SHYCOCAN – Shreis Scalene Therapeutics LLC Position Statement on U.S.FDA Guidance with regards to marketing during the COVID-19 Public Health Emergency

GAITHERSBURG, MD, - July 30, 2020 - Shreis Scalene Therapeutics LLC will fast-track 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’.

Below is the notification to Shreis Scalene Therapeutics LLC from the U.S. FDA:

“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.:

“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:

The SHYCOCAN device is currently 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 SHYCOCAN

1. What does U.S.FDA regulatory terminology ‘cleared’ and ‘approved’ imply?
   a. The term “Cleared” is applied for devices that obtain a 510K
   b. 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 ‘cleared’ or ‘approved’ devices?
   a. The SHYCOCAN will currently be marketed under the “Enforcement Discretion Guidance” during the COVID-19 pandemic/public health emergency
   b. Enforcement Discretion allows for the marketing of the SHYCOCAN device during the pandemic
   c. A 510k submission is simultaneously being prepared by Shreis Scalene Therapeutics LLC together with Emergo (by UL) to submit to the U.S.FDA so that continuous marketing clearance can be achieved post pandemic without a break in distribution
   d. The device is intended for the physical attenuation of the family of coronaviruses and can be used in most public or personal settings.
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 in the USA.
   b. The CDC does only provide a link to NIOSH certifications but does not itself certify them.
      See: https://www.cdc.gov/niosh/npptl/topics/respirators/cel/default.html
      NIOSH certification is not relevant for the Shycocan.

**DISCLAIMER:** Any statement pertaining to the SHYCOCAN device and U.S. FDA regulation requires knowledge of the Enforcement Discretion Guidance so as to not misrepresent or misinterpret the marketability of the SHYCOCAN. Careful attention must be given to specific wording and be followed with regards to any press publication referencing the market availability of the SHYCOCAN 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 SHYCOCAN device project to meet most emergent needs during the COVID-19 Public Health Emergency. 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 US-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 leading-edge platform technologies that will impact the survivorship experience with quality of life, and continue to offer global solutions for safer, patient-centric, affordable healthcare.

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