counter-productive, and unnecessary and it could potentially interfere with future operations.

Your cooperation in maintaining consistent and accurate communications is appreciated and expected. Failure to do so could result in legal or regulatory ramifications for all of us and may also result in revocation of your rights to distribute Prefense products in the future. Compliance is not optional as we move forward — it is necessary and critical in order for us to maintain our mission — and for our customers who rely on us and deserve and expect no less.

We appreciate everyone's efforts and look forward to growing together as we move forward. Please feel free to contact us if you have any questions, comments, or suggestions.

Prefense - General Talking Points - 02/25/20

REVOLUTIONARY , UNIQUE METHOD OF PRO-ACTIVELY PROTECTING YOUR HEALTH

SILICA COMPLEX – WATER BASED --- ALCOHOL FREE --- PATENTED FORMULA ---
EASY, FOAM APPLICATION – DRY IN SECONDS

ACTIVE INGREDIENT – AMOSILQ – BROAD-SPECTRUM ANTIMICROBIAL

PERSISTENCE – INSTANTLY FORMS INVISIBLE, ODORLESS, MOISTURIZING
BARRIER THAT LASTS FOR 24 HOURS OR THROUGH 10 HAND-WASHINGS – WON'T
STAIN SKIN OR CLOTHING --- ADDED BENEFIT OF MOISTURIZING HANDS

SAFE FOR ADULTS AND CHILDREN

DEACTIVATES / KILLS PATHOGENS VIA LYSIS – DISRUPTING CELLULAR WALLS ---
NO INCREASED PATHOGEN RESISTANCE BECAUSE OF THE WAY IT WORKS ---
IMMEDIATE EFFECTIVENESS THAT CONTINUES ALL DAY --- SCIENTIFICALLY
PROVEN --- (OPTIONAL: CITE EXAMPLES)

ENVIRONMENTALLY FRIENDLY --- CONTAINS ONLY WATER, AMOSILQ, &
BOTANICALS --- NON-FLAMMABLE – NON-POISONOUS

FDA-LISTED --- BOTTLED IN FDA REGISTERED FACILITIES

PRODUCTS INTO MARKETPLACE 2010 – NOW INTERNATIONAL (DISTRIBUTION &
SALES)

AVAILABLE ON-LINE AND IN SOME STORES (CHECK STORE LOCATOR AT
PREFENSE.COM)

NEW GENERATION IN HAND SANITIZERS (SKIN) --- ADDITIONAL PRODUCTS
COMING SOON (SURFACE PROTECTION)

ENVIRONMENTALLY FRIENDLY

MISSION TO PROTECT PEOPLES HEALTH --- PROVIDE YOU & YOUR FAMILY A PRO-
ACTIVE & LONG-LASTING DEFENSE FROM THE TRANSFER OF GERMS THAT CAN
MAKE YOU SICK – WHILE MOISTURIZING YOUR HANDS --- AND DISINFECTING
SURFACES YOU COME INTO CONTACT WITH

SOCIALLY CONSCIOUS COMPANY --- DONATIONS TO MEXICO, HAITI, & OTHERS

IOWA BASED COMPANY — FOUNDED IN 2008

WWW.PREFENSE.COM 877.523.9997 INFO@PREFENSE.COM

What We Are

Long lasting
Protective for skin & hands
Cost effective per use basis
Moisturizing
Safe for the whole family
Silica based
No-mess foam
Prefense works when dry
*Apply, rub in until dry,
protected all day*

What We Aren't

NO harsh odor
NO messy gels
NO flammable materials
NO parabens
NO sodium lauryl/laureth
sulfate
NO hydrogen peroxide
NO triclosan
NO butylene glycol
NO harsh chemicals or
solvents



protects
*kills up to 99.99%
of germs on
contact*



moisturizes
*silica based,
alcohol free*



long lasting
*through **10**
washings*

APPENDIX B

Other Hand Sanitizers Using Long-Lasting/24 Hour Claims

April 24, 2020

CVS

<https://www.cvs.com/shop/cvs-health-advanced-antiseptic-hand-sanitizer-foam-1-7-oz-prodid-1030538>

CVS Health Advanced Antiseptic Hand Sanitizer Foam, 1.7 OZ
1.7 OZ, .11 lbs. Item # 437434

Instant foaming hand sanitizer. Kills 99.99% of germs for up to 24 hours*

*Effective at eliminating more than 99.99% of many common harmful germs and bacteria in as little as 15 seconds; lasting effects for up to 24 hours.

Ingredients

Ethyl Alcohol, Fragrances, Silica Complex 3-(Trimethoxysilyl) Propyl Dimethyl Octadecyl Ammonium Chloride, Water

Zoono, Zoono USA

<https://zoonousa.com/hand-sanitizer/>

Zoono Hand Sanitizer vs. Traditional Hand Sanitizer

Not All Hand Sanitizer is Created Equal

It is important to note that [not all hand sanitizers are created equal](#). For example, did you know that [traditional hand sanitizers](#) only work for two minutes at a time? As soon as it dries on your hands, germs start to form again immediately! **[HOWEVER, ZOONO HAND SANITIZER WORKS DIFFERENTLY...](#)** ...by safely bonding to your skin and protecting against germs for a full 24 hours. Nothing on the market can compare:

Durisan

<https://durisan.com/>

Our alcohol-free hand sanitizer & wipes moisturize and condition the skin while **killing 99.9% of illness causing germs for up to 24 hours.**

All Day

<https://www.alldayprotect.com/shop/hand-pocket-pen>

Introducing All Day Hand Sanitizer, a new, patented technology that provides long-lasting protection! Our alcohol-free solution kills 99.99% of germs but then stays active on the surface of your skin to protect you for up to 24 hours through 10 handwashes!

- All Day kills 99.99% of germs, bacteria, viruses, fungi, and molds that may cause illness and infections in as little as 15 seconds

DAB

<https://dabprotects.com/collections/pick-your-perfect-protection>

DAB kills 99.98% of tested bacteria on contact and creates a glove-like barrier that keeps killing bacteria for up to 4 hours per application. This is important because it is in between soap washing and alcohol sanitizer applications that we contract hand transmitted bacteria. And DAB fills that gap.

Our formula has been clinically proven and evaluated in a national peer reviewed medical journal. DAB is tough on germs but easy on your hands leaving them feeling soft.

Purifi/Purify

<https://cleanhandsandmore.com/>

NEXT GENERATION HAND SANITIZER: Purifi's patented, alcohol-free & EPA REGISTERED formulation kills VIRUSES, BACTERIA & MORE AND **LASTS UP To 24 HOURS** – All without drying out your skin & creating cracks that viruses and bacteria can lodge in to harm you later. *Purifi™ is proudly formulated and manufactured in the USA.*

Everest Microbial Defense

<https://shop.everestantimicrobial.com/collections/all/products/24-hour-defense-foaming-hand-purifier>



ESC Brands/GermFree 24 and My-Shield brands

<https://escbrands.com/germfree-24-liquid-hygiene-products/>

<https://escbrands.com/product/my-shield-sanitizing-hand-wipes-80-count-3-pack/>



Up to 24 hours of protection against harmful germs

My-shield® Sanitizing Hand Wipes are formulated with Zetrisil®, a unique nano antimicrobial technology that not only kills on contact but also has a persistent activity that helps prevent infections. The persistence of My-shield® Sanitizing Hand Wipes have been shown to remain effective for up to 24 hours.

Kills 99.99% of harmful germs

My-shield® Sanitizing Hand Wipes kill 99.99% of the harmful germs it comes in contact with by disrupting the outer cell membranes resulting in a physical kill. This physical kill ensures microorganisms don't adapt or become resistant over time.

Orangeld (on Amazon, parent company not known)

<https://escbrands.com/product/my-shield-sanitizing-hand-wipes-80-count-3-pack/>

ORANGELD Hand Sanitizer- Water-Free, Defense 24 Hour, Alcohol Free, Kill 99.99 Pathogenic Microorganisms-for Home Car Phones Glasses

Nifera (on Amazon, parent company unknown)

Nifera 100ML Water-Free Hand Sanitizer Spray-Non-irritating, Kill 99.99 of Germs, Alcohol and Fragrance Free, Defense 24 Hour-for Automotive Interior Home Phones Travel Suitable

Common Sense

<https://smartcommonsense.com/>

**Our Hand Sanitizer Protects your skin and your loved ones for hours and
hours**

when other brands only last seconds