GAITHERSBURG, MD. - Updated Dec. 15th 2020 - Shreis Scalene Therapeutics LLC has fast-tracked the manufacturing and distribution of the Scalene Hypercharge Corona Canon (SHYCOCAN™) under U.S. FDA ‘Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.”

Update to the original U.S.FDA Notification for Marketing and Distribution under the Enforcement Policy for Sterilizers, Disinfectant Devices and Air-Purifiers during the COVID-19 PHE.

On November 12th, 2020 the U.S.FDA once again provided guidance to Shreis Scalene Therapeutics on the marketability of the SHYCOCAN™ Device in the US market, under the Enforcement Policy for Sterilizers, Disinfectant Devices and Air-Purifiers during the COVID-19 Public Health Emergency. Since then, SSTx has updated the website in compliance with the U.S.FDA-based regulatory requirements. Marketing materials including the Product Brief, Instructions for use, Device labeling and Decals have been appropriately and suitably designed for marketing the product with the U.S.

Important Note: Since SSTx is solely and directly responsible for language and narratives used in any and all promotional and marketing material (in print, in press, email notifications, media, videos etc.) within the US, kindly ensure that all such material being created by distributors/retailers or other vested parties are CLEARED and APPROVED by our Technical & Marketing Director (email:marketing@shreis.com). Any deviation from this mandatory clearance by SSTx will be considered as breach and could result in contractual consequences. No third parties are authorized to independently market the product except through approved and signed agreements with SSTx.

Below is the original notification to Shreis Scalene Therapeutics LLC from the U.S. FDA on July 15th 2020:

"Please know that FDA is committed to doing everything possible to help combat the COVID-19 outbreak and appreciated your efforts to make your product(s) available. To help such efforts, FDA issued an immediately in effect guidance on March 29, 2020, “Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency”. The Scalene Hypercharge Corona Canon may fall under one of the policies set forth in this guidance and be distributed without compliance with certain regulatory requirements as outlined in the guidance." – U.S. FDA

Statement from Emergo (by UL), Shreis’ regulatory consultant in the U.S. to original US-FDA notification:

“The guidance that the FDA references allows certain products to be placed on the US market during the public health emergency under enforcement discretion related to requirements that would normally be required. Specifically, the FDA does not intend to object to the distribution and use of products within the scope of the guidance document, such as air purifiers, intended to be effective at killing the SARS-CoV-2 virus provided certain conditions are met. Once these conditions are met, it is Emergo’s understanding based on the FDA statements that this device may be put on the market during the public health emergency.” – Emergo

Enforcement Discretion Guidance can be obtained from the U.S. FDA website, referenced here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-sterilizers-disinfectant-devices-and-air-purifiers-during-coronavirus-disease
The **SHYCOCANTM** device is market-enabled as per the U.S. FDA's Enforcement Discretion Guidance during the COVID-19 Public Health Emergency

**FAQs / Explanation of U.S.FDA guidance for marketing of the SHYCOCANTM**

1. When does a product appear on the FDA website by due process? What does U.S.FDA regulatory terminology ‘cleared’ and ‘approved’ imply?
   a. A Product ONLY appears on the FDA website once it has a 510K or a Pre-market approval (PMA).
   b. The term “Cleared” is applied for devices that obtain a 510K
   c. The term “Approved” is for devices that receive Pre-market approval (PMA)

2. Is the SHYCOCAN ‘cleared’ or ‘approved’ by the FDA? Why is the SHYCOCAN device ‘not found’ in the database of U.S.FDA’s ‘cleared’ or ‘approved’ devices?
   a. Since the SHYCOCAN is currently being marketed under the “Enforcement Discretion Guidance” during the COVID-19 pandemic/public health emergency, the product is NOT EXPECTED TO BE LISTED, on the FDA-website.
   b. Coming under Enforcement Discretion under the U.S.FDA allows for the marketing of the SHYCOCAN device during the pandemic. SSTx is currently in the process of compiling a 510k submission, together with Emergo (by UL) to submit to the U.S.FDA.
   c. The device is intended for attenuation/disabling of certain viruses, including coronaviruses, the virus associated with COVID-19.

3. Does the device have CDC Certification? - Clarification sought by SSTx from Emergo (by UL)
   a. No, certification from other agencies like the CDC is not required for marketing in the USA.
   b. The CDC provides a link to NIOSH certifications but does not itself certify them.
      See: [https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html](https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html)
      NIOSH certification is not relevant for the SHYCOCANTM.

**DISCLAIMER**: Any statement pertaining to the SHYCOCANTM device and U.S.FDA regulation requires knowledge of the Enforcement Discretion Guidance so as to not misrepresent or misinterpret the marketability of the SHYCOCANTM. Careful attention must be given to specific wording and be followed with regards to any press publication referencing the market availability of the SHYCOCANTM under U.S. FDA guidance.

**The SHYCOCAN device is currently market-enabled as per the U.S. FDA’s Enforcement Discretion Guidance during the COVID-19 Public Health Emergency**

**About Shreis Scalene Group of LLCs** - Shreis Scalene Therapeutics LLC prioritized the SHYCOCANTM device project intended to deactivate certain viruses, including coronaviruses, the virus associated with COVID-19. The Shreis Scalene Group of Therapeutic and Diagnostic medical device companies is head-quartered in Montgomery County, MD. Together with the Inventor and Technology partner, Dr. Rajah Vijay Kumar, the Shreis Scalene Group is bringing novel, non-invasive, engineering solutions to human health problems. These include the CYTOTRON® with U.S.FDA Breakthrough Designation granted for solid tumors of the Breast, Liver and Pancreas (among other solid tumors clinically validated in off-shore clinical studies); tissue regeneration (in musculoskeletal disorders, degenerative respiratory disorders, wound healing etc.); the CELLFORN® for safe, non-invasive cancer drug delivery, and the HAEMOSEIS-256® - a diagnostic cardiovascular disease detection device; for North and South American markets, including Mexico and the Caribbean. Shreis’ mission is to introduce patient-centric, leading-edge platform technologies for affordable healthcare.

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