Belliveau, Sébastien

From: Kim, Sabrina
Sent: May 11, 2020 11:02 AM
To: Belliveau, Sébastien; Khalil, Samantha
Subject: FYI - HC interim order & KN95s

Hello,

FYI – HC says this didn't really have anything to do with the FDA from the outset. Pls see below for their explanation. In short – under the Interim Order, we said folks just have to provide an attestation that the quality of their product meets standards (to make the process go faster), but now we're requiring independent testing results to be added to the products covered under the IO.

"In the same way as most other regulators did, we decided to allow KN95-standard masks into Canada in order to increase the supply of PPE. These are held to a standard rather than granted "medical device" licenses. Under the MDEL pathway, license holders are responsible for ensuring their product meets the standard.

***However, under the Interim Order Pathway, we previously required essentially an attestation to the standard. Moving forward, we will require independent testing results to be added to the products covered under the Interim Order**. KN95s will need to be approved under the Interim Order pathway moving forward."*

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