

McKenna, Neil

From: Kim, Sabrina
Sent: Saturday, May 9, 2020 2:53 PM
To: Gordon2, Travis (HC/SC)
Cc: Stickney, Matt; Theis, Rick; pierre-yves.bourque@international.gc.ca; brook.simpson@international.gc.ca; Engel, Natacha (Ext.); Gerasimov, Boyan (SPAC/PSPC); Murdock, Kelly (SPAC/PSPC); Zimmerman, Shannon; Nowers, Kathryn (HC/SC); Bélair, Thierry (HC/SC); Saini, Sabina (HC/SC); MacKnight, Aisling (HC/SC); Chan, Marco (IC); Caira, Celine (IC); Belliveau, Sébastien; Pascale.Massot@international.gc.ca; Travers, Patrick; adam.austen@international.gc.ca
Subject: Re: KN95 Masks - Health Canada Regulatory Action

Adding Patrick Seb Pascale and Adam!

Sabrina Kim
Issues Advisor
Office of the Prime Minister
613-795-7803

On May 9, 2020, at 1:42 PM, Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca> wrote:

Hi friends,

Want to advise you of action our Department is taking in response to the disappointing testing results we're seeing with the KN95s.

As you know, earlier this week the U.S. FDA reduced the number of FDA-approved KN95s manufactured in China. We've run the revised list against our list of authorized devices under the Interim Order as well as have assessed Medical Device Establishment License numbers for implicated product.

In sum, we have six N95s authorized for import under our Interim Order. **Only one** has been removed from the U.S. Authorization List; this importer was advised yesterday to stop selling those particular devices as N95s. They may be sold for use as surgical masks (where the principle benefit is splash protection and is the standard we recommend for generalized healthcare settings outside intubation or other aerosol-generating procedures) or for non-medical use.

Of our MDEL holders, 63 importers **may** be dealing with affected masks. As of May 5, we've approved 831 MDELs but they are not exclusive to importing N95s. Early this coming week, we will issue a letter to these MDEL holders advising of our stance on the import of KN95s not on the U.S. FDA approved list and asking them to provide more detail. They will be asked to label any affected product for use as surgical masks or for non-medical use. After we send the letters, we will have more detail on how many MDEL-holders were actually dealing with the poor-quality KN95s.

It's important to note that provinces and territories generally are not deploying KN95s at this time for primary use in their systems; most are relying on N95s and stockpiling KN95s for use if the N95 supply runs dry. And of course, any masks procured through the collaborative FPT bulk buy will continue to be tested prior to distribution. Most PTs do not conduct independent tests on their masks; as I understand it, only BC and QC do.

I will let PSPC jump in if necessary but early indications are that about half of our bulk buy is in N95s, with half in KN95s. I will stress that **not all KN95s are unfit for use**; this action is targeted at KN95 manufacturers consistently failing to meet testing standards. We will continue to allow KN95s that meet the standard for filtration. My understanding is that the vast majority of PSPC contracts for respirators are N95, not KN95, in any case.

Moving forward, we will ask applicants under the IO to provide testing data for KN95s to validate the filtration standard, and we will not be publishing a broad-based list of “bad manufacturers” – just screening manufacturers more stringently. We will issue a public advisory on the matter once letters have been sent.

Lines are in development and Ash (CC'd) can help you pinch hit if something comes up urgently.

Thanks all and let us know if you have any questions.

Cheers,
Travis

--

Travis Gordon

Senior Policy Advisor / Conseiller principal en politiques
Office of the Minister of Health / Cabinet de la ministre de la Santé
Government of Canada / Gouvernement du Canada
T: 613-410-2938
PIN:EF06BDF5