Lockington, Elliott (SPAC/PSPC)

From: Moe Kirpalani <mohit@hipstreet.com>
Sent: March 27, 2020 2:51 PM
To: Parmar, Dovejot (SPAC/PSPC); Peter Walcot; Elaine Kunda
Subject: Fwd: KN95 Mask availability update

Hello Dove,

Thought we should send you a quick note on the masks with details that will hopefully increase your comfort levels with us and our supppier.

We are completely sold out of the KN95 masks but we are planning a new order.

Product would be as per the attached image, with the delivery schedule as below for next production runs .

1 mill units Early May and 1 mill every 10 days thereafter.

(the numbers on the picture are a typo so pls ignore .)

Along with the product we would provide the following certifications :

- **Factory Level Certifications**
  - FDA Device Establishment Number and Device Listing
    - FDA Registration Page 1 & 2
    - This file would show that the factory is actively registered with the FDA. It also provides every medical device listing for each of their product lines which include medical and surgical masks
  - EN ISO 13485:2016 Medical Device Quality Management Systems
    - Demonstrates ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements
    - Covers their synthetic non-woven products including face masks amongst numerous other medical product lines
  - EC Certificate- Production Quality Assurance System Directive 93/42/EEC on Medical Devices
    - Covers their synthetic non-woven products including face masks amongst numerous other medical product lines
  - FDA Audit Classification
    - File Name: FDA Audit Screenshot.

        - The classification is NAI for 2013, which stands for no action indicated. This shows that the USA FDA inspector has physically visited audited the factory and found no corrective action required.
        - The classification for 2019 was VAI, which stands for voluntary action indicated. Usually for minor corrections that the FDA do not find objectionable or recommend regulatory enforcement action.

- **Product Level Certifications**
    - N95 Nelson Laboratories USA Sodium Chloride (NaCl) Aerosol Test Final Report
        - Evaluation of particulate filter penetration as specified in 42 CFR Part 84
    - N95 Nelson Laboratories USA Determination of Inhalation and Exhalation Resistance for Air-Purifying Respirators Final Test Report
        - Evaluation of the differential pressure of respirators in accordance with 42 CFR Part 84.180
    - 510K Pre-Market Approval and Approval Letter
        - Approval from the FDA to demonstrate that the device to be marketed is as safe and effective, that is substantially equivalent, to a legally market device (section 513(i)(1)(A) FD&C Act)
        - Specific to masks and surgical masks

Please help us understand your volumes required as we are planning to place orders today for the delivery dates mentioned .

Thanks in advance

Stay Safe !

Moe Kirpalani
416-417-7081

USA Standard

Medical K

Item 6443926

Medical-Grad
Adjustable No
Medical grade

Packaging : 5
20 boxes per

MOQ: 60,000
Lead time bas
Best Arrival D
-5/22 20,0000
-6/06 20,0000
-6/22 20,0000

Best Pickup D
Lead time bas
-7/10 20,0000
-5/22 20,000 b

Factory has t
-FDA Registr
-Device Listi
-510K pre-ma
-Pass FDA E

Product pass
laboratories
-Sodium Chl
-Determinati
Air-Purifying

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