

MCKEE, VOORHEES & SEASE, PLC

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

CASSIE J. EDGAR
PATENT & REGULATORY ATTORNEY

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: 5/12/2020

Re: Supplemental Response to Warning Letter Dated 4/23/2020

Dear Mr. Ashley:

In response to the FDA's warning letter issued April 23, 2020, and to further add to the response sent on April 24th, Prefense wishes to update the FDA on the remaining corrective actions taken. With these additional steps, Prefense has completed all corrective actions and is in full compliance with respect to the issues raised in your warning letter.

COVID-19 Efficacy Claims

As previously stated, in addition to the actions already taken and communicated on April 24th an updated compliance memo was sent to all distributors before May 1st (attached as Appendix A).

Compliance with OTC topical antiseptic product labeling requirements

As previously stated, the NDC and label for the product has been updated to clarify the active ingredient and remove reference to the trademark name. The new label (an example for the 1L package for the scented version of the product) is attached as Appendix B.

Time-Specific Extended Efficacy Claims

In order to immediately address the FDA's concerns, in the interest of expediting FDA's acknowledgement on its website noting that Prefense is now in full compliance with all corrective actions taken, and without negating the statements made in our response letter on April 24th, Prefense has also

taken down the time-specific extended efficacy claims on the website and social media, and has revised the product label to remove such statements. (See attached Appendix B).

Summary

With these further actions, in addition to the actions previously communicated on April 24th, Prefense has now addressed all concerns raised by FDA in the letter dated April 23rd 2020. As previously stated, 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

McKee, Voorhees & Sease, PLC
801 Grand Avenue, Suite 3200
Des Moines, Iowa 50309
515.564.5937
cassie.edgar@ipmvs.com



**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: April 30, 2020

Re: Updated - 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 antimicrobial hand sanitizer, Prefense can be effective against pathogens/germs. However no testing has yet been concluded that specifically demonstrates its effectiveness against COVID-19. We cannot currently state that affirmatively or determinatively, in accordance with FDA guidelines. So do not do so until further notice - directly or even indirectly. If you are in doubt about this or any proposed language in your marketing, social media, or on your websites, contact us immediately for clarification. We also cannot cite or list specific pathogens - viruses or bacteria - that Prefense might be effective against - nor can you - under the current regulatory restrictions on hand sanitizers in general.

As you may know, we received a warning letter from the FDA referencing some COVID-19 claims made by some distributors — and additionally referencing even indirect claims and social media posts — so we need to exercise extreme caution in this regard.

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 continuing our efforts to help protect the health of the public - as we have done since our founding in 2008. 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. We will continue to monitor events and regulatory rulings - and to update you as necessary and appropriate.

Please feel free to contact us if you have any questions, comments, or suggestions.

Prefense - General Talking Points - 04/30/20

REVOLUTIONARY METHOD OF PRO-ACTIVELY PROTECTING YOUR HEALTH —
PREFENSE HAS IMPROVED UPON EXISTING PRODUCTS THAT HAVE BEEN IN THE
MARKETPLACE FOR YEARS AND ALREADY BEEN FOUND SAFE AND EFFECTIVE

WATER BASED — ALCOHOL FREE — EASY, FOAM APPLICATION — DRIES IN
SECONDS

ACTIVE INGREDIENT — BAC (BENZALKRONIUM CHLORIDE) — BROAD-SPECTRUM
ANTIMICROBIAL

INSTANTLY FORMS INVISIBLE, ODORLESS BARRIER — WON'T STAIN SKIN OR
CLOTHING --- ADDED BENEFIT OF HELPING SKIN MAINTAIN ITS NATURAL
MOISTURE — WON'T DRY OUT OR CRACK YOUR SKIN (LIKE ALCOHOL-BASED
PRODUCTS CAN DO)

SAFE FOR ADULTS AND CHILDREN

DEACTIVATES / KILLS PATHOGENS VIA LYSIS — DISRUPTING CELLULAR WALLS ---
NO INCREASED PATHOGEN RESISTANCE IS LIKELY BECAUSE OF THE WAY IT
WORKS --- IMMEDIATE EFFECTIVENESS ONCE IT DRIES ON YOUR HANDS

ENVIRONMENTALLY FRIENDLY — NON-FLAMMABLE — NON-POISONOUS

FDA-LISTED --- PRODUCED AND BOTTLED IN FDA REGISTERED FACILITIES

PRODUCTS INTO MARKETPLACE 2009 — NOW INTERNATIONAL (DISTRIBUTION &
SALES)

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

A REVOLUTIONARY IMPROVEMENT IN HAND SANITIZERS (SKIN) --- ADDITIONAL
PRODUCTS COMING SOON (SURFACE PROTECTION: PREFENSE MULTI-
SURFACEPRO)

OUR MISSION IS TO HELP PROTECT PEOPLES HEALTH --- PROVIDE YOU & YOUR
FAMILY WITH A PRO-ACTIVE DEFENSE FROM THE TRANSFER OF GERMS THAT CAN
MAKE YOU SICK

A SOCIALLY CONSCIOUS COMPANY

IOWA BASED COMPANY — FOUNDED IN 2008

WWW.PREFENSE.COM 877.523.9997 INFO@PREFENSE.COM

APPENDIX B: NEW PRODUCT LABEL (shown for scented version, 1L package)

pre-fense™ Hand Sanitizer

Original Lemongrass Scent

protects
kills up to 99.99%
of germs on contact

moisturizes
silica based, alcohol-free

alcohol-free
won't dry out skin

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.12%	Sanitizer

Uses: Hand sanitizer to help reduce germs that potentially cause disease.

Warning: For external use only. Avoid contact with eyes. In case of eye contact, flush with water. Discontinue use if irritation or redness occurs. **Keep out of reach of children.**

Directions: Apply to dry hands, rub together, and let dry.

Inactive Ingredients:
3-Chloropropyltrimethoxysilane, Acetic Acid, Anhydrous Citric Acid, Cocamidopropyl betaine, Octadecyltrimethyl 3-trimethoxysilylpropylammonium chloride, East Indian Lemongrass Oil, Isotonic Sodium Chloride Solution, Orange Oil, Water

8 12551 02004 4

Do Not Freeze

prefense.com
MADE IN THE
USA
33.82 fl. oz. / 1 Liter