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COVID-19 Consumer Health Market: Germ-Blocking Nasal Spray, 99.99% Effective Sanitizer, 'Mask' To **Moisturize Hands**

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Executive Summary

Sensory Cloud's small study showed FEND nasal solution cut by 99% exhalation of bioaerosol to block COVID-19. Global BioProtect's hand sanitizer with proprietary antibacterial technology eliminates 45 bacteria, fungi and virus. Trilogy Labs' solution replenishes moisture in hands irritated by sanitizers.



The novel coronavirus pandemic continues promoting consumer health products to introduce OTC remedies that, at the risk of attracting regulatory scrutiny, are advertised as helping prevent COVID-19 infections.

Some of the latest launches include a nasal spray that removes potentially infectious particles too small for face masks to filter and an air-powered hand sanitizer promoted to stop 45 types of bacteria, fungi and viruses.

Another product launched due to the impact of the pandemic, though, likely is on good regulatory ground. With use of hand sanitizers increasing, a lotion firm offers a formulation intended to "mask" skin from dryness and irritation.

FEND Off Bioaerosol Exhalation

Boston startup Sensory Cloud LLC in September will promote its launch of FEND (Fast Emergency Nasal Defense) with results from a 10 subject-study showing the "salty mist" safely cleans air passages of infectious droplets.

The FEND solution reduced exhalation of bioaerosol by 99% for up to six hours for the entire group, the results showed.

"Around 80% of these particles are less than a single micron in size, and not effectively filtered by conventional face masks," says Sensory Cloud founder David Edwards, a biomedical engineering professor at Harvard University.

"Cleaning our airways of these particles is a new hygienic measure that can be of critical value to health care workers, all of us returning to work and school and to the many in the world for whom social distancing is not an option," Edwards said in an 8 July release.



SENSORY CLOUD FORMULATED ITS FEND NASAL SPRAY WITH PULMATRIX' PROPRIETARY DRUG-FREE SOLUTION.

He authored a paper on the product's safety and efficacy published 7 July in QRB Discovery, an interdisciplinary medical journal of biological function, structure and mechanism.

The human study included in the research, "A New Natural Defense Against Airborne Pathogens," included five volunteers older and five younger than 65 to determine the efficacy of a nasal delivery of calcium and sodium salts, each present in sea water, to diminish exhaled particles of 300 nanometers to 5 microns in diameter from human airways.



GLOBAL BIOPROTECT LAUNCHES ITS NAMESAKE BRAND HAND SANITIZER AND ALSO OFFERS THE

The study aimed to determine whether nasal delivery of the calcium and sodium sales in the FEND formula by the brand's Sensory Cloud Nimbus hand-held nasal mister could substantially suppress exhalation of bioaerosols without targeting the entire lungs.

It found a strong correlation between high number of exhaled particles and age, with the older group 65 exhaling on average 6,641 particles and the younger subjects 440 particles per liter of air.

The finding suggests that seniors, "while among the most vulnerable to COVID-19 infection, may also be those most likely to spread the disease and underscoring the extreme risk seniors face today in nursing homes," the study states.

Although conventional masks, hand-washing and social distancing are essential during the COVID-19 pandemic, those practices "do not cleanse our respiratory system of the majority of potentially infectious particles we exhale during natural breathing."

FORMULATION FOR OWN-BRAND AND PRIVATE LABEL PRODUCTS.

nasal delivery and worldwide commercialization.

FEND will be sold online beginning in September. A start kit, priced at \$49, will include a Nimbus and two FEND bottles containing 0.5 ounces of the formula for 250 nasal cleanings each; FEND refills will be priced at \$6.

The firm says it plans to participate in a clinical trial this year in India and the US and pilots at Beth Israel Hospital in Boston.

Sensory Cloud is one of a number of companies focusing on nasal care or preventing germs from reaching the nose, which is the primary entry point for respiratory infections, to fight against spread of COVID-19. Michigan firm BlueWillow Biologics Inc. recently announced its NanoBio Protect OTC nasal antiseptic was found in in vitro tests conducted with Public Health England to kill the virus. (Also see "OTC Nasal Antiseptic NanoBio Protect 'Lethal' In COVID-19 In Vitro Tests, Amazon Launch Soon" - HBW Insight, 19 May, 2020.)

FEND is based on proprietary drug-free solutions Pulmatrix Inc. licensed to Sensory Cloud for OTC

US COVID-19 Fraud: Tincture, Sanitizer Warnings, Criminal Contempt Charges And Civil Settlement

By Malcolm Spicer 14 Jul 2020

FDA's latest COVID-19 warnings note fewer violative claims than identified in previous warnings to consumer health firms. One had a single noncompliant claim on its website, while another's violations included identifying potential symptoms of COVID-19. Four men associated with a Florida church face counts of conspiracy to defraud the US and of contempt of court stemming from COVID-1 claims for...

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BioProtect Provides More Uses Per Ounce

Global BioProtect LLC, which manufactures cleaning supplies, launches its BioProtect hand sanitizer along with offering the formulation to be used as own-brand and private label products. The Columbus, Ohio, firm says BioProtect eliminates 45 bacteria, fungi and viruses, including germs that cause pneumonia, staph infections, colds and the flu – 99.99% of harmful germs.

The product differs from most available sanitizers with bag-on-valve bottle technology allowing for precise delivery of more than 1,000 sprays from an 8-ounce container compared to 250 pumps from the same amount of gel.

"The pandemic has had a huge impact on businesses, ranging from restaurants to manufacturing facilities," said Global BioProtect president Gary Willett. "We're happy to be able to adapt quickly and provide a much-needed, safe and effective product to protect our customers' employees and consumers."

BioProtect is available in two versions, one with isopropyl alcohol 75% and the other with benzalkonium chloride, an ingredient designated Category III under the US Food and Drug Administration's most recent tentative final monograph rulemaking for OTC antiseptic drug products, meaning the agency deemed data insufficient to support generally recognized as safe and effective decision making.

However, under legislation enacted in March to modernize the OTC drug review framework, products containing Category III ingredients identified in TFMs,



TRILOGY LABS EXTENDS ITS AZUL BLUE DIAMOND LINE WITH A "HAND MASK" TO REPLENISH such as benzalkonium chloride, do not require FDA approval to remain on the market provided they meet other conditions of use outlined in the TFM. RS149929

MOISTURE IN ITCHY, DRY AND IRRITATED HANDS.

Refills of the sanitizer will be available for purchase in 32-, 64- and 128-ounce bottles.

COVID-19 has driven hand sanitizer innovation in recent months, leading to the debut of numerous brands, including the launch of non-contact sanitizers and a product that acts as a shield for up to eight hours. (Also see "DHA/AA Addition To Infant Formula Not Recommended By LSRO" - HBW Insight, 1 Feb, 1999.)

Hands Need 'Mask' Too

Trilogy Laboratories LLC saw high demand for hand sanitizers as an opportunity to extend its skin care line since using the mostly alcohol-containing products can leave skin dry.

The Fort Myers, FL, firm on 14 July announced its Azul Blue Diamond "hand mask" formulation, which replenishes moisture in itchy, dry and irritated hands.

The topical contains active ingredient Pentavitin, a plant-derived substance manufactured by DSM Nutritional Products LLC, which claims the substance delivers "deep hydration" to skin for up to 72 hours.

It also contains mallow extract and edelweiss, which combat the effects of harsh chemicals used to kill germs in both sanitizer and hand soap. The formulation can be used as an overnight hand mask treatment or as a deep hydrating hand dream.

Prices are not yet available for the product available initially on the brand's website.